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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 220

RIN 0584–AE25

Local School Wellness Policy Implementation Under the Healthy, Hunger-Free Kids Act of 2010; Approval of Information Collection Request

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule; notice of approval of Information Collection Request (ICR).

SUMMARY: The final rule titled Local School Wellness Policy Implementation Under the Healthy, Hunger-Free Kids Act of 2010 was published on July 29, 2016. The Office of Management and Budget (OMB) cleared the associated information collection requirements (ICR) on September 12, 2016. This document announces approval of the ICR.

DATES: Effective January 9, 2017. The ICR associated with the final rule published in the **Federal Register** on July 29, 2016, at 81 FR 50151, was approved by OMB on September 12, 2016, under OMB Control Number 0584–0592. The ICR was subsequently merged with 0584–0006.

FOR FURTHER INFORMATION CONTACT: Tina Namian, School Programs Branch, Policy and Program Development Division, Food and Nutrition Service, at (703) 305–2590.

Dated: December 23, 2016.

Richard Lucas,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2016–31954 Filed 1–6–17; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

9 CFR Part 201

RIN 0580–AB25

Scope of Sections 202(a) and (b) of the Packers and Stockyards Act

Correction

In rule document 2016–30424, appearing on pages 92566 through 92594 in the issue of Tuesday, December 20, 2016, make the following correction:

On page 92566, in the first column, in the **DATES** section, the first sentence, ''This interim final rule is February 21, 2017.'' should read, ''This interim final rule is effective February 21, 2017.''

[FR Doc. C1–2016–30424 Filed 1–6–17; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 23, 25, 27, 29, 61, 91, 121, 125, and 135

[Docket No.: FAA–2013–0485; Amdt. Nos. 1–70, 23–63, 25–144, 27–48, 29–56, 61–139, 91–345, 121–376, 125–66, and 135–135]

RIN 2120–AJ94

Revisions to Operational Requirements for the Use of Enhanced Flight Vision Systems (EFVS) and to Pilot Compartment View Requirements for Vision Systems

Correction

In rule document 2016–28714 appearing on pages 90126–90177 in the issue of Tuesday, December 13, 2016, make the following correction:

■ On page 90174, in the third column, in the 18th through 22nd line, paragraph (iii) should read

§ 91.176(b)(3)(iii) [Corrected]

''(iii) At 100 feet above the touchdown zone elevation of the runway of intended landing and below that altitude, the flight visibility must be sufficient for one of the following visual references to be distinctly visible and identifiable to the pilot without reliance on the EFVS—''

[FR Doc. C1–2016–28714 Filed 1–6–17; 8:45 am]

BILLING CODE 1301–00–D

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Hazardous Substances and Articles: Administration and Enforcement Regulations

CFR Correction

■ In Title 16 of the Code of Federal Regulations, Parts 1000 to End, revised as of January 1, 2016, on page 536, in § 1500.42, paragraph (a)(1), remove the second sentence.

[FR Doc. 2017–00240 Filed 1–6–17; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA–2015–N–2002]

RIN 0910–AH19

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses''

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to describe the circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This action is intended to provide direction to regulated industry and to help avoid consumer confusion.

DATES: This rule is effective February 8, 2017.

ADDRESSES: For access to the docket to read background documents or

comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryant Godfrey or Darin Achilles, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *CTPRegulations@fda.hhs.gov.*

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Executive Summary

Purpose of the Rule

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amends the FD&C Act and provides FDA with the authority to regulate tobacco products. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines the term ''tobacco product'' as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Excluded from the definition of a tobacco product is any article that is a drug, device, or combination product. Any article that is a drug, device, or combination product will be regulated as such rather than as a tobacco product.

Because some ambiguity surrounds the circumstances under which a product that is made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product, FDA is taking this action to provide clarity regarding our interpretation of the drug and device definitions in the FD&C Act with respect to products made or derived from tobacco. This final rule will provide assistance for entities intending to market products made or derived from tobacco. FDA expects the rule will also assist investigators planning to use products made or derived from tobacco for an investigational use in determining the investigational use requirements that apply to their proposed studies. The final rule is also intended to increase clarity regarding the intended uses and supporting evidence that make a product made or derived from tobacco subject to regulation as a drug, device, or combination product, helping consumers distinguish products made or derived from tobacco that are intended for medical use from products marketed for other uses.

In addition, FDA is taking the opportunity to make changes to existing regulations at §§ 201.128 and 801.4 (21 CFR 201.128 and 801.4), and to conform them to how the Agency currently applies these regulations to drugs and devices generally.

Summary of the Major Provisions of the Regulatory Action

Conceptually, the final rule follows the disease prong and the structure/function prong (with certain specified limitations) of the statutory definitions of ''drug'' and ''device'' (section 201(g) and (h) of the FD&C Act). Under the final rule, a product made or derived from tobacco and intended for human consumption is regulated as a drug, device, or combination product in two circumstances: (1) If the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or (2) if the product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000. The final rule also clarifies remaining circumstances where a product is subject to regulation as a tobacco product.

In addition, FDA is amending its existing intended use regulations for drugs and devices by inserting in §§ 201.128 and 801.4 a reference to the final rule to clarify the interplay between these regulations and this final rule. FDA has made further changes to conform §§ 201.128 and 801.4 to reflect how the Agency currently applies them to drugs and devices.

Costs and Benefits

The final rule clarifies the regulatory status of products made or derived from tobacco and our interpretation and application of the existing intended use regulations. This will reduce the ambiguity and may create some efficiency gains associated with submitting an application for approval or marketing authorization of a new tobacco-derived product, or with initiating research for a new tobacco-derived product. In addition, we assume that the regulation will clarify for consumers when products made or derived from tobacco are intended for medical uses rather than for other uses.

We assume that all tobacco-derived product manufacturers would incur one-time costs to learn the rule. There may also be a one-time cost incurred by a small number of manufacturers of tobacco products to review and revise product communications such as labeling and associated promotional materials. The following table reports these one-time costs.

TABLE 1—ONE-TIME COSTS

	Low	Mid-point	High
Learning costs	$117,412	$146,779	$176,147
Review communications, such as labeling and promotional materials	486,024	486,024	486,024
Revisions to communications, such as labeling and promotional materials	283,003	1,092,422	1,901,841
Total	886,439	1,725,225	2,564,012

I. Background

In the **Federal Register** of September 25, 2015 (80 FR 57756), FDA issued a proposed rule entitled ''Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses.' '' We received over 1,900 comments on the proposed rule. Two comments requested that the comment period be extended due to the complexity of the legal issues involved. One of these comments related to the original 60-day comment period. In the **Federal Register** of November 30, 2015 (80 FR 74737), FDA reopened the comment period for an additional 30 days. The second comment appears to relate to the additional 30-day comment period announced in 80 FR 74737. With respect to the comment requesting an extension beyond the additional 30-day comment period, FDA believes this comment to be misplaced as it generally references ''nine questions'' that are related to a different rulemaking—the proposed version of the deeming rule.[1]

A. Definition of ''Tobacco Product''

The Tobacco Control Act was enacted on June 22, 2009 (Pub. L. 111–31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 101(a) of the Tobacco Control Act amends section 201 of the FD&C Act by adding paragraph (rr), which defines the term ''tobacco product.'' In general, a ''tobacco product'' is defined as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 201(rr)(2) of the FD&C Act excludes from the definition of a tobacco product any article that is defined as a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). Section 201(rr)(3) of the FD&C Act explains that any article that is a drug, device, or combination product shall be subject to chapter V of the FD&C Act (the authorities for drugs and devices) rather than chapter IX (the authorities for tobacco products).[2]

B. Drug/Device/Combination Product Definitions

1. Medical Product Definitions

As noted in section I.A, the definition of ''tobacco product'' excludes anything that is a ''drug,'' ''device,'' or ''combination product'' under the FD&C Act. The FD&C Act defines ''drug'' (in relevant part) as an article intended either: (1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease (referred to as the ''disease prong'' of the definition) or (2) to affect the structure or any function of the body (the ''structure/function prong'') (section 201(g)(1) of the FD&C Act). The FD&C Act defines a ''device'' (in relevant part) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended either: (1) For use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or (2) to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent on being metabolized for the achievement of its primary intended purposes (section 201(h) of the FD&C Act).[3] Combination products are products that constitute a combination of a drug, device, or biological product (section 503(g) of the FD&C Act). Under the FD&C Act, the Secretary's determination of the primary mode of action of a combination product determines which Center at FDA will have primary jurisdiction over the product (section 503(g) of the FD&C Act).

FDA had previously interpreted the exclusion in the tobacco product definition to mean that if a product made or derived from tobacco is determined to have a drug or device ''intended use,'' it will be regulated as a medical product, not as a tobacco product. As discussed in greater detail in this document, this interpretation was qualified in *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), in which the D.C. Circuit applied the holding of *Food & Drug Administration* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 156 (2000), to all tobacco products. Thus, the determination of whether a product is a medical product or a tobacco product is based on the FD&C Act and associated regulations and also takes into account relevant legal precedent (further described in section I.D).

2. How Intended Use Is Determined

In determining a product's intended use, the Agency may look to ''any . . . relevant source,'' including but not limited to the product's labeling, promotional claims, and advertising (see, *e.g., Action on Smoking and Health* v. *Harris,* 655 F.2d 236, 239 (D.C. Cir. 1980); *United States* v. *Storage Spaces Designated Nos. ''8'' and ''49,''* 777 F.2d 1363, 1366 (9th Cir. 1985), *Hanson* v. *United States,* 417 F. Supp. 30, 35 (D. Minn.), *aff'd,* 540 F.2d 947 (8th Cir. 1976)).

For example, FDA may take into account any claim or statement made by or on behalf of a manufacturer that explicitly or implicitly promotes a product for a particular use (see, *e.g.,* § 201.128 (drugs), § 801.4 (devices)).[4]

To establish a product's intended use, FDA is not bound by the manufacturer or distributor's subjective claims of intent, but rather can consider objective

[1] ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule'' (79 FR 23142, April 25, 2014).

[2] Section 201(rr)(4) of the FD&C Act prohibits a tobacco product from being marketed in combination with any other article or product regulated under the FD&C Act. This rulemaking did not address section 201(rr)(4).

[3] In this final rule, the cited language may be referred to as the ''drug/device definitions.''

[4] Under FDA regulations, the term ''intended use'' relates to the objective intent of the medical product manufacturer, packer, distributor, or seller, including both corporate entities and natural individuals (hereinafter ''manufacturers'' or ''firms'').

evidence, which may include a variety of direct and circumstantial evidence. Thus, FDA may also take into account any circumstances surrounding the distribution of the product or the context in which it is sold (see id.; see also *United States* v. *Travia,* 180 F.Supp.2d 115, 119 (D.D.C. 2001)). In the context of medical products, generally, circumstantial evidence often ensures that FDA is able to pursue firms that attempt to evade FDA medical product regulation by avoiding making express claims about their products. As FDA has previously stated, however, the Agency would not, absent extraordinary circumstances, regard a firm as intending an unapproved new use for an approved drug, or a device that has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (for ease of reference, such a device is referred to as ''an approved or cleared device'' (or similar terms) throughout this preamble) based solely on the firm's knowledge that such product was being prescribed or used by doctors for such use (Ref. 1).

Thus, when a product made or derived from tobacco is marketed or distributed for an intended use that falls within the drug/device definitions, it is regulated as a medical product, subject to the limitations discussed further in this document. Courts have recognized that products made or derived from tobacco marketed with ''disease'' claims and certain ''structure/function'' claims are drugs (see *United States* v. *46 Cartons . . . Containing Fairfax Cigarettes,* 113 F.Supp. 336, 337, 338 (D. N.J. 1953) (cigarettes marketed for the prevention of respiratory diseases); *United States* v. *354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes,* 178 F.Supp. 847, 851 (D. N.J. 1959) (cigarettes marketed for weight reduction)).

C. Comments and Responses Regarding Definitions

Comments were received from tobacco product manufacturers, retailers, academia, medical professionals, advocacy groups, and consumers. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before each comment, and the word ''Response,'' in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with them. We have combined similar comments under one numbered comment. In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received many general comments expressing support or opposition to the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. Other comments outside the scope of this rulemaking also have not been addressed here. Summaries of the remaining comments, as well as FDA's responses, are included in this document.

(Comment 1) At least one comment stated that FDA is not permitted to regulate the nicotine in cigarettes as a drug and should not be permitted to regulate electronic nicotine delivery systems (ENDS) as medical products.

(Response) FDA disagrees. Section 201(g) of the FD&C Act defines ''drug'' as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals. Section 201(h) of the FD&C Act defines ''device'' (in relevant part) as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory,'' that is intended ''for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . to affect the structure or any function of the body,'' and which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent on being metabolized for the achievement of its primary intended purposes. As explained in this final rule, FDA has the authority to regulate a product made or derived from tobacco, including cigarettes and ENDS, as a medical product if it is distributed or marketed for an intended use that falls within the drug/device definitions, unless the product is intended to affect the structure or any function of the body in any way related to the effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

(Comment 2) Several comments stated that there is no need to clarify the medical product and tobacco product definitions that govern FDA regulation of these products. One of those comments also went on to state that there is a clear difference between drug product claims and ''consumer-oriented marketing statements'' about smoking cessation.

(Response) FDA disagrees that there is no need for additional clarity in this area. The Agency frequently receives inquiries regarding jurisdictional distinctions for products made or derived from tobacco, and given the broad range of intended uses for products made or derived from tobacco and the increasing variety of such products on the market, FDA believes that the potential for consumer confusion is increasing. This is especially true when tobacco-derived products that may otherwise appear to be products intended for recreational use make claims related to quitting smoking and treatment of nicotine addiction.

FDA considers claims about smoking cessation to be more than simply ''consumer-oriented marketing statements.'' As noted in the preamble to the proposed rule, claims related to smoking cessation have long been recognized as evidence of intended use, conferring drug or device jurisdiction, and smoking cessation claims also have long been associated with the intended uses of curing or treating nicotine addiction and its symptoms. For example, smoking cessation claims have appeared on the approved labeling for nicotine replacement therapies since the mid-1990s. FDA believes it is important to clarify and reiterate that smoking cessation claims on any product can render that product subject to FDA's medical products authorities.

(Comment 3) Comments had differing opinions on whether ENDS meet the definition of ''tobacco product'' as defined in the FD&C Act. Several comments stated that ENDS fall under the definition of ''tobacco product'' as defined in the FD&C Act if they contain nicotine derived from tobacco and are not intended to be drugs or devices. However, other comments stated that ENDS, including vaping hardware, do not fall within the definition of ''tobacco product.''

(Response) FDA agrees that ENDS meet the definition of ''tobacco product'' if they are not drugs, devices, or combination products. The term ''tobacco product'' is defined in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to mean any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product), and excluding drugs, devices, and

combination products as defined under the FD&C Act. Unless they are marketed for an intended use that falls within the drug/device definitions, ENDS products meet the definition of tobacco product. Additionally, as discussed elsewhere in the preamble, if ENDS products are intended to affect the structure or function of the body in any way related to the effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000, they will be regulated as tobacco products. (See section II.C.)

FDA disagrees with comments stating that vaping hardware does not fall within the definition of ''tobacco product.'' As the Agency explained in the final deeming regulation,[5] the definition of tobacco product includes components and parts. Also included in the final deeming regulation is a non-exhaustive list of examples of components and parts used with ENDS products. Examples of components and parts used with ENDS products includes, but are not limited to: E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, and programmable software. Thus, vaping hardware meets the definition of tobacco product.

D. History of 1996 Rulemaking and Relevant Litigation

Although the courts have recognized that tobacco-derived products can be regulated as medical products under the FD&C Act in certain circumstances, courts have also held that there are limitations on how the drug and device definitions can be applied to products made or derived from tobacco. This section provides a summary of FDA regulatory action and related litigation relevant to those limitations.

In 1996, FDA issued a regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents (the 1996 rule) (61 FR 44396, August 28, 1996). This rule included FDA's determination that it had jurisdiction over cigarettes and smokeless tobacco under the FD&C Act. The basis for this determination was that cigarettes and smokeless tobacco were intended to affect the structure or function of the body, within the FD&C Act definitions of the terms ''drug'' and ''device,'' because nicotine has significant pharmacological effects. In addition, FDA found that cigarettes and smokeless tobacco were combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body. In the 1996 rule, FDA concluded that cigarettes and smokeless tobacco should be regulated under the device authorities of the FD&C Act. The 1996 rule was challenged in court by a group of tobacco manufacturers, retailers, and advertisers on the grounds that FDA lacked jurisdiction to regulate tobacco products ''as customarily marketed;'' that the regulations exceeded FDA's authority to regulate devices; and that the advertising restrictions violated the First Amendment.

The Supreme Court struck down the 1996 rule in *Food & Drug Administration* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 156 (2000), holding that FDA lacked jurisdiction over tobacco products ''as customarily marketed.'' The Court found that Congress intended to exclude tobacco products from FDA's jurisdiction. In *Brown & Williamson,* the Court determined that tobacco products could not be made safe and effective for their intended uses, and therefore, if FDA had authority over them, FDA would have to remove them from the market, but that Congress had foreclosed such action (529 U.S. at 135–139). The Court also observed that Congress, in enacting statutes to regulate the labeling and advertising of conventional tobacco products, such as cigarettes and smokeless tobacco, had ''effectively ratified FDA's long-held position'' that the Agency lacked jurisdiction to regulate tobacco products ''absent claims of therapeutic benefit by the manufacturer'' (529 U.S. at 144).

In 2008 and early 2009, FDA detained multiple shipments of electronic cigarettes from overseas manufacturers and denied them entry into the United States on the ground that electronic cigarettes were unapproved drug-device combination products under the FD&C Act. In April 2009, two of the importers who were affected by this action sought a preliminary injunction to enjoin FDA from regulating electronic cigarettes as drug-device combination products and from denying entry of those products into the United States.[6] Between the filing of the lawsuit and a decision on the motion for a preliminary injunction, Congress passed the Tobacco Control Act and the President signed it into law. The District Court subsequently granted a preliminary injunction, relying on *Brown & Williamson* and the recently enacted Tobacco Control Act (*Smoking Everywhere, Inc.* v. *FDA,* 680 F. Supp. 2d 62 (D.D.C. 2010)). FDA appealed the decision and the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) affirmed in *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010).[7] The D.C. Circuit determined that the decision in *Brown & Williamson* was not limited to tobacco products that were the subject of the specific federal legislation discussed in that case. The D.C. Circuit found that under the Tobacco Control Act, all products made or derived from tobacco and intended for human consumption that are ''marketed for therapeutic purposes'' are subject to FDA's drug and/or device provisions, whereas ''customarily marketed tobacco products'' are subject to regulation as ''tobacco products'' (*Sottera,* 627 F.3d at 898–899; see also *Brown & Williamson,* 529 U.S. at 144–156).

The Court in *Brown & Williamson* frequently referred to ''tobacco products as customarily marketed,'' but never defined that phrase. The Court contrasted that phrase with ''claims of therapeutic benefit'' (see, *e.g.,* 529 U.S. at 127, 158), which it also did not define, although it did indicate that tobacco products' purported ''therapeutic benefits'' included all four of the structure/function intended uses on which FDA had based its 1996 rulemaking: Satisfying addiction, stimulation, sedation, and weight control (529 U.S. at 141). Neither of these terms is used in the FD&C Act. In *Sottera,* the D.C. Circuit relied on *Brown & Williamson* and repeated these phrases in describing contrasting types of products. The court in *Sottera* specifically equated ''therapeutic uses'' with the disease prong of the drug/device definitions in the FD&C Act and said that customarily marketed tobacco products were sold without therapeutic claims (627 F.3d at 894) and should be regulated as tobacco products under the FD&C Act, as amended by the Tobacco Control Act. As noted, the *Brown & Williamson* decision indicated that the four intended structure/function effects FDA had identified (satisfying addiction, stimulation, sedation, and

[5] ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule'' (81 FR 28973, May 10, 2016).

[6] The original district court case was filed by Smoking Everywhere, Inc., and the case was joined by Sottera, Inc., which does business as NJOY.

[7] On January 24, 2011, the D.C. Circuit denied the government's petitions for rehearing and rehearing en banc (by the full court). See *Sottera* v. *Food & Drug Administration,* No. 10–5032 (D.C. Cir. Jan. 24 2011) (per curiam).

weight control) were purported tobacco product ''therapeutic benefits'' (*Brown & Williamson,* 529 U.S. at 141). But neither the *Brown & Williamson* nor the *Sottera* court defined what might constitute claims of therapeutic benefit, nor did they explain the relationship between ''tobacco products as customarily marketed'' and the structure/function prong of the drug/device definitions of the FD&C Act. In addition, no court has addressed whether certain structure/function claims for products made or derived from tobacco that generally were not made for ''tobacco products as customarily marketed'' should be treated as drug or device claims.[8]

II. Purpose of Regulatory Action

Because some ambiguity surrounds the circumstances under which a product that is made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product, we are issuing this final rule to provide clarity regarding our interpretation of the drug/device definitions in the FD&C Act with respect to products made or derived from tobacco. We believe that this final regulation will provide assistance for entities intending to market products made or derived from tobacco and for entities that plan to study these products. For example, the rule is expected to help sponsors determine which FDA Center should be consulted as they develop their products and make appropriate premarket submissions to bring new products to market. FDA expects the rule will also assist investigators planning to use products made or derived from tobacco for an investigational use in determining the investigational use requirements that apply to their proposed studies. In addition, we believe it is important to avoid consumer confusion about which products are intended for medical uses versus recreational or other uses. The rule is expected to increase clarity regarding the types of intended uses and supporting evidence that make a product made or derived from tobacco subject to regulation as a drug or device, which we expect will help consumers distinguish products made or derived from tobacco that are intended for medical use from products marketed for other uses. Finally, the rule is intended to provide clarity for drug and device manufacturers generally regarding FDA's interpretation and application of its existing intended use regulations.

In both the *Brown & Williamson* and *Sottera* decisions, the courts set forth (but did not define) two poles—''tobacco products as customarily marketed'' and ''claims of therapeutic benefit''—and found that the ''customarily marketed'' pole was not within FDA's drug/device jurisdiction, but that the ''claims of therapeutic benefit'' pole was within FDA's drug/device jurisdiction. As noted in section I.D, the terminology used by the courts in establishing these two poles is not the terminology used by the FD&C Act in defining drugs and devices. Instead, the FD&C Act's drug and device definitions reference, in relevant part, diagnosis, cure, mitigation, treatment, or prevention of disease (disease prong) and effects on the structure or any function of the body (structure/function prong). In addition, while certain products and claims may fall clearly at one pole or the other, a spectrum of products and claims may fall somewhere between the two poles. In the sections that follow, we describe our interpretation of the jurisdictional lines established by the FD&C Act's drug, device, and tobacco product definitions as informed by the decisions in *Brown & Williamson* and *Sottera.*

A. Intended Uses For Products Made or Derived From Tobacco That Bring Products Within the Disease Prong

1. Intended Uses That Bring Products Within the Disease Prong

As discussed in section I.B, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs, devices, or combination products under the FD&C Act. Products made or derived from tobacco have historically been regulated as medical products when they are marketed for intended uses that fall within the disease prong. For example, FDA has approved a number of drug products made or derived from tobacco as nicotine replacement therapies with indications to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking. Accordingly, FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to bring products within FDA's ''disease prong'' jurisdiction.

FDA has also taken enforcement action against products made or derived from tobacco that were marketed with claims of therapeutic benefit but that did not have approved new drug applications (NDAs). For example, FDA seized cigarettes on the grounds that they were misbranded drugs when the manufacturer represented that the cigarettes were effective in preventing respiratory diseases, common cold, influenza, pneumonia, and various other ailments (*United States* v. *46 Cartons . . . Containing Fairfax Cigarettes,* 113 F.Supp. 336, 337, 338 (D. N.J. 1953)); see also *United States* v. *354 Bulk Cartons Trim Reducing-Aid Cigarettes,* 178 F.Supp. 847 (D. N.J. 1959) (similar, where manufacturer made weight-reduction claims for its cigarettes).

The ''claims of therapeutic benefit'' language used by the *Brown & Williamson* and *Sottera* courts has a logical relationship to the disease prong of the drug/device definition, in that ''therapeutic'' can be defined as ''relating to the treatment of disease or disorders by remedial agents or methods'' or to ''providing or assisting in a cure.''[9] With this rule, FDA is clarifying the categories of claims relevant to products made or derived from tobacco that FDA considers to be evidence of intended use that brings products within the disease prong in light of the *Sottera* and *Brown & Williamson* decisions. As discussed previously, claims related to smoking cessation have long been recognized as evidence of intended use conferring drug or device jurisdiction. Smoking cessation claims have also long been associated with intended uses of curing or treating nicotine addiction and its symptoms. For example, the approved labeling for nicotine replacement therapies includes the following statements: ''Purpose: Stop smoking aid; Use: reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.''[10] Against this backdrop, smoking cessation claims on any product generally create a strong suggestion of intended therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose.

Given the availability of FDA-approved drugs for smoking cessation,

[8] In *Sottera,* there are a few instances where the court's opinion could be read to suggest that all products made or derived from tobacco ''marketed without claims of therapeutic effect'' are, ipso facto, tobacco products ''as customarily marketed'' (627 F.3d at 895; see also id. at 898–899). However, because the issue of drug/device jurisdiction over structure/function intended uses that are not related to the commonly understood effects of nicotine was not before the court, this reading—even if it were correct—would be dicta.

[9] See, *e.g.,* Merriam-Webster Online Dictionary, available at *http://www.merriam-webster.com/dictionary/therapeutic.*

[10] See, *e.g.,* approved labeling for Nicoderm CQ, Nicorette, Habitrol.

FDA believes that consumers are particularly susceptible to confusion where products made or derived from tobacco that otherwise appear to be products intended for recreational use make claims related to quitting smoking. Therefore, FDA considers claims related to smoking cessation to require careful scrutiny. Where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion. In most cases, as discussed in more detail in response to Comment 13, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion due to the product's claimed therapeutic benefit.

FDA will treat several other categories of claims for products made or derived from tobacco as evidence of intended use that brings the products within the disease prong of the drug/device definition. These categories of claims are discussed further in section IV, Description of the Final Rule). We note that sections 911(c) and 918 of the FD&C Act (21 U.S.C. 387k(c) and 387r), as amended by the Tobacco Control Act, contemplate that products intended for the treatment of tobacco dependence and for relapse prevention, among other things, may be subject to FDA's drug/device jurisdiction.

2. Distinction Between Modified Risk Claims and Claims That Are Evidence of Disease-Prong Intended Uses

With this final rule, FDA is also clarifying the relationship between FDA's regulation of a certain category of tobacco products—modified risk tobacco products (MRTPs)—and FDA's regulation of medical products that are intended to mitigate disease. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products (section 911(b)(1) of the FD&C Act). Tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products means a tobacco product:

(1) That represents in its label, labeling, or advertising, either implicitly or explicitly, that:

- The tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
- the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
- the tobacco product or its smoke does not contain or is free of a substance;

(2) That uses the descriptors ''light,'' ''mild,'' ''low,'' or similar descriptors in its label, labeling, or advertising; or

(3) For which the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

See section 911(b)(2) of the FD&C Act.[11]

Because MRTPs have the potential to be marketed as less harmful than other tobacco products, including as presenting a lower risk of tobacco-related disease than another tobacco product, FDA recognizes that there might be questions about how these products relate to FDA's medical product jurisdiction over products made or derived from tobacco that are intended for use in disease mitigation and prevention. MRTPs may have the ultimate effect of lowering disease risk for users who would otherwise use another, more harmful tobacco product. However, an important distinction between MRTPs and medical products is that, while medical products approved/cleared for disease mitigation or prevention act affirmatively to combat a disease or health condition, MRTPs present *relatively* less risk of disease (*e.g.,* by presenting reduced exposure to harmful constituents relative to another tobacco product), but do not affirmatively act to mitigate, prevent, or otherwise treat disease. In addition, while medical products approved for disease mitigation are determined to be both safe and effective for their approved use, MRTPs are reviewed based, in part, on a ''benefit the health of the population as a whole'' standard, and like other tobacco products, still expose users to inherent (if reduced) harms.

For purposes of illustration, claims of modified risk might include claims like ''contains less nicotine than [tobacco product X]'', ''using [MRTP] reduces your risk of lung cancer compared to using [tobacco product X]'', and ''lower level of nitrosamines than other smokeless tobacco products.'' In contrast, a claim that a product ''inhibits the progression of disease in adult patients with chronic obstructive pulmonary disease'' is evidence of intended uses that would bring the product within drug/device jurisdiction.

B. Comments and Responses Regarding Modified Risk Tobacco Products

(Comment 4) At least one comment remarked that research studies and public opinion may come to reflect that a tobacco product appears to have properties similar to those of a medical drug or MRTP. The comment asserted that acceptance of these properties by the scientific and medical community or by the public should not subject the product to regulation as a medical product or MRTP in the absence of any specific claims by the manufacturer.

(Response) As explained in this final rule, with certain exceptions, products made or derived from tobacco are subject to regulation as medical products if they are distributed for an intended use that falls within the FD&C Act's drug/device definitions, and the Agency may look to any relevant source to determine intended use. To the extent this comment suggests that manufacturer claims are always necessary to establish a medical product's intended use, FDA disagrees. As discussed at various points in this final rule (for example, in response to Comment 18), FDA is not bound by the manufacturer or distributor's subjective claims of intent, but rather can consider objective evidence, which may include a variety of direct and circumstantial evidence. Nevertheless, FDA agrees with the comment that neither the opinions of the scientific and medical communities nor public opinion considered alone should dictate when a product made or derived from tobacco is regulated as a medical product or MRTP. In general, FDA would not regard a manufacturer as intending a medical use for a product made or derived from tobacco based solely on study findings or widespread belief that the product appears to have properties similar to those of a medical product. Similarly, FDA would not regard a manufacturer of a product made or derived from tobacco as selling or distributing a product for use to reduce harm or the risk of tobacco-related disease based solely on study findings

[11] No smokeless tobacco product shall be considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease solely because its label, labeling, or advertising uses the following phrases: ''smokeless tobacco,'' ''smokeless tobacco product,'' ''not consumed by smoking,'' ''does not produce smoke,'' ''smokefree,'' ''smoke-free,'' ''without smoke,'' ''no smoke,'' or ''not smoke'' (section 911(b)(2)(C) of the FD&C Act).

or widespread belief that the product appears to have properties similar to those of an MRTP.

C. Intended Uses For Products Made or Derived From Tobacco That Bring Products Within the Structure/Function Prong

As discussed in section I.B, the drug/device definitions in the FD&C Act include articles ''intended to affect the structure or any function of the body,'' and FDA's assertion of jurisdiction over cigarettes and smokeless tobacco in 1996 was predicated on the pharmacological effects of nicotine on the structure or function of the body. In addition, as explained previously, the Court in *Brown & Williamson* rejected that assertion of jurisdiction, finding that Congress did not intend for FDA to have jurisdiction over cigarettes ''as customarily marketed.''

Based on the *Brown & Williamson* holding and the *Sottera* court's application of that holding to all tobacco products, it is necessary to determine whether the intended use of a product made or derived from tobacco was the subject of claimed structure or function effects for tobacco products ''as customarily marketed''—and therefore outside of FDA's drug/device jurisdiction. FDA believes the appropriate inquiry is whether the intended structure/function effects relate to effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to the date of the Supreme Court's decision in *Brown & Williamson* (March 21, 2000).

For example, as discussed in the 1996 rulemaking, claims related to satisfaction, pleasure, enjoyment, and refreshment are euphemisms for the delivery of a pharmacologically active dose of nicotine and thus relate to effects on the structure or function of the body (61 FR 44396 at 45101 and 45175–45178). Nonetheless, FDA does not consider these tobacco satisfaction and enjoyment claims to bring products within its drug and device regulatory authority because these are structure/function claims related to the effects of nicotine and were commonly and legally made before March 21, 2000. Similarly, FDA does not consider claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product—such as ''satisfying smoking alternative,'' ''provides all the pleasure of smoking,'' ''get your nicotine fix,'' or ''provides smokers the same delight, physical and emotional feelings''—to bring a tobacco product within its drug and device authority.

The *Brown & Williamson* and *Sottera* decisions do not reach the issue of intended uses that fall outside the disease prong of the drug/device definition and that are outside the area of ''customarily marketed'' tobacco product claims. FDA believes certain structure/function intended uses for products made or derived from tobacco continue to fall within our drug/device regulatory authority. FDA believes these structure/function intended uses fall into two main categories: (1) Intended uses that are unrelated to the pharmacological effects of nicotine and (2) intended uses that were not the subject of claims that were commonly and legally made for cigarettes and smokeless tobacco products (*i.e.,* the products addressed in the 1996 rule) prior to the Supreme Court's decision in *Brown & Williamson.* Thus, to the extent manufacturers intend products made or derived from tobacco to be used to affect the structure or function of the body in any way that is not related to the effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000, FDA would consider these intended uses to remain within its drug/device jurisdiction under the final rule. For example, FDA's 1996 rulemaking identified ''sedation,'' ''stimulation,'' and ''weight loss'' as intended structure/function effects related to nicotine in cigarettes and smokeless tobacco products (61 FR 44396 at 44667; see also *Brown & Williamson,* 529 U.S. at 127). These structure/function effects are similar to ''relieve tension,'' ''restore mental alertness,'' and ''promote weight loss,'' which the proposed rule gave as examples of potential intended structure/function effects (80 FR 57756 at 57760; see also Comment 7 in this document). But absent evidence that ''sedation,'' ''stimulation,'' or ''weight loss'' is both a structure/function effect related to nicotine and was commonly and legally claimed in marketing cigarettes or smokeless tobacco products prior to March 21, 2000, FDA will consider products made or derived from tobacco, whose intended use includes such structure/function effects, to be medical products.

Similarly, ''maintain memory''—another example of a potential intended structure/function effect mentioned in the proposed rule (80 FR 57756 at 57760)—was (as FDA's 1996 rulemaking observed) a pharmacological effect that Philip Morris researchers attributed to nicotine and that R.J. Reynolds Tobacco asserted as a ''benefit'' in court filings (61 FR 44396 at 44857–44858 and 45029). But once again, absent evidence that ''maintaining memory'' is both a structure/function effect related to nicotine, and was commonly and legally claimed in marketing cigarettes or smokeless tobacco products prior to March 21, 2000, FDA will consider products made or derived from tobacco, intended for use to ''maintain memory,'' to be medical products.

Different facts but a similar analysis apply to the proposed rule's other examples of potential intended structure/function effects, ''maintain healthy lung function'' and ''support the immune system.'' (80 FR 57760). In contrast to its findings for ''stimulation,'' ''sedation,'' and ''weight loss,'' (61 FR 44396 at 44667), FDA's 1996 rulemaking did not identify ''maintain healthy lung function'' or ''support the immune system'' as intended structure/function effects of cigarettes or smokeless tobacco products. But as with those other potential intended uses, absent evidence that ''maintaining healthy lung function'' or ''supporting the immune system'' are both structure/function effects related to nicotine, and were commonly claimed in marketing cigarettes or smokeless tobacco products prior to March 21, 2000, FDA will consider products made or derived from tobacco, intended for use to achieve such structure/function effects, to be medical products.

FDA believes that it is important to recognize structure/function intended uses that were not commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to the decision in *Brown & Williamson.* Structure/function intended uses are a longstanding and important aspect of FDA's medical product jurisdiction, grounded in the statutory definitions of ''drug'' and ''device'' in the FD&C Act. We recognize that products made or derived from tobacco are unique because of the regulatory regime for tobacco products under the FD&C Act, and that some products made or derived from tobacco making certain structure/function claims are now outside our drug/device jurisdiction. However, we believe it is consistent with the FD&C Act, case law, and our public health mission to determine that medical products include products made or derived from tobacco whose intended use includes effects on the structure or function of the body that are distinct from the pharmacological effects related to nicotine that were commonly and legally claimed before March 21, 2000.

FDA believes this final rule will provide clarity to manufacturers about how products made or derived from tobacco will be regulated if they are marketed or distributed for certain intended uses. This clarification will allow regulated industry to plan accordingly during the product development and postmarketing phases and will help researchers understand the applicable regulatory requirements associated with the investigational use of products made or derived from tobacco.

In addition, we believe this final rule will help to avoid consumer confusion about which products made or derived from tobacco are intended for a medical use (*i.e.,* as a drug/device) versus for a recreational use. Specifically, FDA wishes to avoid situations where products intended to be sold as tobacco products are marketed with the same claims as products sold as drugs or devices.

D. Comments and Responses Regarding Brown & Williamson and Sottera

(Comment 5) At least one comment agreed with FDA that the *Brown & Williamson* and *Sottera* rulings did not define the phrases ''as customarily marketed'' or ''claims of therapeutic benefit,'' leaving the Agency with some discretion as to what claims fall within each category when the distinction is not clear under existing precedent.

(Response) FDA agrees that the lack of definitions of the terms ''customarily marketed'' and ''claims of therapeutic benefit'' as they apply to products made or derived from tobacco in the relevant case law has created ambiguity and resulted in confusion among regulated industry, which has led FDA to promulgate this rule. Specifically, in the absence of clear judicial direction about what might constitute ''claims of therapeutic benefit'' and the relationship between tobacco products ''as customarily marketed'' and the structure/function prong of the drug/device definitions, the Agency believes it is important to clarify its statutory interpretations of the drug/device definitions with respect to products made or derived from tobacco in light of these terms used by the courts.

(Comment 6) Several comments supported FDA's proposal to treat satisfaction, smoking alternative, and nicotine fix claims as tobacco product claims. However, these comments assert that all products derived from tobacco that lack express therapeutic claims must be regulated as tobacco products. These comments maintained that FDA's proposed approach—which provides that some structure/function claims will cause products derived from tobacco to be regulated as drugs, devices, or combination products—is inconsistent with the *Brown & Williamson* and *Sottera* decisions.

Specifically, the comments argued that neither decision ''indicates that 'customarily marketed' means anything other than 'not marketed with therapeutic claims'.'' They maintained that the *Sottera* court ''explicitly concluded that the 'better reading' of *Brown & Williamson* was that it deprives FDA of authority to regulate under the FD&C Act any tobacco products marketed 'without claims of therapeutic effect,' viewing such products as 'customarily marketed.' '' Accordingly, the comments contended that the courts saw only two categories of tobacco products—products marketed with or without therapeutic claims. The comments asked that FDA clarify that it lacks authority to regulate any product made or derived from tobacco as a drug or device absent express therapeutic claims.

(Response) FDA disagrees with these comments and declines to adopt their overly narrow reading of *Brown & Williamson* and *Sottera.* First, *Brown & Williamson* provides no support for the comments' assertion that therapeutic claims must be express for a product to be subject to FDA's drug/device jurisdiction. The plaintiffs in *Brown & Williamson* made this very argument, and the dissenting opinion noted that the FD&C Act ''does not use the word 'claimed'; it uses the word 'intended'.'' See *Brown & Williamson,* 529 U.S. 120, 170 (2000) (dissenting opinion). The majority specifically declined to resolve the question. See *Brown & Williamson,* 529 U.S. 120, 132 (2000).

In addition, as noted in section I.C of the proposed rule, as well as section I.D, neither the *Brown & Williamson* nor the *Sottera* decisions defined the term ''customarily marketed.'' Although the court in *Sottera* did equate the concept of ''therapeutic claims'' with the disease prong of the drug and device definitions, there was no such equating of the term ''customarily marketed'' with the structure/function prong of these definitions. In fact, the term ''customarily marketed'' itself suggests that the term has some meaning independent of its relationship to the structure/function prong of the drug and device definitions. If the Supreme Court had wanted any structure/function claim to exclude a product made or derived from tobacco from FDA's drug/device jurisdiction, it could have said so. The structure of section 201(rr) of the FD&C Act, added by the Tobacco Control Act, further supports this interpretation. Following the Supreme Court's decision in *Brown & Williamson,* Congress enacted the Tobacco Control Act to give FDA explicit authority to regulate tobacco products. Under section 201(rr)(2), the term ''tobacco product'' excludes articles that are drugs under section 201(g)(1) and devices under section 201(h) of the FD&C Act. This statutory carve-out includes the structure/function prong of the drug/device definitions.

Having given FDA regulatory authority over tobacco products, if Congress thought that products made or derived from tobacco should never be regulated as drugs or devices under the structure/function prong of the drug or device definitions in the wake of *Brown & Williamson,* presumably Congress would have written section 201(rr)(2) of the FD&C Act differently. The better reading is that Congress recognized that products made or derived from tobacco as ''customarily marketed'' would be regulated as tobacco products under the Tobacco Control Act, but that products made or derived from tobacco meeting the drug/device definitions (including the structure/function prong, to the extent such products were not ''customarily marketed'') would continue to be regulated as drugs or devices.

(Comment 7) At least one comment disagreed with some of the examples in the proposed rule of structure/function intended uses that FDA believes remain within its drug/device jurisdiction under the proposal. Specifically, the comment argued that claims about nicotine's stimulant and weight-loss structure/function effects ''remain permissible 'tobacco product' claims,'' because FDA's 1996 rulemaking found that stimulant and weight-loss structure/function effects were among the intended uses of cigarettes and smokeless tobacco products (citing 61 FR 44396 at 44630, 44632).

(Response) FDA disagrees with this comment. In the 1996 rulemaking, FDA found that, in addition to causing and sustaining addiction, nicotine in cigarettes and smokeless tobacco causes other psychoactive (mood-altering) effects, including tranquilization and stimulation; and that nicotine in cigarettes and smokeless tobacco controls weight (61 FR 44396 at 44630). The rulemaking further found that these were intended structure/function effects for cigarettes and smokeless tobacco products (id. at 44632). But the central holding of *Brown & Williamson* was that ''customarily marketed'' tobacco products were not subject to FDA's medical product authority, even

assuming that such products could be considered to have the intended structure/function effects that FDA attributed to them if their manufacturers and sellers did not claim such effects (529 U.S. at 131–32). As discussed in section I.D, this current rulemaking applies *Brown & Williamson,* as relevant here, by looking to marketing claims for structure/function effects that were commonly and legally made for ''customarily marketed'' cigarettes and smokeless tobacco products prior to the date the *Brown & Williamson* decision was issued. To the extent the comment read the examples ''relieve tension'' and ''restore mental alertness'' as stimulant intended uses, FDA does not believe that they are structure/function intended uses relating to effects of nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000. Similarly, FDA does not believe that ''promotes weight loss'' was a ''customarily marketed'' tobacco product claim within the meaning of *Brown & Williamson.* Section 1100.5 is written such that, if a particular intended structure/function effect for a product made or derived from tobacco is related to the effects of nicotine commonly and legally claimed prior to March 21, 2000, that product would not be subject to FDA's drug/device jurisdiction. FDA expects that in some cases this would be a fact-specific, case-by-case inquiry.

Sponsors should also keep in mind that, regardless of whether a product is regulated as a tobacco product or a medical product, the claims made for the product would misbrand the product and subject manufacturers to enforcement action if the claims are false or misleading in any particular, including if the claims are unsubstantiated. Thus, if a particular claim related to the effects of nicotine was used in the marketing of a tobacco product prior to March 21, 2000, but that claim is not substantiated by appropriate evidence, the use of such a claim in current labeling or advertising would likely misbrand the product. In addition, both medical products and tobacco products would be subject to enforcement action under section 201(n) of the FD&C Act if their labeling or advertising fails to reveal facts material in the light of the representations made or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates.

(Comment 8) Several comments argued that the proposed rule was an improper attempt to undermine the court's holding in *Sottera* with respect to the regulation of electronic cigarettes. These comments viewed the proposed rule as an attempt to regulate electronic cigarettes as drugs, and characterized it as an effort to bypass the D.C. Circuit's ruling in *Sottera.* They also suggested that *Sottera* made a categorical determination regarding the intended use of electronic cigarettes generally, and maintained that FDA declined to appeal the D.C. Circuit's decision and instead represented that it intended to regulate electronic cigarettes as tobacco products.

(Response) FDA disagrees with these comments. Although the *Sottera* decision determined that the holding in *Brown & Williamson* was not limited to cigarettes and smokeless tobacco, the court did not say that electronic cigarettes could never be regulated as drugs or devices. Rather, the court held that FDA can ''regulate tobacco products marketed for therapeutic purposes under [the FD&C Act's drug/device provisions],'' and observed that ''the FDA may establish that NJOY does in fact make therapeutic claims regarding its electronic cigarettes.'' See *Sottera,* 627 F.3d at 899. The rule FDA issues here clarifies the circumstances under which a product made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product. Manufacturers are free to choose how they would like to market products made or derived from tobacco, but do so in the context of the regulatory framework set forth in the rule.

Moreover, the comments appear to misunderstand the nature of determinations of intended use with respect to FDA-regulated products. As discussed elsewhere in this document, intended use is a case-by-case, fact-specific inquiry in which the Agency may look to any relevant source of evidence, including a variety of direct and circumstantial evidence. See, *e.g.,* Response to Comment 18 in section IV.C. Intended use is not determined on a categorical basis based on product type. Finally, in deciding not to petition for certiorari from the D.C. Circuit's decision in *Sottera,* FDA did not state or signal that it intended to regulate electronic cigarettes as tobacco products under all circumstances. Rather, in the wake of the *Sottera* decision, FDA issued a letter to stakeholders,[12] noting that the Agency would abide by the jurisdictional lines established by *Sottera,* and was considering issuing a guidance or rulemaking regarding therapeutic claims. This final rule is the result of FDA's consideration of the issues raised by the *Sottera* decision and clarifies FDA's interpretation of the statutory definitions of drug and medical device with respect to products made or derived from tobacco.

(Comment 9) Several comments asserted that claims that use euphemisms for the delivery of a pharmacologically active dose of nicotine, or state that a tobacco product provides an alternative way of obtaining the effects of nicotine or will provide the same effects as another tobacco product, do not fall within FDA's medical product authority. Four comments took the opposite view. Three of these latter comments remarked that excluding such claims from FDA's medical product authority would authorize manufacturers to continue using claims that were found to be fraudulent and deceptive by the U.S. District Court for the District of Columbia in *United States* v. *Philip Morris USA Inc.,* 449 F. Supp. 2d 1 (D.D.C. 2006). These comments asserted that claims suggesting a product made or derived from tobacco provides ''satisfaction,'' a ''nicotine fix,'' or ''pleasure'' are claims about the pharmacological effects of nicotine, and suggested that products bearing such claims should be regulated as medical products. Another comment suggested that FDA treat such claims as evidence of an article's intended use as a drug.

(Response) The Agency disagrees with any suggestion that FDA is authorizing fraudulent claims. The purpose of this rule is to increase clarity regarding the types of intended uses and supporting evidence that make a product made or derived from tobacco subject to regulation as a tobacco product versus as a drug, device, or combination product. Regardless of the outcome of that jurisdictional question, the FD&C Act prohibits false and misleading claims in FDA-regulated labeling and advertising (see sections 502(a), 502(n), 502(r), 903(a)(1), and 903(a)(7) (21 U.S.C. 352(a), 352(n), 352(r), 387c(a)(1), and 387c(a)(7)). Similarly, in concluding that certain claims involving ''satisfaction,'' ''pleasure,'' ''enjoyment,'' and ''refreshment'' are claims about the pharmacological effects of nicotine that were commonly and legally made prior to March 21, 2000, FDA is not authorizing such claims. Rather, the Agency is explaining in more detail its understanding of how the D.C. Circuit's interpretation of the Tobacco Control Act in *Sottera* affects the jurisdictional determination. As documented in the annex to the 1996 rule, products made

[12] See *http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm.*

or derived from tobacco were customarily marketed at that time for the pharmacological effects of nicotine, using phrases such as ''smoking pleasure'' and ''satisfaction.'' [13] Such terms, as discussed in section II.C, are recognized euphemisms for the delivery of a pharmacologically active dose of nicotine to satisfy addiction—an intended structure/function effect—and were commonly and legally made claims for customarily marketed cigarettes and smokeless tobacco products prior to the date of the *Brown & Williamson* decision. Thus, FDA continues to believe that *Brown & Williamson,* as extended and applied to the Tobacco Control Act by *Sottera,* precludes the Agency from regulating products made or derived from tobacco as medical products on the basis of such claims.

E. Comments and Responses Regarding Consumer Confusion

(Comment 10) Comments expressed different opinions about the intended uses of products made or derived from tobacco, primarily e-cigarettes, and whether consumers are able to distinguish products that are intended for medical use from products marketed for other uses. Several comments asserted that e-cigarettes are not intended for use as smoking cessation aids, whereas many other comments asserted that e-cigarettes are vital smoking cessation aids. One comment averred that there is no evidence that consumers are confusing e-cigarette products with products that are marketed, labeled, and sold as medical products. Two other comments, however, cited studies that purportedly show many consumers believe e-cigarettes and smokeless tobacco products are effective smoking cessation aids.

(Response) FDA continues to believe that there is consumer confusion about the intended uses of marketed products made or derived from tobacco. Evidence that at least some consumers are confused about the intended uses of products can be found in the comments themselves. We received many comments from individuals who began using e-cigarettes because they believed that e-cigarettes would help them quit smoking. Moreover, as noted in two comments, studies have shown that many consumers are using e-cigarettes to attempt to quit smoking (Ref. 2) despite the fact that no e-cigarette has been approved for use as a smoking cessation aid. We believe that the rule will help to mitigate this confusion and help ensure that consumers do not mistakenly use tobacco products, which are inherently dangerous, for medical uses.

(Comment 11) Several comments expressed concern that this regulation would increase consumer confusion by not allowing ENDS manufacturers to communicate truthful claims to their customers. These comments believed that the regulation would harm, rather than protect public health. Comments also expressed concern that ENDS manufacturers would not be able to state that e-cigarettes could be used for smoking cessation, and ENDS manufacturers would be forced to deceptively market their products. Several comments discussed FDA's authority under section 911 of the FD&C Act to require premarket authorization of modified risk tobacco products. Some commenters urged FDA to implement section 911 in a manner that does not restrict truthful and non-misleading speech.

(Response) FDA disagrees with concerns that ENDS manufacturers will not be able to make claims that accurately represent their products' intended uses. Manufacturers are free to decide how they would like to market their products, but must meet the appropriate statutory and regulatory standards governing the regulatory pathway they choose. Additionally, the proposed rule would not force e-vapor manufacturers to ''deceptively'' market their products or risk ''being categorized as unapproved medical products and forced off the market.'' FDA believes that manufacturers of products made or derived from tobacco, including e-vapor manufacturers, could make many types of claims under the rule that would subject them only to tobacco product jurisdiction; the preamble to the proposed rule provides examples of such tobacco product claims, but is not intended to be an exhaustive list. Moreover, section 911 of the FD&C Act allows manufacturers to make truthful and non-misleading modified risk claims with appropriate authorization. Manufacturers that have data to substantiate modified risk claims for a particular product can submit an MRTP application so that FDA can determine whether the product meets the statutory standard and if appropriate, can issue an order authorizing it to be marketed as an MRTP.

FDA continues to believe that smoking cessation claims require close examination. FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction to be evidence of intended uses that confer drug or device jurisdiction. Manufacturers that have data to substantiate cessation claims for a particular product can submit an NDA so that FDA can determine whether the product meets the statutory standard and can approve the application, if appropriate. The rule's treatment of smoking cessation claims as generally suggestive of a therapeutic purpose means that products marketed with such claims would generally be regulated as medical products. Treating these products as medical products will help assure that such claims are supported by data demonstrating that a product is safe and effective for this intended use. Otherwise, consumers may attempt to quit smoking with unproven products, threatening both individual consumers' health and the public health generally.

(Comment 12) At least one comment suggested that a disclaimer stating that FDA has not approved e-cigarettes for medical use would be sufficient to mitigate any confusion over the intended use of such products. In contrast, several comments argued that disclaimers are insufficient to mitigate any confusion over whether a product made or derived from tobacco is intended for medical use. One of these comments suggested that disclaimers would foster confusion because they often contain statements that conflict with claims that are made elsewhere in the marketing materials and labeling for e-cigarettes and other products.

(Response) FDA does not believe that disclaimers will be sufficient in most cases to mitigate consumer confusion about whether a product made or derived from tobacco is intended for medical use. Studies have shown that disclaimers are frequently ineffective and can actually increase confusion for consumers (Refs. 3 and 4). Thus, where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically.

(Comment 13) Several comments suggested that excluding claims that are euphemisms for the delivery of a pharmacologically active dose of nicotine and those that suggest a tobacco product provides an alternative way of obtaining the effects of nicotine from regulation under the Agency's drug/device authorities would create consumer confusion because such claims may not be distinguishable from drug or device claims related to the symptoms of nicotine addiction or could be perceived as modified risk claims.

(Response) As stated previously in this section, FDA has determined that

[13] See 61 FR 44619 at 44648, August 28, 1996.

the types of claims described in these comments generally do not bring products made or derived from tobacco within its drug and device authority. We acknowledge that there are circumstances in which consumers might be confused by such claims. A consumer might be confused about a product's intended use, for example, if a ''satisfying smoking alternative'' claim is accompanied by other text or images indicating that the product can help smokers reduce withdrawal symptoms associated with quitting smoking. In that case, the product may be subject to regulation as a drug or device. But as a general matter, FDA does not expect claims that use euphemisms for the delivery of a pharmacologically active dose of nicotine or suggest that a tobacco product provides an alternative way of obtaining the effects of nicotine to cause much confusion. FDA will continue to monitor consumer perception and will take appropriate regulatory action if evidence accumulates showing that consumers are confused by such claims.

F. Changes to Existing ''Intended Use'' Regulations

FDA is also making changes to §§ 201.128 and 801.4. First, the final rule inserts a reference to § 1100.5 to clarify the interplay between these regulations and the final rule. Second, as discussed previously, the Agency does not, absent extraordinary circumstances, regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that the product was being prescribed or used by doctors for such use (see Ref. 1). Accordingly, FDA is taking this opportunity to amend §§ 201.128 and 801.4 to better reflect FDA's interpretation and application of these regulations. These changes do not reflect a change in FDA's approach regarding evidence of intended use for drugs and devices. These clarifying changes to the intended use regulations apply to drugs and devices generally, and not just to products made or derived from tobacco and intended for human consumption.

III. Legal Authority

Among the provisions that provide authority for this final rule are sections 201, 503(g), and 701(a) of the FD&C Act (21 U.S.C. 321, 353(g), 371(a)). Section 201 of the FD&C Act defines ''drug,'' ''device,'' and ''tobacco product'' (subsections (g)(1), (h), and (rr)(1) to (rr)(2)), and section 503(g) of the FD&C Act provides that combination products are those ''that constitute a combination of a drug, device, or biological product.'' Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act. FDA believes this rule will assist the Agency with efficient enforcement of the FD&C Act because it provides increased clarity to stakeholders, particularly regulated entities, regarding FDA's interpretation of which regulatory framework will apply to particular products and will help consumers differentiate between products that are intended for medical use and products marketed for other uses.

FDA regulates the manufacture, sale, and distribution of drugs, devices, combination products, and tobacco products under the authority of the FD&C Act. Although the regulatory pathways for each product category differ, each product category is subject to similar types of regulatory requirements. For example, FDA's regulatory authority for drugs, devices, combination products, and tobacco products includes authority to review and authorize the marketing of new products as well as to oversee product labeling and advertising. Thus, whether a product meets the definition of a drug, device, or tobacco product under the FD&C Act and this final regulation, the manufacture, sale, and distribution of the product are subject to the applicable requirements of the FD&C Act.

(Comment 14) At least one comment stated that the proposed rule exceeds FDA's authority.

(Response) FDA disagrees. As described in the proposed rule, FDA has the authority to regulate as a medical product any product that meets the definition of drug, device, or combination product in the FD&C Act, including cigarettes and other tobacco-derived products unless their intended use was the subject of claimed structure/function effects of nicotine commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000. FDA also has tobacco product jurisdiction over all other products made or derived from tobacco intended for human consumption. The final rule seeks to clarify how products containing nicotine derived from tobacco will be regulated.

IV. Description of the Final Rule

A. Exclusion From Tobacco Product Regulation (§ 1100.5)

As described in section II, the goal of this final rule is to provide clarity regarding the types of intended uses of products made or derived from tobacco that may fall within the drug/device definitions and therefore cause those products to be regulated as medical products under the FD&C Act. In describing these intended uses, the final rule aims to assist regulated entities in the research and development of products made or derived from tobacco by clarifying which regulatory framework (*i.e.,* the drug/device frameworks or the tobacco framework) will apply to particular products based on their intended use. The final rule is also intended to reduce consumer confusion regarding which products are intended for medical use (*i.e.,* as a drug, device, or combination product) and which may be marketed for recreational or other purposes. The final rule reflects the legal and regulatory considerations discussed in sections I and II, including the *Brown & Williamson* and *Sottera* holdings. Finally, the final rule amends the existing intended use regulations for drugs and devices by inserting in §§ 201.128 and 801.4 a reference to § 1100.5 to clarify the interplay among these regulations and this final rule.

The codified language states the circumstances in which a product made or derived from tobacco would be excluded from the definition of ''tobacco product'' and be subject to regulation as a drug, device, or combination product. Under the final rule, this exclusion could apply in two circumstances: (1) If the product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or (2) if the product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

Conceptually, the codified language follows the disease prong and the structure/function prong (with certain limitations) of the drug and device definitions.

1. Disease Prong

Section 1100.5(a) follows the disease prong. The paragraph elaborates on the statutory language for the disease prong by describing several categories of intended uses that would cause a product made or derived from tobacco to be regulated as a medical product. The categories identified in § 1100.5(a) are not intended to constitute an exhaustive list; nor are these categories necessarily mutually exclusive. In addition, these categories are intended to capture concepts, rather than to suggest that the use (or omission) of

particular words is dispositive with respect to FDA's medical product jurisdiction. These categories are included as examples of types of intended uses that we believe are particularly relevant for products made or derived from tobacco and that fall within the disease prong.

2. Structure/Function Prong

Section 1100.5(b) follows the structure/function prong, but with some changes to reflect the court decisions in *Brown & Williamson* and *Sottera.* Specifically, the language in § 1100.5(b) beginning ''in any way that is different from . . . .'' reflects the fact that, under *Brown & Williamson* and *Sottera,* intended structure/function effects related to nicotine will not confer drug/device jurisdiction to the extent they reflect claims that were commonly and legally made for ''customarily marketed'' tobacco products before the date of the *Brown & Williamson* decision. This language also references ''the marketing of cigarettes and smokeless tobacco products'' because these were the product categories considered by the Supreme Court in *Brown & Williamson.* March 21, 2000, is the date of the Supreme Court's ruling in *Brown & Williamson.*

FDA believes that it is important to include a date limitation in § 1100.5(b) to provide greater certainty about the universe of historic structure/function claims the Agency intends to consider when determining whether an intended use of a product made or derived from tobacco is different from effects related to nicotine that were commonly and legally claimed for ''customarily marketed'' cigarettes and smokeless tobacco products. This bright-line limitation also avoids creating a shifting standard that will cause confusion among consumers and regulated industry. FDA intends to look to the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000, to determine the types of structure/function claims that constitute customary tobacco product marketing. Cigarettes and smokeless tobacco products provide a reasonable proxy for determining how nicotine-related structure/function claims were conveyed in tobacco product marketing generally. The codified language, however, applies to all products made or derived from tobacco, not just cigarettes and smokeless tobacco.

3. Intended Use

As noted in section I.B.2, intended use may be determined from any relevant source and is not based solely on claims made in a product's labeling or advertising materials. For purposes of illustration, however, claims such as ''treatment of tobacco dependence,'' ''wean yourself off of nicotine,'' ''for people who wish to quit smoking,'' ''stop smoking aid,'' ''prevent relapse,'' or ''stay quit'' generally will bring a product within the intended uses described in § 1100.5(a).[14]

Claims such as ''to reduce withdrawal symptoms,'' ''helps reduce symptoms including things like [list of withdrawal symptoms]'' and ''relieve withdrawal symptoms when you are prohibited from smoking'' would be associated with an intended use for relief of nicotine withdrawal symptoms, and would also fall within the intended uses described in § 1100.5(a). Withdrawal symptoms that are medically recognized as relevant to nicotine addiction may be determined by reference to standard classification and diagnostic tools such as the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5) and the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD–10).

Certain structure/function claims that were not commonly and legally made in the marketing of cigarettes and smokeless tobacco products before March 21, 2000, such as ''promotes weight loss,'' would fall within the intended uses described in § 1100.5(b).

In contrast to the examples of medical product intended use claims given in the previous paragraphs, certain other claims made about products made or derived from tobacco would not on their own create an intended use that falls within the codified language.[15] For example, claims such as ''smoke free, spit free tobacco pleasure'' or ''full taste and satisfaction'' may be associated with the marketing of tobacco products for refreshment, satisfaction, or enjoyment (which, as discussed in section II.C, are recognized euphemisms for the delivery of a pharmacologically active dose of nicotine to satisfy addiction—an intended structure/function effect—and were commonly and legally made claims for customarily marketed cigarettes and smokeless tobacco products prior to the date of the *Brown & Williamson* decision). Claims such as ''great tasting tobacco satisfaction when you can't smoke,'' ''satisfying tobacco alternative,'' or ''provides the look, feel, and experience of a cigarette'' may be associated with the marketing of tobacco products as smoking substitutes. And claims such as ''healthier alternative to smoking,'' ''contains less nicotine than [another product],'' or ''reduces your risk of lung cancer compared to cigarettes'' might be associated with MRTPs, as discussed in section II.A.2.

For products made or derived from tobacco that are intended for investigational use, FDA will consider whether the product is being used in a clinical investigation for an intended use that brings it within the codified language. If it is, the product would meet the definition of ''investigational new drug'' in § 312.3 (21 CFR 312.3), and the clinical investigation would be subject to the applicable requirements in part 312 (21 CFR part 312).[16] Products made or derived from tobacco that are intended for investigational use but that do not meet the definition of ''investigational new drug'' in § 312.3 may be subject to regulation as investigational tobacco products.

B. Existing ''Intended Use'' Regulations (§§ 201.128 and 801.4)

In the proposed rule, FDA proposed certain changes to FDA's existing regulations describing the types of evidence that may be considered in determining a medical product's intended uses (see § 201.128 (drugs), § 801.4 (devices)). These changes were intended to revise the language of the regulations to better reflect how the Agency applies them. As explained in the preamble to the proposed rule, these amendments were intended to clarify FDA's existing position on intended use, not to change it (80 FR 57756 at 57761). Some comments, however, misunderstood FDA's proposal, particularly with respect to the proposed deletion of the last sentence of both regulations (§§ 201.128 and 801.4). FDA has now determined that its clarification goals can be better achieved by amending the last sentence of each regulation, rather than deleting them.

Accordingly, the last sentence of § 201.128 is amended to provide that if

[14] These and other specific claims mentioned in this document are provided solely as examples. Other claims not mentioned in this document could also reflect an intended use described in the codified language. In addition, as discussed elsewhere in this document, FDA intends to consider the full context of claims for products made or derived from tobacco in making jurisdictional determinations.

[15] As previously, the specific claims mentioned in this paragraph are provided solely as examples. Other claims not mentioned here could fall outside the intended uses described in § 1100.5.

[16] Note that studies performed to meet statutory requirements in chapter IX of the FD&C Act relating to the impact of tobacco products on cessation behavior are not required to be designed as clinical investigations subject to the investigational new drug application requirements in part 312. Whether a study is considered a clinical investigation of an ''investigational new drug'' would depend on the study's design and specific objectives.

the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved (if any), he is required, in accordance with section 502(f) of the FD&C Act, or, as applicable, duly promulgated regulations exempting the drug from the requirements of section 502(f)(1), to provide for the drug adequate labeling that accords with such other intended uses.

Similarly, the last sentence of § 801.4 is amended to provide that if the totality of the evidence establishes that a manufacturer objectively intends that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (if any), he is required, in accordance with section 502(f) of the FD&C Act, or, as applicable, duly promulgated regulations exempting the device from the requirements of section 502(f)(1), to provide for the device adequate labeling that accords with such other intended uses.

As described in the preamble to the proposed rule, FDA's longstanding position is that, in determining a product's intended use, the Agency may look to any relevant source of evidence. This position has solid support in the case law (see, *e.g., United States* v. *Storage Spaces Designated Nos. 8 and 49,* 777 F.2d 1363, 1366 (9th Cir. 1985); *Action on Smoking and Health* v. *Harris,* 655 F.2d 236, 239 (D.C. Cir. 1980); *Nat'l Nutritional Foods Ass'n* v. *Matthews,* 557 F.2d 325, 334 (2d Cir. 1977); *United States* v. *Article of 216 Cartoned Bottles, ''Sudden Change,''* 409 F.2d 734, 739 (2d Cir. 1969); *V.E. Irons, Inc.* v. *United States,* 244 F.2d 34, 44 (1st Cir. 1957); *Hanson* v. *United States,* 417 F. Supp. 30, 35 (D. Minn.), *aff'd,* 540 F.2d 947 (8th Cir. 1976)). This position is unchanged.

In the preamble to the proposed rule, FDA also stated ''the Agency would not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on the firm's knowledge that such product was being prescribed or used by doctors for such use'' (80 FR 57756 at 57757). Health care providers prescribe or use approved/cleared medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their individual patients.[17] In these limited circumstances, FDA does not consider a firm's knowledge that a health care provider has used or prescribed its approved/cleared medical product for an unapproved use, by itself, as sufficient to establish the intended use element of a prohibited act related to the lack of premarket approval/clearance of that use or the lack of adequate directions for use.[18] Instead, FDA examines all relevant evidence, which could include, among other facts, a manufacturer's knowledge that health care providers are prescribing or using its approved/cleared medical product for an unapproved use, to determine whether there is sufficient evidence to establish a new intended use.

Before FDA issued the proposed rule, some drug sponsors had expressed concern with the last sentence of § 201.128. That sentence provided, ''if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses.'' (Section 801.4 contains comparable language.) They asserted that, literally read, this sentence would require that, whenever a manufacturer knew that its approved drug was being prescribed for an unapproved use, it would be required to alter the labeling of a drug to provide adequate directions for an off-label use. They further asserted that this addition to FDA-approved labeling would transform the drug into a new drug that cannot be sold without first obtaining approval of a supplemental new drug application pursuant to 21 U.S.C. 321(p) and 355(a). From this they concluded that, under the last sentence of § 201.128, a manufacturer's mere knowledge of an unapproved use of its approved drug automatically triggers requirements for new labeling that in turn render distribution of that approved product unlawful without approval of a supplemental NDA.

In the proposed rule, the proposed deletion of the last sentence of §§ 201.128 and 801.4 was intended to clarify the following: Where a manufacturer is distributing an approved or cleared medical product, evidence that the manufacturer knows that health care providers are prescribing or using that approved or cleared medical product for an unapproved use would not, by itself, automatically trigger obligations for the manufacturer to provide labeling for the uses for which the health care providers are prescribing or using the product.

FDA's clarification of its position and proposed deletion of the last sentence of these regulations in the proposed rule did not suggest that FDA sought to otherwise narrow the scope of evidence of intended use that FDA may consider. However, some of the comments misunderstood the proposal. For example, some comments asserted—incorrectly—that FDA intended to eliminate manufacturer knowledge altogether as a source of evidence of intended use.

FDA has determined that its clarification goals can be better achieved by amending the last sentence of each regulation, rather than by deleting them. The amended language no longer suggests that a manufacturer's mere knowledge that its approved or cleared product was being prescribed or used for an unapproved use was sufficient to trigger the requirement to provide adequate labeling. In addition, this amended language provides further clarification by reminding manufacturers that, where the totality of evidence is sufficient to establish a new intended use for a medical product, relevant provisions of the FD&C Act and its implementing regulations will be triggered.

In addition, these amendments reflect FDA's longstanding position, upheld by the courts, that FDA may consider a variety of direct and circumstantial evidence to establish intended use. For example, FDA may also take into account any circumstances surrounding the distribution of the product or the context in which it is sold (see, *e.g.,*

[17] FDA generally does not seek to interfere with the exercise of the professional judgment of health care providers in prescribing or administering, for unapproved uses for individual patients, most legally marketed medical products. This longstanding position has been codified with respect to devices (see 21 U.S.C. 396). While FDA generally does not seek to interfere with the exercise of the professional judgment of veterinarians, certain unapproved uses of drugs in animals are not permitted and result in the drug being deemed unsafe under section 512 of the FD&C Act (see section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) and 21 CFR part 530).

[18] See 21 U.S.C. 331(d), 351(f), 352(f)(1), 355(a). That position does not apply to products that are not already legally marketed as medical products for at least one use. Similarly, nothing in this regulation or preamble is intended to impact the application of 21 U.S.C. 333(e), which, subject to limited exceptions, penalizes anyone who ''knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of disease or other recognized medical conditions, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician.'' Further, Congress or the Agency could promulgate other provisions regarding specific products or classes of medical products that recognize knowledge as sufficient evidence of a particular element of a prohibited act.

United States v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001)). In the context of medical products, generally, circumstantial evidence often ensures that FDA is able to hold accountable firms that attempt to evade FDA medical product regulation by avoiding making express claims about their products.

C. Comments and Responses Regarding Intended Use

(Comment 15) Some comments stated that this clarification of the Agency's interpretation and application of the intended use regulations (§§ 201.128 and 801.4) was helpful because it clarifies a point that has been confusing to industry. Another comment stated that the proposed changes to §§ 201.128 and 801.4 provide less information to manufacturers, not more clarity.

(Response) FDA agrees that clarification was warranted because of the apparent confusion over this point. With this final rule, the Agency is making additional changes to the codified language and providing more explanation to further clarify the meaning of the regulations.

(Comment 16) Some comments asserted that FDA should eliminate another reference to ''knowledge'' in § 201.128. Before the amendments implemented by this rule, both §§ 201.128 and 801.4 contained the following sentence: ''[Intended use] may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.'' The comments recommended that FDA delete either the phrase ''with the knowledge of such person or their representatives'' or the entire sentence from the regulation. At least one comment asserted that its recommended change to delete that phrase is consistent with FDA's intent in amending the regulations.

(Response) FDA disagrees with these comments. It was not the Agency's intention to entirely remove manufacturer knowledge from the types of evidence that may be considered in determining a product's intended use. FDA's proposed and final rule not only retained this sentence containing the other reference to ''knowledge'' in the text of both §§ 201.128 and 801.4, but also added ''for example'' to emphasize that FDA may rely on *any* relevant source of evidence of intended use. Accordingly, the amended version of this sentence (in both regulations) now reads that ''intended use may be shown, for example, by circumstances in which the article is, with the knowledge of such person or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.''

In the context of medical products, generally, varied types of evidence, including evidence of a manufacturer's knowledge that a product is being used for an unapproved use, often enables FDA to pursue medical product manufacturers who attempt to evade FDA jurisdiction by avoiding express claims with respect to their products. In addition, as courts have recognized, evidence of a manufacturer's knowledge that a product is being used for an unapproved use can also be used to corroborate other evidence of intended use (see, *e.g., United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients, together with other evidence regarding a training program and financial arrangements offered by the defendant).

FDA's intention in proposing to amend §§ 201.128 and 801.4 was more focused than these comments suggest. First, FDA's statement about not relying solely on manufacturer knowledge was limited to *approved and cleared products* because health care practitioners can generally use and prescribe such products for unapproved uses. That position does not apply to products that are not already legally marketed as medical products for at least one use. Second, manufacturer knowledge may be relevant to intended use, but the Agency would not bring an enforcement action based *solely* on manufacturer knowledge that an approved/cleared product was being prescribed or used by doctors for an unapproved use. If there is other evidence of intended use, FDA may consider manufacturer knowledge as well as other evidence. Third, FDA proposed deleting, and is now amending, the last sentence of the regulations to avoid the potential misinterpretation that a manufacturer's knowledge of an unapproved use of an approved/cleared medical product, without more, automatically triggers requirements for that manufacturer to provide additional labeling.

(Comment 17) At least one comment suggested that the First Amendment requires the exclusion of knowledge as a category of evidence that may be considered as evidence of intended use.

(Response) FDA disagrees. The First Amendment protects, among other things, freedom of speech, and knowledge and speech are not coextensive. A variety of direct and circumstantial evidence can establish a person's knowledge; a person's speech can be one source—but is not the only source—of evidence of that person's knowledge. Thus, the inclusion of evidence of knowledge within the types of evidence that may be relevant to establishing intended use does not in itself implicate the First Amendment.

(Comment 18) At least one comment asserted that, under relevant statutory text, legislative history, and case law, evidence of intended use is limited to a manufacturer's promotional claims. Another comment similarly proposed that the Agency focus principally on statements in the product labeling to establish intended use (using advertising material only to a lesser extent). In contrast, still another comment urged FDA to consider manufacturer statements in a variety of contexts, including advertising; press statements; official or unofficial statements made by corporate officials; statements made in social media and other online arenas; and statements made in point-of-sale locations (both traditional retail and online).

(Response) FDA disagrees with the comments urging FDA to narrow the scope of evidence it will consider in determining intended use, and FDA agrees with the comment asserting that evidence relevant to intended use should include a manufacturer's statements in a variety of contexts. Under the former set of comments, FDA could not consider, for example, evidence of a manufacturer's marketing plans or directions to its sales force, evidence of the well-known uses and abuses of its products, and circumstantial evidence relating to the sale and distribution of the product. These comments' suggested narrow view of evidence of intended use would not only create a loophole for manufacturers and distributors to evade FDA oversight of the marketing of approved/cleared medical products for unapproved uses but would also open the door to the marketing of wholly unapproved medical products—all to the detriment of the public health.

As courts have recognized, ''[s]elf-serving labels cannot be allowed to mask the vendor's true intent as indicated by the overall circumstances'' (*United States* v. *Storage Spaces Designated Nos. 8 and 49,* 777 F.2d 1363, 1366 n.5 (9th Cir. 1985)). As one court explained, ''[a] disease claim made with a wink and a nudge is still a disease claim. To hold otherwise would create an 'obviously wide loophole' that would defeat the 'high purpose of the Act to protect consumers.' '' (*United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166 (D. Or. 2015)

(citation omitted)). Examples of cases where the government has relied on circumstantial evidence to establish intended use include situations where products were labeled as herbal supplements, leather cleaner, incense, potpourri, bath salts, or 'for research purposes only,' but in fact contained a pharmacological ingredient such as the active ingredient from approved erectile dysfunction and hair-loss products, albuterol, steroids, or street-drug pharmacological agents (''synthetic marijuana'' or ''imitation cocaine''). Similar examples for devices include products labeled as laser pointers, massagers, exercise equipment or diving chambers, but actually intended to treat serious conditions such as cancer, HIV, and autism. The government has also considered manufacturers' directions to their sales forces in determining intended use.

Nothing in the statute requires the narrow scope the comments suggest. As four justices of the Supreme Court recognized in rejecting the arguments reflected in these comments, ''The [FD&C Act] . . . does not use the word 'claimed'; it uses the word 'intended' '' (*FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 170 (2000) (dissenting opinion) (the majority declined to resolve the issue, id. at 131–32)). The language of the regulations is consistent with the statutory framework. As one court recently explained, ''[N]owhere does the regulation state that such statements or claims cannot be used to show objective intent unless they were published to the marketplace. To see the absurdity of defendants' argument, consider a hypothetical in which a medical device manufacturer sells device D, which is approved for use A but frequently prescribed by doctors for off-label use B. If the manufacturer creates a bumper sticker with the words 'I intend D to be used for B: Prescribe D for B Today,' by defendants' logic that poster is inadmissible evidence of subjective intent so long as it sits in his briefcase, but admissible evidence of objective intent once he sticks it on his car. The Court is not persuaded that there is a legally relevant distinction here; in either scenario, the defendant has manifested into the physical world 'oral or written statements' that may be weighed as evidence of objective intent'' (*United States* v. *Vascular Solutions, Inc.,* 181 F. Supp. 3d 342, 347 (W.D. Tex. 2016)).

FDA also disagrees that the case law requires that evidence of intended use be limited to marketing representations by firms, to the exclusion of other types of evidence such as internal firm documents and circumstances surrounding the sale of products. Courts have repeatedly held that intended use is determined by looking to all relevant evidence, including statements and circumstances surrounding the manufacture and distribution of a medical product (see, *e.g., United States* v. *Article of 216 Cartoned Bottles, ''Sudden Change,''* 409 F.2d 734, 739 (2d Cir. 1969) (''It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source.'') (citations omitted); *V.E. Irons, Inc.* v. *United States,* 244 F.2d 34, 44 (1st Cir. 1957) (observing that a court is ''free to look to all relevant sources in order to ascertain what is the 'intended use' of a drug'')). As explained by one court: ''Whether a product's intended use makes it a device depends, in part, on the manufacturer's *objective* intent in promoting and selling the product. All of the circumstances surrounding the promotion and sale of the product constitute the 'intent'. It is not enough for the manufacturer to merely *say* that he or she did not 'intend' to sell a particular product as a device. Rather, the actual circumstances surrounding the product's sale . . . determine the 'intended' use of the product as a device under the Act'' (*United States* v. *789 Cases, More or Less, of Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1285 (D. Puerto Rico 1992) (emphasis in original) (internal citations omitted)).

Indeed, courts have rejected the comments' proposition that evidence of intended use is limited to a manufacturer's public claims concerning a device or drug (see *Nat'l Nutritional Foods Ass'n* v. *Matthews,* 557 F.2d 325, 334 (2d Cir. 1977) (''In determining whether an article is a 'drug' because of an intended therapeutic use, the FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence. Such intent also may be derived or inferred from labeling, promotional material, advertising, and any other relevant source.'') (internal citation and quotations omitted); *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (''Labeling is not exclusive evidence of the sellers' intent. Rather, as the very language quoted by the defendants themselves states, 'it is well established 'that the intended use of a product, within the meaning of the [FD&C Act], is determined from its label, accompanying labeling, promotional claims, advertising, *and any other relevant source*' . . . even *consumer* intent could be relevant, so long as it was pertinent to demonstrating the seller's intent . . . [I]f the government's allegations are true, the sellers did not need to label or advertise their product, as the environment provided the necessary information between buyer and seller. In this context, therefore, the fact that there was no labeling may actually bolster the evidence of an intent to sell a mind-altering article without a prescription—that is, a misbranded drug.'') (citations omitted); *United States* v. *Vascular Solutions, Inc.,* 181 F. Supp. 3d 342, 347 (W.D. Tex. 2016) (''Even were this Court at liberty to depart from the Fifth Circuit's position, however, it would still deny defendants' motion; though [21 CFR] § 801.4 indeed says that 'objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives,' nowhere does the regulation state that such statements or claims cannot be used to show objective intent unless they were published to the marketplace.''); see also *United States* v. *Storage Spaces Designated Nos. 8 and 49,* 777 F.2d 1363, 1366 n.5 (9th Cir. 1985) (concluding that products innocuously labeled as ''incense'' and ''not for drug use'' were in fact drugs where the ''overall circumstances'' demonstrated vendor's intent that products be used as cocaine substitutes); *United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients, together with other evidence regarding a training program and financial arrangements offered by the defendant); *United States* v. *Undetermined Quantities of an Article of Drug Labeled as ''Exachol'',* 716 F. Supp. 787, 791 (S.D.N.Y. 1989) (explaining that ''FDA is not bound by the vendor's subjective claims of intent'' and that ''[a]n article intended to be used as a drug will be regulated as a drug . . . even if the products labeling states that it is not a drug'')).

(Comment 19) At least two comments asserted that FDA should significantly contract its proposed definitions of ''intended uses'' because the First Amendment protects truthful speech. One comment stated that, under *Central Hudson Gas and Electric Corp.* v. *Public Services Commission,* 447 U.S. 557, 566 (1980), government regulation of truthful speech concerning a lawful activity violates the First Amendment unless government regulators can

establish that: (1) They have identified a substantial government interest; (2) the regulation directly advances that asserted interest; and (3) the regulation is no more extensive than is necessary to serve that interest. The comment then argued that a complete prohibition of truthful speech by manufacturers and their representatives concerning the off-label uses of a drug or device does not satisfy this test.

Similarly, another comment urged FDA to confirm that truthful and non-misleading speech cannot form the basis of a manufacturer's intended use of a medical product. That comment asserted that courts have recently held that enforcement actions based on truthful, non-misleading speech to health care professionals violates core First Amendment values, citing *United States* v. *Caronia,* 703 F.3d 149 (2d Cir. 2012) and *Amarin Pharma, Inc.* v. *FDA,* 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

(Response) FDA is separately examining its rules and policies relating to firm communications regarding unapproved uses of approved/cleared medical products, with the goal of determining how best to integrate the significant and sometimes competing public health and safety interests served by FDA's regulatory approach related to unapproved uses of medical products with ongoing developments in science and technology, medicine, health care delivery, and constitutional law. To that end, FDA held a two-day public hearing on November 9 and 10, 2016, to obtain input on these issues, and created a docket for the submission of written comments (see, *e.g.,* 81 FR 60299, Sept 1, 2016, announcing a public hearing and request for comments on Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, available at: *http://www.fda.gov/NewsEvents/MeetingsConferences Workshops/ucm489499.htm*). That examination is ongoing. In contrast, the purpose of amending §§ 201.128 and 801.4 in this rulemaking is to clarify the scope of these regulations in response to assertions by industry that they did not understand the meaning of the regulations in their previous form.

The broader policy questions and the related First Amendment issues are thus being considered in a separate proceeding. Nevertheless, it is important to note here that we do not agree with the assertion that the current case law allows FDA to consider speech as evidence of intended use only when it is false or misleading. Courts have held that the government's reliance on speech as evidence of intended use under the FD&C Act does not infringe the right of free speech under the First Amendment based on Supreme Court precedent establishing that ''[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent'' (*Wisconsin* v. *Mitchell,* 508 U.S. 476, 489 (1993)). The D.C. Circuit applied that precedent in the context of the FD&C Act and held that ''th[e] use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid'' and hence ''it is constitutionally permissible for the FDA to use speech [by the manufacturer] . . . to infer intent for purposes of determining that [the manufacturer's] proposed sale . . . would constitute the forbidden sale of an unapproved drug'' (*Whitaker* v. *Thompson,* 353 F.3d 947, 953 (D.C. Cir. 2004); see also *Flytenow, Inc.* v. *FAA,* 808 F.3d 882, 894 (D.C. Cir. 2015) (upholding ''us[e of] speech (postings on Flytenow.com) as evidence that pilots are offering service that exceeds the limits of their certifications'')). Courts applying that reasoning have found that the government's reliance on speech as evidence of intended use under the FD&C Act does not infringe the right of free speech under the First Amendment (see *United States* v. *Lebeau,* 654 Fed. App'x 826, 830–31 (7th Cir. 2016) (per curiam), petition for cert. filed, NO. 16–7125 (U.S. Oct. 13, 2016); *Whitaker* v. *Thompson,* 353 F.3d 947, 953 (D.C. Cir. 2004); *United States* v. *Article of Drug Designated B-Complex Cholinos Capsules,* 362 F.2d 923, 927 (3d Cir. 1966); *United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166 (D. Or. 2015); *United States* v. *Regenerative Sciences,* LLC, 878 F. Supp. 2d 248, 255–56 (D.D.C. 2012), *aff'd,* 741 F.3d 1314 (D.C. Cir. 2014); *United States* v. *Livdahl,* 459 F. Supp. 2d 1255, 1268 (S.D. Fla. 2005); *United States* v. *Lane Labs-USA, Inc.,* 324 F. Supp. 2d 547, 579–80 (D.N.J. 2004); *United States* v. *General Nutrition, Inc.,* 638 F. Supp. 556, 562 (W.D.N.Y. 1986); see also *Spectrum Pharms., Inc.* v. *Burwell,* 824 F.3d 1062 (D.C. Cir. 2016) (manufacturer promotion of a generic drug for use approved for the sponsor but not for the generic may lead to enforcement action for misbranding)).

Although the district court in *Amarin Pharma, Inc.* v. *FDA* held that the *Caronia* decision foreclosed reliance (in the Second Circuit) on this doctrine in the context of an FDA enforcement action where the misbranding was based solely on truthful, non-misleading speech regarding the unapproved use of an approved drug, the Second Circuit has more recently confirmed that ''*Caronia* left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label'' (*United States ex rel. Polansky* v. *Pfizer, Inc.,* 822 F.3d 613 n.2 (2d Cir. 2016)).

In addition, FDA's consideration of speech as evidence of intended use under its statutory and regulatory framework advances substantial public health interests relevant to analyses under *Central Hudson Gas & Electric Corp.* v. *Public Service Comm'n,* 447 U.S. 557, 563–64 (1980). The medical products FDA regulates have the potential to adversely impact public health and safety. Congress specifically developed the premarket review frameworks for medical products in response to public health tragedies [19] and after determining that: (1) Exclusive reliance on postmarket remedies, such as enforcement actions for false or misleading labeling, is unacceptable as a public health strategy for medical products because it does not sufficiently prevent harm and injury to patients and (2) safety and effectiveness must be evaluated for each marketed intended use of a medical product to prevent the harm that occurs when patients are prescribed or use ineffective treatments and to ensure that the benefits of an intended use outweigh its risks. The premarket review requirements of the FD&C Act and the Public Health Service Act provide mechanisms to help ensure that protections are in place that will allow the public to obtain the benefits of these products while mitigating the risks. More specifically, FDA's statutory authorities, regulations, and implementation policies advance substantial public health interests including: Motivating the development of robust scientific data on safety and

[19] The Federal Food, Drug, and Cosmetic Act of 1938, which introduced the requirement that firms demonstrate a drug product to be safe before being marketed, followed the deaths of approximately 100 people from ingesting ''Elixir Sulfanilamide,'' in which the lethal substance diethylene glycol was used as a solvent. Prior to 1938, there were no premarket requirements that mandated that the firm test its product's safety. The passage of the 1962 drug amendments was precipitated in part by the distribution of thalidomide, a sleeping pill that caused birth defects when taken by pregnant women. See W.F. Janssen article (Ref. 20). Significant problems with medical devices likewise preceded the Medical Device Amendments of 1976, including significant defects in cardiac pacemakers that led to 34 voluntary recalls involving 23,000 units, and serious side effects following implantation of intraocular lenses, including serious impairment of vision and the need to remove the eyes of some patients (*H.R. Rep. No. 94–853,* at 8 (1976)).

efficacy;[20] maintaining the premarket review process for safety and efficacy of each intended use in order to prevent harm, protect against fraud, misrepresentation, and bias, and prevent the diversion of healthcare resources toward ineffective treatments;[21] ensuring required labeling is accurate and informative; protecting the integrity and reliability of promotional information regarding medical product uses; protecting human subjects receiving experimental treatments; ensuring informed consent; maintaining incentives for clinical trial participation; protecting innovation incentives, including statutory grants of exclusivity; and promoting the development of products for underserved patients.

At the same time, health care providers also prescribe and use approved/cleared medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their individual patients. Scientific or medical information regarding unapproved uses of products may in some cases help health care providers make better decisions regarding patients, such as where the patient has a disease for which there is no approved/cleared treatment, where the patient is part of a population that has not been studied, or where all approved/cleared treatments have been exhausted. However, in other cases, the use of approved/cleared medical products for unapproved uses has also been associated with significant harm to patients, fraud, and waste of health care resources.[22]

FDA's current implementation approach seeks to integrate the complex mix of numerous and sometimes competing interests at play while also taking into account First Amendment issues. For example, FDA has issued guidance documents to describe some of the circumstances when it would not consider a firm's distribution of reprints, clinical practice guidelines, or reference texts regarding unapproved uses of approved/cleared medical products to be evidence of intended use; and issued a draft guidance on unsolicited requests, confirming FDA's longstanding position that it would not consider a firm's providing truthful, balanced, non-misleading, and non-promotional scientific or medical information (including information about an unapproved use) that is responsive to unsolicited requests for information about FDA-regulated medical products to be evidence of intended use. FDA takes the same view of firms' presenting truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences when done in non-promotional settings and not accompanied by promotional materials.

There are several points worth noting regarding the *Central Hudson* evaluation conducted by Second Circuit panel majority in *United States* v. *Caronia.* First, the panel majority's analysis was limited to addressing the constitutionality of a specific ''construction of the FDCA's misbranding provisions to prohibit and criminalize off-label promotion'' (see 703 F.3d 149, 161–64, 166–69 (2d Cir. 2012)). The *Caronia* majority did not conduct a *Central Hudson* evaluation of FDA's actual approach to manufacturer communications regarding unapproved uses of approved medical products, as described in the preceding paragraph. Second, the panel majority did not consider the multiple facets of public health advanced by FDA's statutory authorities, regulations, and implementation policies, which include motivating the development of reliable scientific evidence that enables the evaluation of the safety and effectiveness of each intended use of a medical product; maintaining the premarket review process for safety and efficacy of each intended use in order to prevent harm, protect against fraud, misrepresentation, and bias, and prevent the diversion of healthcare resources toward ineffective treatments; ensuring required labeling is accurate and informative; protecting the integrity and reliability of promotional information regarding medical product uses; protecting human subjects receiving experimental treatments; ensuring informed consent; maintaining incentives for clinical trial participation; protecting innovation incentives, including statutory grants of exclusivity; and promoting the development of products for underserved patients. The court's limited review of the interests at stake necessarily affected the rest of its *Central Hudson* analysis. Furthermore, the results of an exceptionally large Canadian study showing an association between unapproved uses and adverse drug events[23] were released more than three years after the *Caronia* decision. Accordingly, the *Caronia* court, in conducting its *Central Hudson* evaluation, did not have the benefit of considering the significant findings of this study.

(Comment 20) Several comments asserted that FDA should take this opportunity to bring other related regulations and guidance documents into conformance with modern First Amendment case law. These comments suggested, for example, that FDA reconsider its approach to substantial evidence to support manufacturer communications to health care professionals about approved drugs, reconsider its interpretation of the term

[20] See R. Eisenberg article (Ref. 11) (''By requiring that firms conduct rigorous clinical trials before bringing their products to market and before making promotional claims for their products, the FDA plays an important structural role in promoting a valuable form of biomedical R&D that private firms are undermotivated to perform on their own.''); A. Kesselheim and M. Mello article (Ref. 12) (''There [would] be no need for companies to design these studies to meet the FDA's standards for methodological rigor if the companies have no intention of submitting an application for approval of the new use but rather intend to use the study findings only in marketing communications. Companies [could] design studies in ways that maximize the chances of obtaining a desired result and select which studies to emphasize in promotional communications, ignoring others that do not support their promotional message.''); R. Stafford article (Ref. 13) (Encouraging unapproved uses ''undermines the incentives for manufacturers to perform rigorous studies—and instead subtly encourages them to game the system by seeking approval for secondary indications for which clinical trials are less complicated and less expensive. And off-label use may discourage evidence-based practice.'').

[21] See, *e.g.,* S. Kesselheim and J. Avorn article (Ref. 5) (''In the pharmaceutical market, determining whether a drug is safe and effective for an intended use can involve dozens of FDA scientists poring over extensive databases of studies in animals, toxicologic evaluations, and clinical trials. In essence, the agency acts as a learned intermediary on behalf of prescribing physicians.''); C. Good and W. Gellad article (Ref. 6) (''Even in situations where an off-label indication has been studied, pharmacokinetics, drug-disease interactions, and other safety considerations are unlikely to have been studied systematically to the level required during the FDA drug approval process. Likewise, few clinicians have the time or the motivation to review evidence for those off-label indications to arrive at a balanced assessment of the risks and benefits to support the appropriate use of that drug''); T. Eguale et al. article (Ref. 7) (summarizing study across cohort of 46,000 patients, and concluding that unapproved use of prescription drugs is associated with adverse drug events, particularly where those uses lack strong scientific evidence in the form of at least one randomized controlled trial).

[22] See J. Avorn et al. article (Ref. 8) (''Considerable research shows that marketing can drive prescribing practices, which in turn can lead to adverse patient outcomes if those decisions are not evidence-based.''); A. Kapczynski article (Ref. 9) (''To be effective, a company's marketing must also influence the prescribing patterns of physicians. . . . [T]here is a strong and specific association between pharmaceutical marketing and physician behavior, independent of the evidence supporting the products.''); R. Cardarelli et al. article (Ref. 10) (pharmaceutical industry marketing to prescribing physician creates the potential for prescribing practices that may not benefit the patient, which contribute to escalating health care costs); T. Eguale et al. article (Ref. 7).

[23] T. Eguale et al. article (Ref. 7) (as noted above, summarizing study across cohort of 46,000 patients, and concluding that unapproved use of prescription drugs is associated with adverse drug events, particularly where those uses lack strong scientific evidence in the form of at least one randomized controlled trial).

labeling, and revise its regulations to confirm that FDA will abide by restrictions on FDA authority imposed by federal courts in *United States* v. *Caronia,* 703 F.3d 149 (2d Cir. 2012), and similar First Amendment decisions. At least one comment asserted, citing *United States* v. *Caronia,* that FDA's interpretation and implementation of the FD&C Act restricts speech based on the identity of the speaker. The comment further asserted that any restrictions on truthful and non-misleading speech are subject to ''heightened judicial scrutiny'' and are ''presumptively invalid'' under *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552, 565, 571 (2011), *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218, 2226 (2015), and *Rosenberger* v. *Rector & Visitors of the Univ. of Va.,* 515 U.S. 819, 828 (1995). Another comment, quoting *Bolger* v. *Youngs Drug Prods.,* 463 U.S. 60, 66 (1983), asserted that FDA should recognize that commercial speech is limited to speech that ''does no more than propose a commercial transaction.'' Another comment urged FDA to open a separate docket related to free speech issues regarding medical products.

(Response) To the extent these comments propose that FDA consider, in this rulemaking, issues that are beyond the scope of this rulemaking, FDA declines the suggestion. FDA agrees with the comment that suggests that broader First Amendment issues should be considered in the context of separate proceedings. FDA notes that there are separate proceedings that are currently ongoing (see, *e.g.,* 81 FR 60299, Sept 1, 2016, announcing a public hearing and request for comments on Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, available at: *http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm489499.htm*).

In addition, FDA notes its disagreement with certain characterizations of the existing case law. First, as discussed earlier, the court in *Caronia* based its analysis on a legal theory that is more proscriptive than the one FDA actually holds. Second, the cited Supreme Court cases did not overrule the *Central Hudson* test for commercial speech. The Supreme Court in *Sorrell* confirmed that, where, as here, the speech in question is commercial, the Court applies the ''commercial speech inquiry'' as outlined in *Central Hudson* (*Sorrell* v. *IMS Health Inc.,* 564 U.S. 552, 571–72 (2011); see also *1–800–411-Pain Referral Service, LLC* v. *Otto,* 744 F.3d 1045, 1055 (8th Cir. 2014) (observing that *Sorrell* held that content- or speaker-based restrictions on commercial speech are subject to ''heightened scrutiny,'' and using the *Central Hudson* test to determine the constitutionality of such restrictions)). The *Sorrell* Court also confirmed that ''content-based restrictions on protected expression are sometimes permissible, and that principle applies to commercial speech'' (*Sorrell,* 564 U.S. at 579).

In *Reed* v. *Town of Gilbert,* the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. That holding has no bearing on the commercial speech at issue here (see, *e.g., Sarver* v. *Chartier,* 813 F.3d 891, 903 n.5 (9th Cir. 2016) (stating that *Reed* does not apply to laws governing commercial speech); *Mass. Ass'n of Private Career Sch.* v. *Healey,* 159 F. Supp. 3d 173, 192–93 (D. Mass. 2016) (same); *San Francisco Apt. Ass'n* v. *City & Cnty. of San Francisco,* 142 F. Supp. 3d 910, 922 (N.D. Cal. 2015) (same), appeal docketed, No. 15–17381 (9th Cir. Dec. 3, 2015). The Supreme Court's 1995 decision, *Rosenberger* v. *Rector & Visitors of the Univ. of Va.,* 515 U.S. 819, likewise did not involve commercial speech.

Third, we disagree with the one comment that asserts, quoting *Bolger* v. *Youngs Drug Prods.,* 463 U.S. 60, 66 (1983), that the Supreme Court limited the application of the *Central Hudson* test to speech that literally ''does no more than propose a commercial transaction.'' Although the Court in *Bolger* referred to speech that proposes a commercial transaction as ''the core notion of commercial speech,'' the Court then explained that ''informational pamphlets'' that ''*cannot* be characterized merely as proposals to engage in commercial transactions'' were nevertheless commercial speech based on a combination of relevant circumstances, such as mentioning the seller's product in the pamphlet and the economic motivation of the seller (see *Bolger,* 463 U.S. at 66–68 (emphasis added); see also *Conn. Bar Ass'n* v. *United States,* 620 F.3d 81, 93–94 (2d Cir. 2010)).

(Comment 21) Several comments suggested that FDA replace the phrase ''is intended for use'' in the first sentence of § 1100.5 with other phrases, such as ''is commonly used'' or ''is primarily used.''

(Response) FDA declines this suggestion. The phrase ''is intended for use'' is necessary because it reflects the fact that FDA's regulatory authority over a product made or derived from tobacco is, in the context of regulating them as medical products, dependent upon the product's intended use.

(Comment 22) Several comments urged FDA not to consider a manufacturer's knowledge when determining a manufacturer's intent with respect to the regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The comments also request that the Agency use notice and comment rulemaking instead of guidance to make changes regarding manufacturer intent related to HCT/Ps.

(Response) These comments concern regulations and guidance documents relating specifically to HCT/Ps and are outside the scope of this rulemaking.

D. Comments and Responses Regarding Marketing Concerns

(Comment 23) At least one comment suggested that FDA amend § 1100.5(a) to incorporate the following points: (1) Products intended for use in the cure and treatment of smoking or any other tobacco product use are subject to regulation as medical products; (2) products intended for use for the prevention of relapse into any smoking, tobacco product, or nicotine relapse are subject to regulation as medical products; and (3) relief from nicotine withdrawal symptoms also includes relief from smoking or tobacco use withdrawal symptoms.

(Response) FDA agrees that the three uses identified in the comment appear to be intended uses that would render the products subject to regulation as medical products. Section 1100.5(a) explains that a product made or derived from tobacco is subject to regulation as a medical product if it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. For illustrative purposes, the section also provides several examples of intended uses that will subject a product to regulation as a medical product. We believe the list of examples, which is not intended to be exhaustive, adequately illustrates the types of intended uses that will subject a product made or derived from tobacco to regulation as a medical product. Thus, while we agree that the three identified uses appear to be intended uses that would render the products subject to regulation as medical products, we decline to amend the list to incorporate the uses identified by the comment.

(Comment 24) At least one comment objected that the rule would limit e-cigarettes to marketing claims of ''smoking pleasure'' and ''smoking satisfaction'' since that is how traditional tobacco products were ''customarily marketed'' prior to March

21, 2000. The comment asserted that the rule would either force e-cigarettes off the market as unapproved medical products, or require e-cigarettes to be marketed similar to how traditional tobacco products were marketed prior to March 21, 2000, which would be deceptive because e-cigarettes are not intended for *smoking* pleasure or *tobacco* satisfaction. The comment argued that FDA should treat e-cigarettes differently from products that both contain tobacco leaf and were commercially available before March 21, 2000, when considering the types of claims that will subject a product made or derived from tobacco to regulation as a medical product.

(Response) FDA disagrees. As explained elsewhere in this document, we believe that the rule gives manufacturers and retailers ample flexibility to market e-cigarettes in a manner that is distinct from how cigarettes were marketed prior to March 21, 2000. The date of March 21, 2000, is relevant only to considering claims about a product's effects related to nicotine on the structure or function of the body as evidence of a product's intended use. E-cigarette manufacturers' and retailers' claims related to customizability, number of puffs per cartridge or charge, and various other differentiating features that do not relate to nicotine structure/function effects, irrespective of whether such claims were customarily and legally made in the marketing of cigarettes and smokeless tobacco products before March 21, 2000, should generally not affect the determination of a product's intended use. A manufacturer's making a modified risk claim for a specific tobacco product renders the product an MRTP, which can be marketed only after the manufacturer substantiates any modified risk claims in an MRTP application and after FDA determines that the product meets the statutory standard. Additionally, if a manufacturer intends that its product be used for cessation, it can submit an NDA, Abbreviated New Drug Application (ANDA), Premarket Approval Application (PMA), or premarket notification submission so that FDA can determine whether the product meets the statutory standard and can approve the application or clear the submission, if appropriate.

(Comment 25) At least one comment questioned whether the marketing for tobacco products that are not MRTPs may contain useful contextual information (*e.g.,* ingredient information).

(Response) This comment is outside the scope of this rulemaking because it does not relate to the circumstances in which a product that is made or derived from tobacco will be regulated as a medical product or a tobacco product.

(Comment 26) Several comments stated that ENDS manufacturers need to be able to inform and explain how to properly use vaping devices to help novices to prevent them from having accidents. The comments stated that vape shops need to be able to correctly educate consumers on how to use the products they sell.

(Response) FDA agrees. FDA recognizes that manufacturers may wish to provide instructions to consumers on how to use novel tobacco products, and instructions may be helpful in some cases in preventing consumer injury, such as nicotine poisoning or injuries from exploding batteries. Manufacturers may provide instructions to the consumer in many ways, including verbal instruction. However, if the instructions provided by the manufacturer convey that the product is to be used as a cessation device, then the product will generally be regulated as a medical product. Additionally, if the instructions make a modified risk claim, then the manufacturer must submit an MRTP application so that FDA can determine whether the product meets the statutory standard and can issue an order authorizing it to be marketed as an MRTP.

(Comment 27) Several commenters noted that tobacco products are advertised in a variety of media, including traditional print or mainstream media, blogs, social media, testimonials, and links to studies or media reports on Web sites. One comment observed that manufacturers of ENDS products often use online blogs as a way to make implicit or explicit cessation claims, and in some cases such assertions run counter to disclaimers posted on the same Web site that hosts the blog. Another comment noted that manufacturers used consumer testimonials that make cessation or MRTP claims on their company Web sites. Commenters observed that conflicting claims in advertising caused confusion among consumers regarding whether ENDS products are FDA-approved smoking cessation aids.

(Response) FDA agrees. Tobacco products are advertised in a variety of media, and advertisements may include conflicting information regarding whether the product is a recreational tobacco product or an FDA-approved smoking cessation product. When conflicting claims are made to the consumer, consumers can be confused by those claims. Thus, FDA believes that manufacturers' making smoking cessation claims for any product creates a strong suggestion of therapeutic benefit to the user that would subject the product to regulation under FDA's medical products authority. Such a suggestion generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose. As discussed in response to Comment 12, where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion. In most cases, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion related to the intended therapeutic use of the product.

(Comment 28) Several comments stated that adolescent smokers are especially vulnerable to cessation and therapeutic claims in tobacco product marketing. These comments believe that adolescents misperceive the supposed benefits and underestimate the relative harms, risks, and addictive properties of e-cigarettes and other non-cigarette products.

(Response) FDA agrees that youth and young adults generally ''underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose'' (Ref. 14). For example, one survey found that ''nearly 60 percent of adolescents believed that they could smoke for a few years and then quit'' (Ref. 15). FDA also believes that unsubstantiated cessation claims that reach adolescents may confuse teens and lead teens to believe that these products are FDA-approved smoking cessation products. For example, a teenager in a recent qualitative study said, ''I heard that the only reason they were made is to help people get off from cigarettes for people that want to quit. You would use an e-cigarette to help you quit supposedly. It was on the news'' (Ref. 16). FDA believes it is important to avoid consumer confusion about which products are intended for medical uses versus recreational or other tobacco product uses among both adolescents and adults, and this rule will help consumers.

(Comment 29) At least one comment stated that users consider ENDS and smokeless tobacco products effective cessation interventions. The comment believed that many people use these products to try to stop smoking because they are influenced by manufacturers' and sellers' marketing messages that

make cessation and therapeutic claims about ENDS and other non-cigarette tobacco products.

(Response) FDA agrees that marketing can influence how consumers perceive tobacco products, and products advertised with cessation claims can lead consumers to believe that the product is an FDA-approved smoking cessation device. FDA also agrees that many consumers are using ENDS products for therapeutic purposes. One study concluded that, among State tobacco cessation quitline callers, the most common reported reason for using e-cigarettes was to cut down on, or quit, traditional tobacco use (Ref. 17). Another study concluded that some smokers who were interested in quitting were using ENDS for cessation purposes, possibly discouraging the use of proven smoking cessation treatments, delaying cessation, and thus prolonging exposure to harmful agents in combusted tobacco as an unintended consequence. Additionally, FDA received a large number of comments from individuals using ENDS for therapeutic purposes. One purpose of this regulation is to avoid consumer confusion about which products made or derived from tobacco are intended for a medical use versus for a recreational use.

E. Other Comments and Responses

(Comment 30) At least one comment expressed concern that since the *Sottera* decision, FDA has not taken action against products made or derived from tobacco and making claims that were ''clearly therapeutic.'' In order to protect consumers from ''false, misleading, and confusing tobacco industry claims,'' the comment asks that products made or derived from tobacco making claims without an MRTP order be regulated as drug/device products in the Center for Drug Evaluation and Research.

(Response) FDA disagrees with the comment to the extent that the comment suggests that tobacco products properly regulated as MRTPs be regulated as drugs or devices in the absence of an MRTP order. Tobacco products making modified risk claims are regulated under the tobacco product authorities in the FD&C Act, and an MRTP marketed without an MRTP order would be subject to enforcement as a tobacco product, rather than subject to regulation as a drug or medical device product. With respect to enforcement generally, FDA notes that it is issuing this rule to clarify its interpretation of the drug and device definitions with respect to products made or derived from tobacco, and that it expects this clarification to assist industry in determining the applicable regulatory framework for particular products and help consumers differentiate between products that are intended for medical use and products intended for other uses.

(Comment 31) At least one comment observed that researchers may wish to study the effects that a product made or derived from tobacco has on health outcomes (*e.g.,* withdrawal symptoms, hypertension, etc.) or on the structure and function of the body (*e.g.,* blood pressure, lung function), or the effects of substituting one product made or derived from tobacco for another product. The comment asserted that the methods and measures of such studies are not evidence that the product being investigated is a drug and that FDA should not require an investigational new drug application (IND) for these studies unless they are sponsored by a manufacturer with the intention of supporting a health or medical drug claim.

(Response) The regulations in part 312 set forth the circumstances in which an IND is required for clinical investigations in which a drug is administered to human subjects. The IND requirement applies irrespective of whether the investigation is sponsored by a manufacturer or an academic institution. A study involving a product made or derived from tobacco will generally require an IND if the product, as used in the study, is subject to regulation as a drug. Whether the product, as used in the study, is subject to regulation as a drug depends on whether the product is being investigated for any of the purposes described in § 1100.5(a) or (b) of this rule. To determine if a product made or derived from tobacco is being investigated for one of these purposes, FDA generally would review the protocol for the study, including the proposed methods and measures. In the Agency's experience, the proposed methods and measures for a study can provide insight into the purposes for which a product is being investigated. Ultimately, however, whether a product is being investigated for a therapeutic purpose, and thus whether the study requires an IND, is a fact-specific, case-by-case inquiry. Additional information about the IND requirement can be found in the FDA guidance document entitled ''Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.'' We encourage researchers to review this guidance document, which is available on FDA's Web site at *http://www.fda.gov/downloads/UCM229175.pdf.*

(Comment 32) At least one comment encouraged FDA to coordinate between centers to promote development of safer tobacco products as well as more effective medical products for the treatment of nicotine addiction. This comment also argued that FDA should not allow similar or identical products to be marketed as both tobacco products and medical products, and should consider approving categories of products, rather than individual products, for smoking cessation. This comment also expressed concern about dual use between tobacco product categories.

(Response) FDA agrees with this comment to the extent the comment considers the proposed rule to promote effective coordination between centers by clarifying which center should take the lead in review of premarket applications and postmarketing regulation of particular products. We note that FDA currently interprets the standards in various medical and tobacco product premarket review pathways to refer to individual products rather than product categories, and the question of whether a particular product could obtain marketing authorization as both a tobacco product and as a medical product is beyond the scope of this rule. By clarifying the jurisdictional lines between tobacco and medical products, FDA believes that finalization of this rule will make it less likely that manufacturers will attempt to market products made or derived from tobacco both as tobacco products and as medical products—for example, if a tobacco product manufacturer attempts to add claims to a currently marketed tobacco product that would require the product to be regulated as drug, device, or combination product.

(Comment 33) Several comments recommended that the Center for Tobacco Products (CTP) have sole regulatory jurisdiction over tobacco and nicotine-containing products and provided suggestions for how CTP should structurally reorganize itself to better regulate these products.

(Response) CTP oversees the regulation of products made or derived from tobacco that are intended for human consumption. As stated in this preamble, when a product made or derived from tobacco is marketed or distributed for an intended use that falls within the drug/device definitions, it would be regulated as a medical product unless it is intended to affect the structure or any function of the body in any way related to the effects of nicotine that were commonly and legally claimed prior to March 21, 2000. In this situation, one of FDA's medical product

centers would have regulatory oversight over these products because CTP does not oversee the regulation of medical products. As these comments relate to potentially undertaking a structural reorganization, CTP is not considering a structural reorganization at this time.

(Comment 34) At least one comment suggested that FDA create a separate regulatory category for e-cigarettes that is based on the Agency's medical product regulations, but with less stringent quality standards.

(Response) This recommendation is not consistent with the statutory definitions in the FD&C Act. Under the FD&C Act, a product made or derived from tobacco is subject to regulation as a tobacco product unless it meets the definition of a drug or device or is a combination product, in which case it is subject to regulation as a medical product.

(Comment 35) Several comments stated that the cost and resources required to complete FDA's drug application process would be simply too great and would shut down many small manufacturers.

(Response) This regulation simply clarifies the circumstances under which a product made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product; it does not create new jurisdictional lines or impose new obligations on product manufacturers. Because the jurisdictional lines already exist, tobacco product manufacturers currently making claims that would render their product subject to regulation as a medical product or who wish to make such claims in the future are within FDA's drug and device jurisdiction, absent limited exceptions, and they must follow the applicable statutory and regulatory requirements.

(Comment 36) Many comments believed that the regulation would make e-cigarettes less available to consumers.

(Response) FDA disagrees. This regulation simply clarifies the circumstances under which a product made or derived from tobacco will be regulated as a drug, device, or combination product, and the circumstances under which it will be regulated as a tobacco product. This regulation will not add any additional burden to manufacturers who sell ENDS for recreational use. However, if a manufacturer is selling ENDS and making medical product claims, then the product would be subject to regulation as a drug, device, or combination product if those claims are not structure/function claims related to the effects of nicotine that were commonly and legally claimed prior to March 21, 2000.

(Comment 37) At least one comment suggested that the final rule should include a discussion of how the regulation will affect public health.

(Response) The preamble to the proposed rule contained some discussion of this topic, and this preamble to the final rule further expands on various public health protections.

(Comment 38) FDA proposed that a product made or derived from tobacco that is intended for use in smoking cessation be subject to regulation as a medical product. Several comments objected that smoking is not a disease, but a behavior, and that a product that claims to help individuals quit smoking should not be regulated as a medical product absent any assertions that it will prevent disease or treat nicotine dependence. One comment asserted that promoting a product as suitable for continued nicotine use after stopping smoking traditional cigarettes is the functional equivalent of a ''smoking alternative'' claim, which FDA has said does not fall within the Agency's medical product authority, and, therefore, should not subject the product to regulation as a medical product.

(Response) Over the past 50 years, smoking has been causally linked to diseases of nearly all organs of the body, diminished health status, and fetal harm. Most current adult smokers want to quit smoking completely for health reasons (Ref. 18). Given these facts, we believe that statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose. We recognize, however, that public perception can change and evidence may be developed showing that, in some situations, ''smoking cessation'' is understood in context as referring to ending the use of traditional cigarettes and switching to a non-combustible product made or derived from tobacco. We have revised the codified language in § 1100.5(a) in the final rule, to reflect that ''smoking cessation'' is one type of intended use related to ''the cure or treatment of nicotine addiction.'' FDA intends to closely scrutinize ''smoking cessation'' claims to ensure that consumers are not misled about the intended use of a product made or derived from tobacco.

(Comment 39) One comment stated that this regulation should not require companies that handle raw materials to determine whether those raw materials would be used in tobacco products or whether those materials would be used in medical products. The comment stated that the intended use of the product is completely within the discretion of the sellers and distributors of the finished products, and the Agency should not extend regulations to cover companies that handle raw materials.

(Response) This comment is beyond the scope of this rule. This regulation does not create new jurisdictional lines or impose new obligations on product manufacturers or companies that handle raw materials. Rather, this rulemaking simply clarifies the circumstances under which a product made or derived from tobacco would be regulated as a drug, device, or combination product, and the circumstances under which it would be regulated as a tobacco product. If FDA were to consider extending its authority in such a way that would place additional requirements on companies handling raw materials, the Agency would do so through a separate rulemaking.

F. Other Changes to the Codified Text

To eliminate redundancy, we deleted ''or prevention or mitigation of disease'' from the end of § 1100.5(a), as the opening text already includes similar language. Because of this deletion, we inserted the word ''or'' in front of ''relief of nicotine withdrawal symptoms.''

G. Effective Date

This final rule will become effective 30 days after the date of its publication in the **Federal Register**. During those 30 days, manufacturers will continue to be under an obligation to comply with all applicable provisions of the FD&C Act and applicable regulations.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Executive Order 13175: Tribal Consultation

We have analyzed this rule in accordance with the principles set forth

in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

VII. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because, as described in detail in the section entitled ''Final Small Entity Analysis'' in the full analysis of economic impacts available in the docket for this final rule (Ref. 19) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm,* the clarifications in this final rule will not significantly increase costs on manufacturers of products made or derived from tobacco, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in expenditure in any year that meets or exceeds this amount.

The final rule will reduce ambiguity in the market for products made or derived from tobacco and clarify FDA's interpretation and application of its existing intended use regulations. The rule clarifies the intended uses and supporting evidence that would result in these products being regulated as drugs, devices, or combination products rather than tobacco products. Products derived from tobacco that are intended to: (1) Diagnose, cure, mitigate, treat or prevent disease, including use in smoking cessation or (2) affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco prior to March 21, 2000, such as an intended use for improving respiratory function, will be subject to regulation as drugs, devices, or combination products. We estimate that there would be one-time costs for tobacco manufacturers to evaluate current product communications such as labeling and associated promotional materials in light of the clarifications in this final rule, and to revise them if needed. We expect that only a small number of product communications such as labeling and associated materials will undergo a one-time change as a result of this rule.

The final rule will provide greater clarity to producers regarding the regulatory requirements for products made or derived from tobacco and to consumers to distinguish products intended for medical uses from those marketed for other uses. The reduction in ambiguity will enhance consumers' understanding of the products they purchase and may increase consumer welfare as a result.

TABLE 2—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits							
Annualized					7		
Monetized ($millions/year)					3		
Annualized					7		
Quantified					3		
Qualitative	Reduce regulatory ambiguity						
Costs							
Annualized	$0.246	$1.126	$0.365	2014	7	10	
Monetized ($millions/year)	0.202	0.202	0.202				
	0.202	0.104	0.301	2014	3	10	
Annualized					7		
Quantified					3		
Qualitative							

TABLE 2—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Transfers							
Federal					7		
Annualized					3		
Monetized ($millions/year)							
From/To	From:			To:			
Other					7		
Annualized					3		
Monetized ($millions/year)							
From/To	From:			To:			

Effects
State, Local or Tribal Government: No Effect
Small Business: No effect
Wages: No estimated effect
Growth: No estimated effect

The full analysis of economic impacts is available in the docket for this final rule (Ref. 19) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IX. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Defendants' Memorandum of Points and Authorities in Support of Motion to Dismiss or for Summary Judgment. *Allergan* Inc. v. *United States of America, et al.,* 1:09–cv–01879–JDB (D.D.C. Jan. 11, 2010), 2010 WL 11211158.
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15. Institute of Medicine of the National Academies, ''Ending the Tobacco Problem: A Blueprint for the Nation,'' 2007, available at *https://www.nap.edu/read/11795/chapter/1.*
16. Roditis, M.L., and B. Halpern-Felsher, ''Adolescents' Perceptions of Risks and Benefits of Conventional Cigarettes, E-Cigarettes and Marijuana: A Qualitative Analysis,'' *Journal of Adolescent Health,* 57(2):179–185, 2015.
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18. Gallup Consumption Habits poll, July 2013 (see *http://www.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx*).
19. Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination; Amendments to Regulations Regarding ''Intended Uses,'' Final Rule; Final Regulatory Impact Analysis.
20. Janssen, W.F., ''Outline of the History of U.S. Drug Regulation and Labeling,'' *Food Drug Cosmetic Law Journal,* 36: 420, 437–438, 1981.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1100

Combination products, Devices, Drugs, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter 1 is amended as follows:

PART 201—LABELING

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Revise § 201.128 to read as follows:

§ 201.128 Meaning of "intended uses".

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. And if the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved (if any), he is required, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly promulgated regulations exempting the drug from the requirements of section 502(f)(1), to provide for such drug adequate labeling that accords with such other intended uses.

PART 801—LABELING

■ 3. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360d, 360i, 360j, 371, 374.

■ 4. Revise § 801.4 to read as follows:

§ 801.4 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the device, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. And if the totality of the evidence establishes that a manufacturer objectively intends that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements (if any), he is required, in accordance with section 502(f) of the Federal Food, Drug, and Cosmetic Act, or, as applicable, duly promulgated regulations exempting the device from the requirements of section 502(f)(1), to provide for such device adequate labeling that accords with such other intended uses.

PART 1100—TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY

■ 5. The authority citation for part 1100 is revised to read as follows:

Authority: 21 U.S.C. 387a(b), 387f(d); Secs. 901(b) and 906(d), Pub. L. 111–31; 21 CFR 16.1 and 1107.1; 21 CFR 1.1, 1.20, 14.55, 17.1, and 17.2. Section 1100.5 is issued under 21 U.S.C. 321, 353(g), and 371(a); 21 CFR 1.1.

■ 6. Part 1100 is amended by adding § 1100.5 to read as follows:

§ 1100.5 Exclusion from tobacco regulation.

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

(a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction (*e.g.,* smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms;

(b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

Dated: December 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31950 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2014–N–1205]

Orthopedic Devices; Reclassification of Pedicle Screw Systems, Henceforth To Be Known as Thoracolumbosacral Pedicle Screw Systems, Including Semi-Rigid Systems

Correction

In rule document 2016–31670 beginning on page 96366 in the issue of Friday, December 30, 2016, make the following correction:

On page 96372, in the second column, in the 25th, 51st, and 67th lines, and in the third column, in the tenth line, ''June 28, 2018'' should read ''July 1, 2019''.

[FR Doc. C1–2016–31670 Filed 1–6–17; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–446]

Schedules of Controlled Substances: Temporary Placement of Six Synthetic Cannabinoids (5F–ADB–, 5F–AMB, 5F–APINACA, ADB–FUBINACA, NDMB–CHMICA and MDMB–FUBINACA) Into Schedule I

Correction

Document 2016–30595 was inadvertently classified a rule and published in the Rules and Regulations section in the issue of December 21, 2016, beginning on page 93595. It should have appeared in the Proposed Rules section.

As a result of the error, an amendment was made to 21 CFR 1308.11 which the DEA did not intend. This classification correction removes added paragraphs (h)(23) through (28) from 21 CFR 1308.11.

Accordingly, 21 CFR part 1308 is corrected as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

§ 1308.11 [Corrected]

■ 2. In § 1308.11, remove paragraphs (h)(23) through (28).

[FR Doc. C1–2016–30595 Filed 1–6–17; 8:45 am]

BILLING CODE 1301–00–D

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 241

Republic of Iraq Loan Guarantees Issued Under the Further Continuing and Security Assistance Appropriations Act of 2017—Standard Terms and Conditions

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This regulation prescribes the procedures and standard terms and conditions applicable to loan guarantees to be issued for the benefit of the Republic of Iraq pursuant to the Further Continuing and Security Assistance Appropriations Act, 2017.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: D. Bruce McPherson, Office of the General Counsel, U.S. Agency for International Development, Washington, DC 20523–6601; tel. 202–712–1611, fax 202–216–3055.

SUPPLEMENTARY INFORMATION: Pursuant to the Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254), the United States of America, acting through the U.S. Agency for International Development, may issue certain loan guarantees applicable to sums borrowed by the Republic of Iraq (the ''Borrower''), not exceeding an aggregate total of U.S. $1 billion in principal amount. Upon issuance, the loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such borrowings and the full faith and credit of the United States of America shall be pledged for the full payment and performance of such guarantee obligations.

This rulemaking document is not subject to rulemaking under 5 U.S.C. 553 or to regulatory review under Executive Order 12866 because it involves a foreign affairs function of the United States. The provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) do not apply.

List of Subjects in 22 CFR Part 241

Foreign aid, Foreign relations, Guaranteed loans, Loan programs—foreign relations.

Authority and Issuance

■ Accordingly, part 241 is added to title 22, chapter II, of the Code of Federal Regulations, as follows:

PART 241—REPUBLIC OF IRAQ LOAN GUARANTEES ISSUED UNDER THE FURTHER CONTINUING AND SECURITY ASSISTANCE APPROPRIATIONS ACT OF 2017

Sec.
241.1 Purpose.
241.2 Definitions.
241.3 The Guarantee.
241.4 Guarantee eligibility.
241.5 Non-impairment of the Guarantee.
241.6 Transferability of Guarantee; Note Register.
241.7 Fiscal Agent obligations.
241.8 Event of Default; Application for Compensation; payment.
241.9 No acceleration of Eligible Notes.
241.10 Payment to USAID of excess amounts received by a Noteholder.
241.11 Subrogation of USAID.
241.12 Prosecution of claims.
241.13 Change in agreements.
241.14 Arbitration.
241.15 Notice.
241.16 Governing law.
Appendix A to Part 241—Application for Compensation

Authority: Security Assistance Appropriations Act, 2017 (Div. B, Pub. L. 114–254).

§ 241.1 Purpose.

The purpose of the regulations in this part is to prescribe the procedures and standard terms and conditions applicable to loan guarantees issued for the benefit of the Borrower, pursuant the Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254) (the ''Authority''). The loan guarantees will be issued as provided herein pursuant to the Loan Guarantee Agreement, executed in January 2017, between the United States of America and the Republic of Iraq (the ''Loan Guarantee Agreement''). The loan guarantee will apply to sums borrowed during a period beginning on the date that the Loan Guarantee Agreement enters into force and ending thirty days after such date, not exceeding an aggregate total of one billion United States Dollars ($1,000,000,000) in principal amount. The loan guarantees shall ensure the Borrower's repayment of 100% of principal and interest due under such borrowings. The full faith and credit of the United States of America is pledged for the full payment and performance of such guarantee obligations.

§ 241.2 Definitions.

Wherever used in the standard terms and conditions set out in this part:

Applicant means a Noteholder who files an Application for Compensation with USAID, either directly or through the Fiscal Agent acting on behalf of a Noteholder.

Application for Compensation means an executed application in the form of Appendix A to this part which a Noteholder, or the Fiscal Agent on behalf of a Noteholder, files with USAID pursuant to § 241.8.

Borrower means the Republic of Iraq.

Business Day means any day other than a day on which banks in New York, NY are closed or authorized to be closed or a day which is observed as a federal holiday in Washington, DC, by the United States Government.

Date of Application means the date on which an Application for Compensation is actually received by USAID pursuant to § 241.15.

Defaulted Payment means, as of any date and in respect of any Eligible Note, any Interest Amount and/or Principal Amount not paid when due, regardless of the reason the Borrower fails to pay, including without limitation withholding taxes.

Eligible Note(s) means [a] Note[s] meeting the eligibility criteria set out in § 241.4.

Fiscal Agency Agreement means the agreement among USAID, the Borrower and the Fiscal Agent pursuant to which the Fiscal Agent agrees to provide fiscal agency services in respect of the Note[s], a copy of which Fiscal Agency Agreement shall be made available to Noteholders upon request to the Fiscal Agent.

Fiscal Agent means the bank or trust company or its duly appointed successor under the Fiscal Agency Agreement which has been appointed by the Borrower with the consent of USAID to perform certain fiscal agency services for specified Eligible Note[s] pursuant to the terms of the Fiscal Agency Agreement.

Further Guaranteed Payments means the amount of any loss suffered by a Noteholder by reason of the Borrower's failure to comply on a timely basis with any obligation it may have under an Eligible Note to the Noteholders, including late fees under the Eligible Note, but not including any taxes or governmental charges or any expense arising out of taxes or any other governmental charges relating to the Eligible Note in the country of the Borrower.

Guarantee means the guarantee of USAID pursuant to the Authority.

Guarantee Payment Date means a Business Day not more than three (3) Business Days after the related Date of Application.

Interest Amount means for any Eligible Note the amount of interest accrued on the Principal Amount of such Eligible Note at the applicable Interest Rate.

Interest Rate means the interest rate borne by an Eligible Note.

Loss of Investment means, in respect of any Eligible Note, an amount in Dollars equal to the total of the:

(1) Defaulted Payment unpaid as of the Date of Application,

(2) Further Guaranteed Payments unpaid as of the Date of Application, and

(3) Interest accrued and unpaid at the Interest Rate(s) specified in the Eligible Note(s) on the Defaulted Payment and Further Guaranteed Payments, in each case from the date of default with respect to such payment to and including the date on which full payment thereof is made to the Noteholder.

Note[s] means any debt securities issued by the Borrower.

Noteholder means the owner of an Eligible Note who is registered as such on the Note Register.

Note Register means the register of Eligible Notes required to be maintained by the Fiscal Agent.

Person means any legal person, including any individual, corporation, partnership, joint venture, association, joint stock company, trust, unincorporated organization, or government or any agency or political subdivision thereof.

Principal Amount means the principal amount of the Eligible Notes issued by the Borrower. For purposes of determining the principal amount of the Eligible Notes issued by the Borrower, the principal amount of each Eligible Note shall be the stated principal amount thereof.

USAID means the United States Agency for International Development or its successor.

§ 241.3 The Guarantee.

Subject to the terms and conditions set out in this part, the United States of America, acting through USAID, guarantees to Noteholders the Borrower's repayment of 100% of principal and interest due on Eligible Notes. Under this Guarantee, USAID agrees to pay to any Noteholder compensation in Dollars equal to such Noteholder's Loss of Investment under its Eligible Note; provided, however, that no such payment shall be made to any Noteholder for any such loss arising out of fraud or misrepresentation for which such Noteholder is responsible or of which it had knowledge at the time it became such Noteholder. This Guarantee shall apply to each Eligible Note registered on the Note Register required to be maintained by the Fiscal Agent.

§ 241.4 Guarantee eligibility.

(a) Eligible Notes only are guaranteed hereunder. Notes in order to achieve Eligible Note status:

(1) Must be signed on behalf of the Borrower, manually or in facsimile, by a duly authorized representative of the Borrower;

(2) Must contain a certificate of authentication manually executed by the Fiscal Agent whose appointment by the Borrower is consented to by USAID in the Fiscal Agency Agreement; and

(3) Shall be approved and authenticated by USAID by either:

(i) The affixing by USAID on the Notes of a guarantee legend incorporating these Standard Terms and Conditions signed on behalf of USAID by either a manual signature or a facsimile signature of an authorized representative of USAID; or

(ii) The delivery by USAID to the Fiscal Agent of a guarantee certificate incorporating these Standard Terms and Conditions signed on behalf of USAID by either a manual signature or a facsimile signature of an authorized representative of USAID.

(b) The authorized USAID representatives for purposes of the regulations in this part whose signature(s) shall be binding on USAID shall include the USAID Chief and Deputy Chief Financial Officer, Assistant Administrator and Deputy, Bureau for the Middle East, Mission Director and Acting Mission Director for USAID/Iraq, and such other individual(s) designated in a certificate executed by an authorized USAID Representative and delivered to the Fiscal Agent. The certificate of authentication of the Fiscal Agent issued pursuant to the Fiscal Agency Agreement shall, when manually executed by the Fiscal Agent, be conclusive evidence binding on USAID that an Eligible Note has been duly executed on behalf of the Borrower and delivered.

§ 241.5 Non-impairment of the Guarantee.

After issuance of a Guarantee, that Guarantee will be an unconditional, full faith and credit obligation of the United States of America, and will not be affected or impaired by any subsequent condition or event. This non-impairment of the guarantee provision shall not, however, be operative with respect to any loss arising out of fraud or misrepresentation for which the claiming Noteholder is responsible or of which it had knowledge at the time it became a Noteholder. Moreover, the Guarantee shall not be affected or impaired by:

(a) Any defect in the authorization, execution, delivery or enforceability of any agreement or other document executed by a Noteholder, USAID, the Fiscal Agent or the Borrower in connection with the transactions contemplated by this Guarantee; or

(b) The suspension or termination of the program pursuant to which USAID is authorized to guarantee the Eligible Notes.

§ 241.6 Transferability of Guarantee; Note Register.

A Noteholder may assign, transfer or pledge an Eligible Note to any Person, provided that such transfer is permitted under applicable law and regulation, including, without limitation, the Office of Foreign Assets Control (OFAC) regulations. Any such assignment, transfer or pledge shall be effective on the date that the name of the new Noteholder is entered on the Note Register required to be maintained by

the Fiscal Agent pursuant to the Fiscal Agency Agreement. USAID shall be entitled to treat the Persons in whose names the Eligible Notes are registered as the owners thereof for all purposes of this Guarantee and USAID shall not be affected by notice to the contrary.

§ 241.7 Fiscal Agent obligations.

Failure of the Fiscal Agent to perform any of its obligations pursuant to the Fiscal Agency Agreement shall not impair any Noteholder's rights under this Guarantee, but may be the subject of action for damages against the Fiscal Agent by USAID as a result of such failure or neglect. A Noteholder may appoint the Fiscal Agent to make demand for payment on its behalf under this Guarantee.

§ 241.8 Event of Default; Application for Compensation; payment.

At any time after an Event of Default, as this term is defined in an Eligible Note, any Noteholder hereunder, or the Fiscal Agent on behalf of a Noteholder hereunder, may file with USAID an Application for Compensation in the form provided in Appendix A to this part. USAID shall pay or cause to be paid to any such Applicant any compensation specified in such Application for Compensation that is due to the Applicant pursuant to the Guarantee as a Loss of Investment not later than the Guarantee Payment Date. In the event that USAID receives any other notice of an Event of Default, USAID may pay any compensation that is due to any Noteholder pursuant to a Guarantee, whether or not such Noteholder has filed with USAID an Application for Compensation in respect of such amount.

§ 241.9 No acceleration of Eligible Notes.

Eligible Notes shall not be subject to acceleration, in whole or in part, by USAID, the Noteholder or any other party. USAID shall not have the right to pay any amounts in respect of the Eligible Notes other than in accordance with the original payment terms of such Eligible Notes.

§ 241.10 Payment to USAID of excess amounts received by a Noteholder.

If a Noteholder shall, as a result of USAID paying compensation under this Guarantee, receive an excess payment, it shall refund the excess to USAID.

§ 241.11 Subrogation of USAID.

In the event of payment by USAID to a Noteholder under this Guarantee, USAID shall be subrogated to the extent of such payment to all of the rights of such Noteholder against the Borrower under the related Note.

§ 241.12 Prosecution of claims.

After payment by USAID to an Applicant hereunder, USAID shall have exclusive power to prosecute all claims related to rights to receive payments under the Eligible Notes to which it is thereby subrogated. If a Noteholder continues to have an interest in the outstanding Eligible Notes, such a Noteholder and USAID shall consult with each other with respect to their respective interests in such Eligible Notes and the manner of and responsibility for prosecuting claims.

§ 241.13 Change in agreements.

No Noteholder will consent to any change or waiver of any provision of any document contemplated by this Guarantee without the prior written consent of USAID.

§ 241.14 Arbitration.

Any controversy or claim between USAID and any Noteholder arising out of this Guarantee shall be settled by arbitration to be held in Washington, DC in accordance with the then prevailing rules of the American Arbitration Association, and judgment on the award rendered by the arbitrators may be entered in any court of competent jurisdiction.

§ 241.15 Notice.

Any communication to USAID pursuant to this Guarantee shall be in writing in the English language, shall refer to the Republic of Iraq Loan Guarantee Number inscribed on the Eligible Note and shall be complete on the day it shall be actually received by USAID at the Office of Development Credit, Bureau for Economic Growth, Education and Environment, United States Agency for International Development, Washington, DC 20523–0030. Other addresses may be substituted for the above upon the giving of notice of such substitution to each Noteholder by first class mail at the address set forth in the Note Register.

§ 241.16 Governing law.

This Guarantee shall be governed by and construed in accordance with the laws of the United States of America governing contracts and commercial transactions of the United States Government.

Appendix A to Part 241—Application for Compensation

United States Agency for International Development

Washington, DC 20523

Ref: Guarantee dated as of _____, 20 ____:

To Whom It May Concern: You are hereby advised that payment of $_____ (consisting of _____ of principal, _____ of interest and $_____ in Further Guaranteed Payments, as defined in § 241.2 of the Standard Terms and Conditions of the above-mentioned Guarantee) was due on _____, 20__, on $_____ Principal Amount of Notes issued by the Republic of Iraq (the ''Borrower'') held by the undersigned. Of such amount $_____ was not received on such date and has not been received by the undersigned at the date hereof. In accordance with the terms and provisions of the above-mentioned Guarantee, the undersigned hereby applies, under § 241.8 of said Guarantee, for payment of $_____, representing $_____, the Principal Amount of the presently outstanding Note(s) of the Borrower held by the undersigned that was due and payable on _____ and that remains unpaid, and $_____, the Interest Amount on such Note(s) that was due and payable by the Borrower on _____ and that remains unpaid, and $_____ in Further Guaranteed Payments,[1] plus accrued and unpaid interest thereon from the date of default with respect to such payments to and including the date payment in full is made by you pursuant to said Guarantee, at the rate of ____% per annum, being the rate for such interest accrual specified in such Note. Such payment is to be made at [state payment instructions of Noteholder or Fiscal Agent, as applicable].

All capitalized terms herein that are not otherwise defined shall have the meanings assigned to such terms in the Standard Terms and Conditions of the above-mentioned Guarantee.

[Name of Applicant]

By: _____

Name: _____

Title: _____

Dated: _____

Dated: January 5, 2017.

D. Bruce McPherson,

Attorney Advisor, Office of the General Counsel, U.S. Agency for International Development.

[FR Doc. 2017–00294 Filed 1–6–17; 8:45 am]

BILLING CODE P

[1] In the event the Application for Compensation relates to Further Guaranteed Payments, such Application must also contain a statement of the nature and circumstances of the related loss.

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Parts 1, 3, 4, 5, and 6

Wage and Hour Division

29 CFR Parts 500, 505, 516, 519, 520, 525, 530, 547, 549, 553, 570, 575, 578, 580, 801, and 825

RIN 1235–AA17

Updating Regulations Issued Under the Fair Labor Standards Act, Service Contract Act, Davis-Bacon and Related Acts, Contract Work Hours and Safety Standards Act, the Family and Medical Leave Act, Employee Polygraph Protection Act, and the Migrant and Seasonal Agricultural Worker Protection Act

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Final rule; technical corrections.

SUMMARY: In this final rule, the Department of Labor (DOL or Department) revises regulations issued pursuant to the Fair Labor Standards Act of 1938 (FLSA), the Davis-Bacon and Related Acts (DBRA), the Service Contract Act (SCA), Contract Work Hours and Safety Standards Act (CWHSSA), Family and Medical Leave Act (FMLA), Employee Polygraph Protection Act (EPPA), and the Migrant and Seasonal Agricultural Worker Protection Act (MSPA) that include reference to the ''Employment Standards Administration'' at the DOL. The Employment Standards Administration was eliminated as part of agency reorganization in 2009 and its authorities and responsibilities were devolved into its constituent components, including the Wage and Hour Division (WHD). This action deletes reference to the Employment Standards Administration in the regulations administered by WHD. Additionally, this action updates Office of Management and Budget (OMB) control numbers associated with information collections in the appropriate regulations. WHD was assigned new control numbers by OMB and this action updates those references in the regulations to the current corresponding OMB control number. Further, this action updates cross-references that were not revised in the FMLA Final Rule published February 25, 2015.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Robert Waterman, Compliance Specialist, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW., Washington, DC 20210, telephone: (202) 693–0406 (this is not a toll-free number) or email: *WHDPRAComments@dol.gov.*

SUPPLEMENTARY INFORMATION: The Department is eliminating references to the Employment Standards Administration at the DOL. The Employment Standards Administration is a former branch of the DOL and was eliminated in an agency reorganization in 2009. In addition, the Department is updating references to OMB information collection control numbers. OMB has assigned different information collection control numbers to WHD information collections and the Department is updating these references in the appropriate regulations so the reader can find the information collection corresponding to a specific regulation.

The Department is also correcting cross-references to the FMLA's definitions section in two sections of its FMLA regulations, § 825.104(b) and § 825.209(a). A recent rulemaking moved the definitions section of the FMLA regulations from § 825.800 to § 825.102 but did not update the cross-references to the definitions section in § 825.104(b) and § 825.209(a). Additionally, the Department is updating the reference in 29 CFR 3.3 to the Web site location where the public may access the WH–347 form. As part of the agency reorganization of the Web site, the location of the form has changed. Finally, the Department is replacing the term firefighter with the term employee engaged in fire protection activities in two sections of its regulations, 29 CFR 553.221 and 553.231, to conform to an amendment to the FLSA. In December 1999, Congress amended the FLSA to add a definition of employee engaged in fire protection activities. The Department published an FLSA Final Rule on April 5, 2011 (76 FR 18832) that incorporated the new definition into the regulations and made several conforming revisions in part 553, subpart C, but did not conform the language of these provisions.

Administrative Procedure Act

Section 553(b)(3) of the Administrative Procedure Act (APA) provides that an agency is not required to publish a notice of proposed rulemaking in the **Federal Register** and solicit public comments when the agency has good cause to find that doing so would be ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3). The Department finds that good cause exists to dispense with the notice and public comment procedures for this technical correction to its regulations, as it concludes that such procedures are unnecessary. This rule merely memorializes the delegation of administrative authority within the Department; updates references to OMB control numbers and WHD's Web site which are now out of date; corrects cross-references to another section of the Department's regulations; and conforms the terminology in the Department's regulations to an amendment to the definitions section of the FLSA. This rule does not impose any new regulatory obligations or information collection requirements on employers or affect the rights of workers. Therefore, the Department is issuing this technical correction as a final rule.

Section 553(d) of the APA also provides that substantive rules should take effect not less than 30 days after the date they are published in the **Federal Register** unless ''otherwise provided by the agency for good cause found[.]'' 5 U.S.C. 553(d)(3). Since this rule is a technical correction that does not change the substance of the Department's regulations, the Department finds that it is unnecessary to delay the effective date of the rule. Accordingly, the Department finds that it has good cause exists to make this technical correction effective on the date of publication.

Summary of Changes to the Regulations

In 29 CFR 1.2, 1.5, 4.1a, 4.3, 4.5, 4.6, 4.10, 4.11, 4.12, 4.101, 4.191, 5.2, 5.12, 5.13, 6.2, 500.7, 500.20, 500.41, 500.56, 500.215, 505.2, 520.300, 525.22, 530.1, 530.101, 530.102, 530.403, 570.1, 575.2, 575.3, 578.2, 580.1, 801.2, 801.7, and 825.401, the Department has removed the reference to the Employment Standards Administration and replaced it with the Wage and Hour Division where appropriate. In 29 CFR 519.11, the Department has removed the reference to the Assistant Secretary for Employment Standards. The Employment Standards Administration is a former branch of the DOL and was eliminated in an agency reorganization in 2009. *See* Secretary's Order No. 09–2009 (Nov. 6, 2009), 74 FR 58836 (Nov. 13, 2009). In 29 CFR 5.5, the Department has removed the reference to the Employment Standards Administration and made two additional technical corrections: Correcting an error made in the instructions to the Final Rule issued under the DBRA in 2000 (65 FR 69674)

that resulted in the retention of an editorial note referencing a 1993 suspension of paragraph (a)(1)(ii) that should have been removed at that time; and incorporating the undesignated language that follows paragraph (a)(1)(i) into that paragraph.

In 29 CFR 3.3, the Department has updated the referenced Web site location where the public may access the WH–347 form. As part of the agency reorganization of the Web site, the location of the form has changed.

In 29 CFR 3.4, 5.15, 505.5, 520.403, 520.405, 520.501, 520.502, 525.16, 530.3, 530.4, 547.1, 549.1, 570.6, 570.36, 570.37 and 801.30, the Department has updated the OMB control number where the public may access the relevant information collection approved by OMB under the Paperwork Reduction Act. In 29 CFR 4.6, 5.5 and 516.0, the Department has provided updated information collection requests tables showing the current OMB control numbers associated with the referenced recordkeeping requirements. OMB changed the agency information collection control numbers. The correction will allow the public to access the currently approved information collection.

In 29 CFR 553.221 and 553.231, the Department has replaced references to firefighters with references to employees engaged in fire protection activities to conform to a recent amendment to the FLSA. In December 1999, Congress amended the FLSA to add a definition of employee engaged in fire protection activities. *See* Public Law 106–151, Sec. 1, 113 Stat 1731 (Dec. 9, 1999). The Department published an FLSA Final Rule on April 5, 2011 (76 FR 18832) that incorporated the new definition into the regulations and made several conforming revisions in part 553, subpart C, but did not conform the language of these provisions.

In 29 CFR 825.104 and 825.209, the Department has corrected cross-references to the definitions section of the FMLA regulations. On February 6, 2013, the Department published a final rule under the FMLA. In that rule, the Department moved the FMLA definitions section from the end of the regulations in § 825.800 to the front of the regulations in § 825.102. However, the Department did not update the cross-references to the definitions section in §§ 825.104 and 825.109. The Department is making this correction so the reader may easily locate the definitions section of the regulations currently located in § 825.102.

Executive Orders 12866 and 13563; Small Business Regulatory Enforcement Fairness Act; Regulatory Flexibility

This rule has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulations. The agency has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, there is no requirement for an assessment of potential costs and benefits under section 6(a)(3) of that order.

This action is not classified as a ''rule'' under Chapter 8 of the Small Business Regulatory Enforcement Fairness Act of 1996, because it is pertaining to agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties. See 5 U.S.C. 804(3)(C).

Because no notice of proposed rulemaking is required for this rule under section 553(b) of the Administrative Procedure Act (APA), the requirements of the Regulatory Flexibility Act (5 U.S.C. 601) pertaining to regulatory flexibility do not apply to this rule. See 5 U.S.C. 601(2).

Paperwork Reduction Act

This final rule is not subject to section 350(h) of the Paperwork Reduction Act (44 U.S.C. 3501) since it does not contain any new collection of information requirements. The final rule does, however, update the information collection control numbers assigned by OMB to allow the reader to locate the collections where referenced in the regulations. The information collections referenced herein are not subject to OMB review as they do not amend information collection requirements.

Unfunded Mandates Reform Act

This Final Rule has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA). 2 U.S.C. 1501 *et seq.* For the purposes of the UMRA, this rule does not impose any Federal mandate that may result in increased expenditures by State, local or Tribal governments, or increased expenditures by the private sector, of more than $100 million in any year.

Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999). This rule does not have federalism implications as outlined in E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Indian Tribal Governments

The Department has reviewed this rule under the terms of Executive Order 13175 (65 FR 67249, November 6, 2000) and determined it did not have ''tribal implications.'' The rule does not have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' As a result, no Tribal summary impact statement has been prepared.

Effects on Families

The Department certifies that this rule will not adversely affect the well-being of families, as discussed under section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277).

Executive Order 13045, Protection of Children

The Department has reviewed this rule under the terms of Executive Order 13045 (62 FR 19885, April 21, 1997, as amended by 68 FR 19931, April 18, 2003) and determined this action is not subject to E.O. 13045 because it is not economically significant as defined in E.O. 12866 and it does not impact the environmental health or safety risks of children.

Environmental Impact Assessment

The Department has reviewed this rule in accordance with the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.,* the regulations of the Council of Environmental Quality, 40 CFR 1500.1 *et seq.,* and the Departmental NEPA procedures, 29 CFR part 11, and determined that this rule will not have a significant impact on the quality of the human environment. There is, therefore, no corresponding environmental assessment or an environmental impact statement.

Executive Order 13211, Energy Supply

The Department has determined that this rule is not subject to Executive Order 13211 (66 FR 28355, May 18, 2001). It will not have a significant adverse effect on the supply, distribution, or use of energy.

Executive Order 12630, Constitutionally Protected Property Rights

The Department has determined that this rule is not subject to Executive Order 12630 (53 FR 8859, March 15, 1988) because it does not involve implementation of a policy ''that has taking implications'' or that could impose limitations on private property use.

Executive Order 12988, Civil Justice Reform Analysis

The Department drafted and reviewed this Final Rule in accordance with Executive Order 12988 (61 FR 4729, February 5, 1996) and determined that the rule will not unduly burden the Federal court system. The rule was: (1) Reviewed to eliminate drafting errors and ambiguities; (2) written to minimize litigation; and (3) written to provide a clear legal standard for affected conduct and to promote burden reduction.

List of Subjects

29 CFR Part 1

Administrative practice and procedure, Construction industry, Government contracts, Minimum wages.

29 CFR Part 3

Community facilities, Construction industry, Federal buildings and facilities, Government contracts, Grant programs, Loan programs, Minimum wages, Reporting and recordkeeping requirements.

29 CFR Part 4

Administrative practice and procedure, Employee benefit plans, Government contracts, Law enforcement, Minimum wages, Occupational safety and health, Reporting and recordkeeping requirements.

29 CFR Part 5

Administrative practice and procedure, Construction industry, Employee benefit plans, Government contracts, Law enforcement, Minimum wages, Reporting and recordkeeping requirements.

29 CFR Part 6

Administrative practice and procedure, Construction industry, Employee benefit plans, Government contracts, Minimum wages, Occupational safety and health.

29 CFR Part 500

Administrative practice and procedure, Aliens, Housing, Insurance, Intergovernmental relations, Investigations, Migrant labor, Motor vehicle safety, Occupational safety and health, Reporting and recordkeeping requirements, Wages.

29 CFR Part 505

Arts and crafts, Grant programs—education, Minimum wages, National Foundation on Arts and Humanities, Occupational safety and health, Reporting and recordkeeping requirements.

29 CFR Part 516

Minimum wages, Reporting and recordkeeping requirements, Wages.

29 CFR Part 519

Agriculture, Colleges and universities, Minimum wages, Students, Reporting and recordkeeping requirements.

29 CFR Part 520

Manpower training programs, Minimum wages, Reporting and recordkeeping requirements, Students.

29 CFR Part 525

Administrative practice and procedure, Individuals with disabilities, Minimum wages, Reporting and recordkeeping requirements, Vocational rehabilitation.

29 CFR Part 530

Administrative practice and procedure, Clothing, Homeworkers, Indian—arts and crafts, Penalties, Reporting and recordkeeping requirements, Surety bonds, Watches and jewelry.

29 CFR Part 547

Employee benefit plans, Reporting and recordkeeping requirements.

29 CFR Part 549

Employee benefit plans, Reporting and recordkeeping requirements, Trusts and trustees.

29 CFR Part 553

Firefighters, Government employees, Intergovernmental relations, Law enforcement officers, Prisons, Reporting and recordkeeping requirements, Volunteers, Wages.

29 CFR Part 570

Administrative practice and procedure, Agriculture, Child labor, Intergovernmental relations, Occupational safety and health, Reporting and recordkeeping requirements.

29 CFR Part 575

Agriculture, Child labor, Reporting and recordkeeping requirements.

29 CFR Part 578

Penalties, Wages.

29 CFR Part 580

Administrative practice and procedure, Child labor, Penalties, Wages.

29 CFR Part 801

Administrative practice and procedure, Employment, Lie detector tests, Penalties, Reporting and recordkeeping requirements.

29 CFR Part 825

Administrative practice and procedure, Airmen, Employee benefit plans, Health insurance, Health, Labor management relations, Maternal and child health, Penalties, Reporting and recordkeeping requirements, Teachers.

Dated: December 20, 2016.

David Weil,

Wage and Hour Administrator.

■ For the reasons set forth above, the Department of Labor amends title 29, parts 1, 3, 4, 5, 6, 500, 505, 516, 519, 520, 525, 530, 547, 549, 553, 570, 575, 578, 580, 801, and 825 of the Code of Federal Regulations as follows:

PART 1—PROCEDURES FOR PRE-DETERMINATION OF WAGE RATES

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 5 U.S.C. 301; R.S. 161, 64 Stat. 1267; Reorganization Plan No. 14 of 1950, 5 U.S.C. appendix; 40 U.S.C. 3141 *et seq.;* 40 U.S.C. 3145; 40 U.S.C. 3148; and the laws listed in appendix A of this part.

■ 2. In § 1.2, revise paragraph (c) to read as follows:

§ 1.2 Definitions.[1]

* * * * *

(c) The term *Administrator* shall mean the Administrator of the Wage and Hour Division, U.S. Department of Labor, or authorized representative.

* * * * *

■ 3. In § 1.5, revise paragraph (b)(1) to read as follows:

§ 1.5 Procedure for requesting wage determinations.

* * * * *

(b)(1) If a general wage determination is not available, the Federal agency shall request a wage determination under the Davis-Bacon Act or any of its related prevailing wage statutes by submitting Form SF–308 to the Department of Labor at this address: U.S. Department of Labor, Wage and Hour Division,

[1] These definitions are not intended to restrict the meaning of the terms as used in the applicable statutes.

Branch of Government Construction Contract Wage Determination, Washington, DC 20210. In preparing Form SF–308, the agency shall check only those classifications that will be needed in the performance of the work. Inserting a note such as ''entire schedule'' or ''all applicable classifications'' is not sufficient. Additional classifications needed that are not on the form may be typed in the blank spaces or on a separate list and attached to the form.

* * * * *

PART 3—CONTRACTORS AND SUBCONTRACTORS ON PUBLIC BUILDING OR PUBLIC WORK FINANCED IN WHOLE OR IN PART BY LOANS OR GRANTS FROM THE UNITED STATES

■ 4. The authority citation for part 3 is revised to read as follows:

Authority: R.S. 161, sec. 2, 48 Stat. 848; Reorg. Plan No. 14 of 1950, 64 Stat. 1267; 5 U.S.C. 301; 40 U.S.C. 3145; Secretary's Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

■ 5. In § 3.3, revise paragraph (b) to read as follows:

§ 3.3 Weekly statement with respect to payment of wages.

* * * * *

(b) Each contractor or subcontractor engaged in the construction, prosecution, completion, or repair of any public building or public work, or building or work financed in whole or in part by loans or grants from the United States, shall furnish each week a statement with respect to the wages paid each of its employees engaged on work covered by this part 3 and part 5 of this title during the preceding weekly payroll period. This statement shall be executed by the contractor or subcontractor or by an authorized officer or employee of the contractor or subcontractor who supervises the payment of wages, and shall be on the back of Form WH 347, ''Payroll (For Contractors Optional Use)'' or on any form with identical wording. Copies of WH 347 may be obtained from the Government contracting or sponsoring agency or from the Wage and Hour Division Web site at *http://www.dol.gov/whd/forms/index.htm* or its successor site.

* * * * *

■ 6. In § 3.4, revise the parenthetical at the end of section to read as follows:

§ 3.4 Submission of weekly statements and the preservation and inspection of weekly payroll records.

* * * * *

(Reporting and recordkeeping requirements in paragraph (b) have been approved by the Office of Management and Budget under control number 1235–0008).

PART 4—LABOR STANDARDS FOR FEDERAL SERVICE CONTRACTS

■ 7. The authority citation for part 4 is revised to read as follows:

Authority: 41 U.S.C. 351 *et seq.;* 41 U.S.C. 38 and 39; 5 U.S.C. 301; Pub. L. 104–188, 2105(b); Pub. L. 110–28, 121 Stat. 112; Secretary's Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

■ 8. In § 4.1a, revise paragraphs (b) and (c) to read as follows:

§ 4.1a Definitions and use of terms.

* * * * *

(b) *Secretary* includes the Secretary of Labor or their authorized representative.

(c) *Wage and Hour Division* means the organizational unit of the Department of Labor to which is assigned the performance of functions of the Secretary under the Service Contract Act of 1965, as amended.

* * * * *

■ 9. In § 4.3, revise paragraph (e) to read as follows:

§ 4.3 Wage determinations.

* * * * *

(e) Wage determinations will be available for public inspection during business hours at the Wage and Hour Division, U.S. Department of Labor, Washington, DC, and copies will be made available upon request at Regional Offices of the Wage and Hour Division. In addition, most prevailing wage determinations are available online from WDOL. Archived versions of SCA wage determinations that are no longer current may be accessed in the ''Archived SCA WD'' database of WDOL for information purposes only. Contracting officers should not use an archived wage determination in a contract action without prior approval of the Department of Labor.

■ 10. In § 4.5, revise paragraph (a)(1) to read as follows:

§ 4.5 Contract specifications of determined minimum wages and fringe benefits.

(a) * * *

(1) Any wage determination from the Wage and Hour Division, Department of Labor, responsive to the contracting agency's submission of an e98 or obtained through WDOL under § 4.4; or

* * * * *

■ 11. In § 4.6, revise paragraphs (b)(2)(ii) and (b)(3), the first sentence in paragraph (g)(1), and the table in paragraph (r) to read as follows:

§ 4.6 Labor standards clauses for Federal service contracts exceeding $2,500.

* * * * *

(b) * * *

(2) * * *

(ii) Such conforming procedure shall be initiated by the contractor prior to the performance of contract work by such unlisted class of employee. A written report of the proposed conforming action, including information regarding the agreement or disagreement of the authorized representative of the employees involved or, where there is no authorized representative, the employees themselves, shall be submitted by the contractor to the contracting officer no later than 30 days after such unlisted class of employees performs any contract work. The contracting officer shall review the proposed action and promptly submit a report of the action, together with the agency's recommendation and all pertinent information including the position of the contractor and the employees, to the Wage and Hour Division, U.S. Department of Labor, for review. The Wage and Hour Division will approve, modify, or disapprove the action or render a final determination in the event of disagreement within 30 days of receipt or will notify the contracting officer within 30 days of receipt that additional time is necessary.

* * * * *

(3) If, as authorized pursuant to section 4(d) of the Service Contract Act of 1965 as amended, the term of this contract is more than 1 year, the minimum monetary wages and fringe benefits required to be paid or furnished thereunder to service employees shall be subject to adjustment after 1 year and not less often than once every 2 years, pursuant to wage determinations to be issued by the Wage and Hour Division of the Department of Labor as provided in such Act.

* * * * *

(g)(1) The contractor and each subcontractor performing work subject to the Act shall make and maintain for 3 years from the completion of the work records containing the information specified in paragraphs (g)(1)(i) through (vi) of this section for each employee subject to the Act and shall make them available for inspection and transcription by authorized representatives of the Wage and Hour Division of the U.S. Department of Labor: * * *

* * * * *

(r) * * *

Paragraph	OMB Control No.
(b)(2)(i)–(iv)	1235–0007
(e)	1235–0007
(g)(1)(i)–(iv)	1235–0007 1235–0018
(g)(1)(v)–(vi)	1235–0007
(l)(1), (2)	1235–0007
(q)(3)	1235–0007

■ 12. In § 4.10, revise paragraph (b)(1)(i) introductory text to read as follows:

§ 4.10 Substantial variance proceedings under section 4(c) of the Act.

* * * * *

(b) * * *

(1)(i) A request for a hearing under this section may be made by the contracting agency or other person affected or interested, including contractors or prospective contractors and associations of contractors, representatives of employees, and other interested Governmental agencies. Such a request shall be submitted in writing to the Administrator, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210, and shall include the following:

* * * * *

■ 13. In § 4.11, revise the second sentence of paragraph (b)(1) introductory text to read as follows:

§ 4.11 Arm's length proceedings.

* * * * *

(b) * * *

(1) * * * Such a request shall be submitted in writing to the Administrator, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210. * * *

* * * * *

■ 14. In § 4.12, revise paragraph (c)(1) to read as follows:

§ 4.12 Substantial interest proceedings.

* * * * *

(c)(1) A request for a determination under this section may be made by any interested party, including contractors or prospective contractors, and associations of contractors, representatives of employees, and interested Government agencies. Such a request shall be submitted in writing to the Administrator, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210.

* * * * *

■ 15. In § 4.101, revise paragraph (g) to read as follows:

§ 4.101 Official rulings and interpretations in this subpart.

* * * * *

(g) It should not be assumed that the lack of discussion of a particular subject in this subpart indicates the adoption of any particular position by the Department of Labor with respect to such matter or to constitute an interpretation, practice, or enforcement policy. If doubt arises or a question exists, inquiries with respect to matters other than safety and health standards should be directed to the Administrator of the Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210, or any regional office of the Wage and Hour Division. Safety and health inquiries should be addressed to the Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210, or to any OSHA regional office. A full description of the facts and any relevant documents should be submitted if an official ruling is desired.

■ 16. In § 4.191, revise paragraph (d) to read as follows:

§ 4.191 Complaints and compliance assistance.

* * * * *

(d) In the event that an Assistant Regional Administrator for the Wage and Hour Division, is notified of a breach or violation which also involves safety and health standards, the Regional Administrator of the Wage and Hour Division shall notify the appropriate Regional Administrator of the Occupational Safety and Health Administration who shall with respect to the safety and health violations take action commensurate with his responsibilities pertaining to safety and health standards.

* * * * *

PART 5—LABOR STANDARDS PROVISIONS APPLICABLE TO CONTRACTS COVERING FEDERALLY FINANCED AND ASSISTED CONSTRUCTION (ALSO LABOR STANDARDS PROVISIONS APPLICABLE TO NONCONSTRUCTION CONTRACTS SUBJECT TO THE CONTRACT WORK HOURS AND SAFETY STANDARDS ACT

■ 17. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 301; R.S. 161, 64 Stat. 1267; Reorganization Plan No. 14 of 1950, 5 U.S.C. appendix; 40 U.S.C. 3141 *et seq.;* 40 U.S.C. 3145; 40 U.S.C. 3148; 40 U.S.C. 3701 *et seq.;* and the laws listed in 5.1(a) of this part; Secretary's Order No. 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014); 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990); Pub. L. 114–74 at § 701, 129 Stat 584.

■ 18. In § 5.2, revise paragraph (b) to read as follows:

§ 5.2 Definitions.

* * * * *

(b) The term *Administrator* means the Administrator of the Wage and Hour Division, U.S. Department of Labor, or authorized representative.

* * * * *

■ 19. In § 5.5, lift the suspension and revise paragraphs (a)(1)(i) and (a)(1)(ii)(B) to read as follows:

§ 5.5 Contract provisions and related matters.

(a) * * *

(1) * * *

(i) All laborers and mechanics employed or working upon the site of the work (or under the United States Housing Act of 1937 or under the Housing Act of 1949 in the construction or development of the project), will be paid unconditionally and not less often than once a week, and without subsequent deduction or rebate on any account (except such payroll deductions as are permitted by regulations issued by the Secretary of Labor under the Copeland Act (29 CFR part 3)), the full amount of wages and bona fide fringe benefits (or cash equivalents thereof) due at time of payment computed at rates not less than those contained in the wage determination of the Secretary of Labor which is attached hereto and made a part hereof, regardless of any contractual relationship which may be alleged to exist between the contractor and such laborers and mechanics. Contributions made or costs reasonably anticipated for bona fide fringe benefits under section 1(b)(2) of the Davis-Bacon Act on behalf of laborers or mechanics are considered wages paid to such laborers or mechanics, subject to the provisions of paragraph (a)(1)(iv) of this section; also, regular contributions made or costs incurred for more than a weekly period (but not less often than quarterly) under plans, funds, or programs which cover the particular weekly period, are deemed to be constructively made or incurred during such weekly period. Such laborers and mechanics shall be paid the appropriate wage rate and fringe benefits on the wage determination for the classification of work actually performed, without regard to skill, except as provided in § 5.5(a)(4). Laborers or mechanics performing work in more than one classification may be compensated at the rate specified for each classification for the time actually worked therein: *Provided,* That the employer's payroll records accurately set forth the time spent in each classification in which work is performed. The wage determination (including any additional classification and wage rates conformed under

paragraph (a)(1)(ii) of this section) and the Davis-Bacon poster (WH–1321) shall be posted at all times by the contractor and its subcontractors at the site of the work in a prominent and accessible place where it can be easily seen by the workers.

(ii) * * *

(B) If the contractor and the laborers and mechanics to be employed in the classification (if known), or their representatives, and the contracting officer agree on the classification and wage rate (including the amount designated for fringe benefits where appropriate), a report of the action taken shall be sent by the contracting officer to the Administrator of the Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210. The Administrator, or an authorized representative, will approve, modify, or disapprove every additional classification action within 30 days of receipt and so advise the contracting officer or will notify the contracting officer within the 30-day period that additional time is necessary.

* * * * *

■ 20. In § 5.5, revise the table following paragraph (c) to read as follows:

* * * * *

(c) * * *

Paragraph	OMB Control No.
(a)(1)(ii)(B)	1235–0023
(a)(1)(ii)(C)	1235–0023
(a)(1)(iv)	1235–0023
(a)(3)(i)	1235–0023
(a)(3)(ii)(A)	1235–0023 1235–0008
(c)	1235–0023

■ 21. In § 5.12, revise paragraphs (c) and (d)(3)(i) to read as follows:

§ 5.12 Debarment proceedings.

* * * * *

(c) Any person or firm debarred under paragraph (a)(1) of this section may in writing request removal from the debarment list after six months from the date of publication by the Comptroller General of such person or firm's name on the ineligible list. Such a request should be directed to the Administrator of the Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210, and shall contain a full explanation of the reasons why such person or firm should be removed from the ineligible list. In cases where the contractor or subcontractor failed to make full restitution to all underpaid employees, a request for removal will not be considered until such underpayments are made. In all other cases, the Administrator will examine the facts and circumstances surrounding the violative practices which caused the debarment, and issue a decision as to whether or not such person or firm has demonstrated a current responsibility to comply with the labor standards provisions of the statutes listed in § 5.1, and therefore should be removed from the ineligible list. Among the factors to be considered in reaching such a decision are the severity of the violations, the contractor or subcontractor's attitude towards compliance, and the past compliance history of the firm. In no case will such removal be effected unless the Administrator determines after an investigation that such person or firm is in compliance with the labor standards provisions applicable to Federal contracts and Federally assisted construction work subject to any of the applicable statutes listed in § 5.1 and other labor statutes providing wage protection, such as the Service Contract Act, the Walsh-Healey Public Contracts Act, and the Fair Labor Standards Act. If the request for removal is denied, the person or firm may petition for review by the Administrative Review Board pursuant to 29 CFR part 7.

(d) * * *

(3)(i) A request for a determination of interest (or substantial interest, as appropriate), may be made by any interested party, including contractors or prospective contractors and associations of contractor's representatives of employees, and interested Government agencies. Such a request shall be submitted in writing to the Administrator, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210.

* * * * *

■ 22. Revise § 5.13 to read as follows:

§ 5.13 Rulings and interpretations.

All questions relating to the application and interpretation of wage determinations (including the classifications therein) issued pursuant to part 1 of this subtitle, of the rules contained in this part and in parts 1 and 3, and of the labor standards provisions of any of the statutes listed in § 5.1 shall be referred to the Administrator for appropriate ruling or interpretation. The rulings and interpretations shall be authoritative and those under the Davis-Bacon Act may be relied upon as provided for in section 10 of the Portal-to-Portal Act of 1947 (29 U.S.C. 259). Requests for such rulings and interpretations should be addressed to the Administrator, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210.

■ 23. In § 5.15, revise the parenthetical at the end of the section to read as follows:

§ 5.15 Limitations, variations, tolerances, and exemptions under the Contract Work Hours and Safety Standards Act.

* * * * *

(Reporting and recordkeeping requirements in paragraph (d)(2) have been approved by the Office of Management and Budget under control numbers 1235–0023 and 1235–0018. Reporting and recordkeeping requirements in paragraph (d)(3)(ii) have been approved by the Office of Management and Budget under control number 1235–0018).

PART 6—RULES OF PRACTICE FOR ADMINISTRATIVE PROCEEDINGS ENFORCING LABOR STANDARDS IN FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION CONTRACTS AND FEDERAL SERVICE CONTRACTS

■ 24. The authority citation for part 6 continues to read as follows:

Authority: Secs. 4 and 5, 79 Stat. 1034, 1035 as amended by 86 Stat. 789, 790, 41 U.S.C. 353 and 354; 5 U.S.C. 301; Reorg. Plan No. 14 of 1950, 64 Stat. 1267, 5 U.S.C. Appendix; 46 Stat. 1494, as amended by 49 Stat. 1011, 78 Stat. 238, 40 U.S.C. 276a–276a–7; 76 Stat. 357–359, 40 U.S.C. 327–332; 48 Stat. 948, as amended by 63 Stat. 108, 72 Stat. 967, 40 U.S.C. 276c.

■ 25. In § 6.2, revise paragraph (a) to read as follows:

§ 6.2 Definitions.

(a) *Administrator* means the Administrator of the Wage and Hour Division, U.S. Department of Labor, or authorized representative.

* * * * *

PART 500—MIGRANT AND SEASONAL AGRICULTURAL WORKER PROTECTION

■ 26. The authority citation for part 500 continues to read as follows:

Authority: Pub. L. 97–470, 96 Stat. 2583 (29 U.S.C. 1801–1872); Secretary's Order No. 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014); 28 U.S.C. 2461 Note (Federal Civil Penalties Inflation Adjustment Act of 1990); and Pub. L. 114–74, 129 Stat 584.

■ 27. In § 500.7, revise paragraph (c) to read as follows:

§ 500.7 Investigation authority of the Secretary.

* * * * *

(c) Any person may report a violation of the Act or these regulations to the Secretary by advising any local office of the Employment Service of the various States, or any office of the Wage and Hour Division, U.S. Department of Labor, or any other authorized

representative of the Administrator. The office or person receiving such a report shall refer it to the appropriate office of the Wage and Hour Division, for the region or area in which the reported violation is alleged to have occurred.

* * * * *

■ 28. In § 500.20, revise paragraph (a) to read as follows:

§ 500.20 Definitions.

* * * * *

(a) *Administrator* means the Administrator of the Wage and Hour Division, United States Department of Labor, and such authorized representatives as may be designated by the Administrator to perform any of the functions of the Administrator under this part.

* * * * *

■ 29. In § 500.41, revise paragraph (b) to read as follows:

§ 500.41 Farm labor contractor is responsible for actions of his farm labor contractor employee.

* * * * *

(b) Farm Labor Contractor Employee Certificate of Registration is valid only during the period in which the holder is an employee of the registered farm labor contractor named on the Farm Labor Contractor Employee Certificate. If prior to the expiration of the Employee Certificate, the holder through a change in employment, should become an employee of a different registered farm labor contractor, a replacements Employee Certificate which names the new employer may be obtained by submitting to the regional office that issued the original employee certificate or to any regional office of the Wage and Hour Division, a written statement that includes the date of the change in employment status and the name, the permanent place of residence and certificate registration number of the new employer. Any such change should be reported immediately.

■ 30. Revise § 500.56 to read as follows:

§ 500.56 Replacement of Certificate of Registration or Farm Labor Contractor Employee Certificate.

If a Certificate of Registration or a Farm Labor Contractor Employee Certificate is lost or destroyed, a duplicate certificate may be obtained by the submission to the regional office that issued it or to any regional office of the Wage and Hour Division, of a written statement explaining its loss or destruction, indicating where the original application was filed and requesting that a duplicate be issued.

■ 31. In § 500.215, revise paragraph (b) to read as follows:

§ 500.215 Change of address.

* * * * *

(b) The notification required in paragraph (a) of this section shall be in writing, by certified mail and addressed to the Administrator, Wage and Hour Division, 200 Constitution Avenue NW, Washington, DC 20210.

* * * * *

PART 505—LABOR STANDARDS ON PROJECTS OR PRODUCTIONS ASSISTED BY GRANTS FROM THE NATIONAL ENDOWMENT FOR THE ARTS AND HUMANITIES

■ 32. The authority citation for part 505 is revised to read as follows:

Authority: Sec. 5(j), Pub. L. 89–209, 79 Stat. 848 (20 U.S.C. 954(i)); sec. 7(g), Pub. L. 94–462, 90 Stat. 1971, as amended by sec. 107(4), Pub. L. 99–194, 99 Stat. 1337 (20 U.S.C. 956(g)); Secretary's Order No. 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014); Secretary's Order 01–2012 (Jan. 18, 2012), 77 FR 3912 (Jan. 25, 2012).

■ 33. In § 505.2, revise paragraph (c) to read as follows:

§ 505.2 Definitions.

* * * * *

(c) The term *Administrator* means the Administrator of the Wage and Hour Division, U.S. Department of Labor, or authorized representative, to whom is assigned the performance of functions of the Secretary pertaining to wages under the National Foundation on the Arts and the Humanities Act of 1965, as amended.

* * * * *

■ 34. In § 505.5, revise the parenthetical at the end of the section to read as follows:

§ 505.5 Adequate assurances.

* * * * *

(The requirements in paragraph (b) were approved by the Office of Management and Budget under control number 1235–0018).

PART 516—RECORDS TO BE KEPT BY EMPLOYERS

■ 35. The authority citation for part 516 continues to read as follows:

Authority: Sec. 11, 52 Stat. 1066, as amended, 29 U.S.C. 211. Section 516.28 also issued under Pub. L. 104–188, 2105(b); Pub. L. 110–28, 121 Stat. 112. Section 516.33 also issued under 52 Stat. 1060, as amended; 29 U.S.C. 201 *et seq.* Section 516.34 also issued under Sec. 7, 103 Stat. 944, 29 U.S.C. 207(q).

■ 36. Revise § 516.0 to read as follows:

Subpart or section where information collection equirement is located	Currently assigned OMB Control No.
Subpart A	1235–0018
Subpart B	1235–0018
516.31 also discussed in	1235–0001

PART 519—EMPLOYMENT OF FULL-TIME STUDENTS AT SUBMINIMUM WAGES

■ 37. The authority citation for part 519 continues to read as follows:

Authority: Secs. 11 and 14, 52 Stat. 1068; sec. 11, 75 Stat. 74; secs. 501 and 602, 80 Stat. 843, 844 (29 U.S.C. 211, 214).

■ 38. In § 519.11, revise the first sentence of paragraph (a) to read as follows:

§ 519.11 Applicability of the regulations in this subpart.

(a) *Statutory provisions.* Under section 14 of the Fair Labor Standards Act of 1938, as amended, and the authority and responsibility delegated to him/her by the Secretary of Labor (36 FR 8755), the Administrator of the Wage and Hour Division is authorized and directed, to the extent necessary in order to prevent curtailment of employment opportunities for employment, to provide by regulation or order for the employment, under certificates, of full-time students in institutions of higher education. * * *

* * * * *

PART 520—EMPLOYMENT UNDER SPECIAL CERTIFICATE OF MESSENGERS, LEARNERS, (INCLUDING STUDENT-LEARNERS), AND APPRENTICES

■ 39. The authority citation for part 520 continues to read as follows:

Authority: Sec. 14, 52 Stat. 1062, 1064 (29 U.S.C. 214); secs. 2–12, 60 Stat. 237–244; (5 U.S.C. 1001–1011); 52 Stat. 1068, as amended, 29 U.S.C. 214.

■ 40. Amend § 520.300 by revising the definitions of ''Administrator'' and ''Wage and Hour Division'' to read as follows:

§ 520.300 Definitions.

Administrator means the Administrator of the Wage and Hour Division, United States Department of Labor, or his/her authorized representative.

* * * * *

Wage and Hour Division means the Wage and Hour Division, United States Department of Labor.

■ 41. In § 520.403, revise the parenthetical at end of section to read as follows:

§ 520.403 What information is required when applying for authority to pay less than the minimum wage?

* * * * *

(The information collection requirements contained in paragraphs (a), (b), and (c) were approved by the Office of Management and Budget under control number 1235–0001).

■ 42. In § 520.405, revise the parenthetical at the end of section to read as follows:

§ 520.405 Must I notify my employees that I am applying for a certificate to employ messengers and/or learners at subminimum wages?

* * * * *

(The information collection requirements contained herein were approved by the Office of Management and Budget under control number 1235–0001).

■ 43. In § 520.501, revise the parenthetical at end of section to read as follows:

§ 520.501 How do I obtain authority to employ student-learners at subminimum wages?

* * * * *

(The information collection requirements contained in paragraph (b) were approved by the Office of Management and Budget under control number 1235–0001).

■ 44. In § 520.502, revise parenthetical at end of section to read as follows:

§ 520.502 What information must an application to employ student-learners at subminimum wages contain?

* * * * *

(The information collection requirements in paragraphs (a), (b), (c), (d), (e), (f), (g), (h), and (i) were approved by the Office of Management and Budget under control number 1235–0001).

PART 525—EMPLOYMENT OF WORKERS WITH DISABILITIES UNDER SPECIAL CERTIFICATES

■ 45. The authority citation for part 525 continues to read as follows:

Authority: 52 Stat. 1060, as amended (29 U.S.C. 201–219); Pub. L. 99–486, 100 Stat. 1229 (29 U.S.C. 214).

■ 46. In § 525.16, revise the parenthetical at the end of section to read as follows:

§ 525.16 Records to be kept by employers.

* * * * *

(Approved by the Office of Management and Budget under control number 1235–0001).

■ 47. In § 525.22, revise paragraph (a) to read as follows:

§ 525.22 Employee's right to petition.

(a) Any employee receiving a special minimum wage at a rate specified pursuant to subsection 14(c) of FLSA or the parent or guardian of such an employee may petition the Secretary to obtain a review of such special minimum wage rate. No particular form of petition is required, except that a petition must be signed by the individual, or the parent or guardian of the individual, and should contain the name and address of the employee and the name and address of the employee's employer. A petition may be filed in person or by mail with the Administrator of the Wage and Hour Division, U.S. Department of Labor, Room S3502, 200 Constitution Avenue NW., Washington, DC 20210. The petitioner may be represented by counsel in any stage of such proceedings. Upon receipt, the petition shall be forwarded immediately to the Chief Administrative Law Judge.

* * * * *

PART 530—EMPLOYMENT OF HOMEWORKERS IN CERTAIN INDUSTRIES

■ 48. The authority citation for part 530 continues to read as follows:

Authority: Sec. 11, 52 Stat. 1066 (29 U.S.C. 211) as amended by sec. 9, 63 Stat. 910 (29 U.S.C. 211(d)); Secretary's Order No. 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014); 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990); Pub. L. 114–74 at § 701, 129 Stat 584.

■ 49. In § 530.1, revise paragraph (b) to read as follows:

§ 530.1 Definitions.

* * * * *

(b) *Administrator* as used in this part means the Administrator of the Wage and Hour Division, U.S. Department of Labor, or an authorized representative of the Administrator.

* * * * *

■ 50. In § 530.3, revise the parenthetical at end of section to read as follows:

§ 530.3 Application forms for individual homeworker certificates.

* * * * *

(Approved by the Office of Management and Budget under control number 1235–0001).

■ 51. In § 530.4, revise parenthetical at end of section to read as follows:

§ 530.4 Terms and conditions for the issuance of individual homeworker certificates.

* * * * *

(Information collection requirements contained in paragraph (a) were approved by the Office of Management and Budget under control number 1235–0001).

■ 52. In § 530.101, revise paragraph (c) to read as follows:

§ 530.101 General.

* * * * *

(c) Certificates authorizing such employment may be issued on the following terms and conditions upon written application to the Administrator, Wage and Hour Division, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

■ 53. Revise § 530.102 to read as follows:

§ 530.102 Requests for employer certificates.

The initial request for certification or renewal application shall be signed by the employer and shall contain the name of the firm, its mailing address, the physical location of the firm's principal place of business and a description of the business operations and items produced. In addition, the initial or renewal application shall contain the names, addresses, and languages (if other than English) spoken by the homeworkers that are currently employed (if any) or expected to be employed. The employer shall also provide the Administrator, within thirty (30) days, a notice of each change of address of the principal place of business. The notification shall be in writing and addressed to the Administrator, Wage and Hour Division, 200 Constitution Avenue NW., Washington, DC 20210.

■ 54. In § 530.403, revise paragraph (a) to read as follows:

§ 530.403 Request for hearing.

(a) Except in the case of an emergency revocation under § 530.411 of this subpart, a request for an administrative hearing on a determination referred to in § 530.402 of this subpart shall be made in writing to the Administrator of the Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210, and must be received no later than thirty (30) days after issuance of the notice referred to in § 530.402 of this subpart.

* * * * *

PART 547—REQUIREMENTS OF A "BONA FIDE THRIFT OR SAVINGS PLAN"

■ 55. The authority citation for part 547 continues to read as follows:

Authority: Sec. 7, 52 Stat. 1063, as amended; 29 U.S.C. 207.

■ 56. In § 547.1, revise parenthetical at end of section to read as follows:

§ 547.1 Essential requirements for qualifications.

* * * * *

(Approved by the Office of Management and Budget under control number 1235–0013).

PART 549—REQUIREMENTS OF A "BONA FIDE PROFIT SHARING PLAN OR TRUST"

■ 57. The authority citation for part 549 continues to read as follows:

Authority: Sec. 7, 52 Stat. 1063, as amended; 29 U.S.C. 207.

■ 58. In § 549.1, revise the parenthetical at the end of the section to read as follows:

§ 549.1 Essential requirements for qualifications.

* * * * *

(Approved by the Office of Management and Budget under control number 1235–0013).

PART 553—APPLICATION OF THE FAIR LABOR STANDARDS ACT TO EMPLOYEES OF STATE AND LOCAL GOVERNMENTS

■ 59. The authority citation for part 553 continues to read as follows:

Authority: Secs. 1–19, 52 Stat. 1060, as amended (29 U.S.C. 201–219); Pub. L. 99–150, 99 Stat. 787 (29 U.S.C. 203, 207, 211). Pub. L. 106–151, 113 Stat. 1731 (29 U.S.C. 203(y)).

■ 60. In § 553.221, revise paragraph (a) to read as follows:

§ 553.221 Compensable hours of work.

(a) The general rules on compensable hours of work are set forth in 29 CFR part 785 which is applicable to employees for whom the section 7(k) exemption is claimed. Special rules for sleep time (§ 553.222) apply to both law enforcement and employees in fire protection activities for whom the section 7(k) exemption is claimed. Also, special rules for meal time apply in the case of employees in fire protection activities (§ 553.223). Part 785 does not discuss the special provisions that apply to State and local government workers with respect to the treatment of substitution, special details for a separate and independent employer, early relief, and work performed on an occasional or sporadic and part-time basis, all of which are covered in this subpart.

* * * * *

■ 61. In § 553.231, revise paragraph (b) to read as follows:

§ 553.231 Compensatory time off.

* * * * *

(b) Section 7(k) permits public agencies to balance the hours of work over an entire work period for law enforcement and fire protection employees. For example, if an employee engaged in fire protection activities' work period is 28 consecutive days, and he or she works 80 hours in each of the first two weeks, but only 52 hours in the third week, and does not work in the fourth week, no overtime compensation (in cash wages or compensatory time) would be required since the total hours worked do not exceed 212 for the work period. If the same employee in fire protection activities had a work period of only 14 days, overtime compensation or compensatory time off would be due for 54 hours (160 minus 106 hours) in the first 14 day work period.

PART 570—CHILD LABOR REGULATIONS, ORDERS AND STATEMENTS OF INTERPRETATION

Subpart A—General

■ 62. The authority citation for subpart A continues to read as follows:

Authority: Secs. 3, 11, 12, 52 Stat. 1060, as amended, 1066, as amended, 1067, as amended; 29 U.S.C. 203, 211, 212.

■ 63. In § 570.1, revise paragraph (g) to read as follows:

§ 570.1 Definitions.

* * * * *

(g) *Wage and Hour Division* means the Wage and Hour Division, United States Department of Labor.

* * * * *

■ 64. The authority citation for subpart B continues to read as follows:

Subpart B—Certificates of Age

Authority: 29 U.S.C. 203(l), 211, 212.

■ 65. In § 570.6, revise the parenthetical at the end of the section to read as follows:

§ 570.6 Contents and disposition of certificates of age.

* * * * *

(The information collection requirements contained in paragraph (a) were approved by the Office of Management and Budget under control number 1235–0018.)

■ 66. The authority citation for subpart C continues to read as follows:

Subpart C—Employment of Minors Between 14 and 16 Years of Age (Child Labor Reg. 3)

Authority: 29 U.S.C. 203(l), 212, 213(c).

■ 67. In § 570.36, revise the parenthetical at the end of the section to read as follows:

§ 570.36 Work experience and career exploration program.

* * * * *

(The information collection requirements contained in paragraphs (b)(3)(vi) and (4) were approved by the Office of Management and Budget under control number 1235–0018.)

■ 68. In § 570.37, revise the parenthetical at the end of section to read as follows:

§ 570.37 Work-study program.

* * * * *

(The information collection requirements contained in § 570.37 were approved by the Office of Management and Budget under control number 1235–0018.)

PART 575—WAIVER OF CHILD LABOR PROVISIONS FOR AGRICULTURAL EMPLOYMENT OF 10 AND 11 YEAR OLD MINORS IN HAND HARVESTING OF SHORT SEASON CROPS

■ 69. The authority citation for part 575 is revised to read as follows:

Authority: Secs. 11, 12, 13, 18, 52 Stat. 1067, 1069, as amended; 29 U.S.C. 211, 212, 213, 218; Secretary's Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

■ 70. In § 575.2, revise the definition of ''Administrator'' to read as follows:

§ 575.2 Definitions.

* * * * *

Administrator means the Administrator of the Wage and Hour Division, U.S. Department of Labor, and includes an authorized representative designated by the Administrator to perform any of the functions of the Administrator under this part.

* * * * *

■ 71. In § 575.3, revise paragraph (a) to read as follows:

§ 575.3 Application for waiver.

(a) An application for a waiver shall be filed with the Administrator of the Wage and Hour Division, United States Department of Labor, Washington, DC 20210. To permit adequate time for processing, it is recommended that such applications be filed 6 weeks prior to the period the waiver is to be in effect.

* * * * *

PART 578—MINIMUM WAGE AND OVERTIME VIOLATIONS—CIVIL MONEY PENALTIES

■ 72. The authority citation for part 578 continues to read as follows:

Authority: Sec. 9, Pub. L. 101–157, 103 Stat. 938, sec. 3103, Pub. L. 101–508, 104 Stat. 1388–29 (29 U.S.C. 216(e)), Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note), as amended by Pub. L. 104–134, section 31001(s), 110 Stat. 1321–358, 1321–373, and Pub. L. 114–74, 129 Stat. 584.

■ 73. In § 578.2, revise paragraph (b) to read as follows:

§ 578.2 Definitions.

* * * * *

(b) *Administrator* means the Administrator of the Wage and Hour

Division, U.S. Department of Labor, and includes any official of the Wage and Hour Division who is authorized by the Administrator to perform any of the functions of the Administrator under this part.

* * * * *

PART 580—CIVIL MONEY PENALTIES—PROCEDURES FOR ASSESSING AND CONTESTING PENALTIES

■ 74. The authority citation for part 580 is revised to read as follows:

Authority: 29 U.S.C. 9a, 203, 209, 211, 212, 213(c), 216; Reorg. Plan No. 6 of 1950, 64 Stat. 1263, 5 U.S.C. App; secs. 25, 29, 88 Stat. 72, 76; Secretary's Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014); 5 U.S.C. 500, 503, 551, 559; 103 Stat. 938.

■ 75. In § 580.1, revise the definition of ''Administrator'' to read as follows:

§ 580.1 Definitions.

* * * * *

Administrator means the Administrator of the Wage and Hour Division, U.S. Department of Labor, and includes any official of the Wage and Hour Division authorized by the Administrator to perform any of the functions of the Administrator under this part and parts 578 and 579 of this chapter.

* * * * *

PART 801—APPLICATION OF THE EMPLOYEE POLYGRAPH PROTECTION ACT OF 1988

■ 76. The authority citation for part 801 continues to read as follows:

Authority: Pub. L. 100–347, 102 Stat. 646, 29 U.S.C. 2001–2009; 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990); Pub. L. 114–74 at § 701, 129 Stat. 584.

■ 77. In § 801.2:

■ a. Remove paragraph (h);

■ b. Redesignate paragraphs (i) and (j) as paragraphs (h) and (i), respectively; and

■ c. Revise newly redesignated paragraph (h).

The revision reads as follows:

§ 801.2 Definitions.

* * * * *

(h) *Wage and Hour Division* means the organizational unit of the Department of Labor to which is assigned primary responsibility for enforcement and administration of the Act.

* * * * *

■ 78. In § 801.7, revise paragraph (d) to read as follows:

§ 801.7 Authority of the Secretary.

* * * * *

(d) Any person may report a violation of the Act or these regulations to the Secretary by advising any local office of the Wage and Hour Division, U.S. Department of Labor, or any authorized representative of the Administrator. The office or person receiving such a report shall refer it to the appropriate office of the Wage and Hour Division for the region or area in which the reported violation is alleged to have occurred.

* * * * *

■ 79. In § 801.30, revise the parenthetical at the end of section to read as follows:

§ 801.30 Records to be preserved for 3 years.

* * * * *

(Approved by the Office of Management and Budget under control number 1235–0005.)

PART 825—THE FAMILY AND MEDICAL LEAVE ACT OF 1993

■ 80. The authority citation for part 525 continues to read as follows:

Authority: 29 U.S.C. 2654; 28 U.S.C. 2461 Note (Federal Civil Penalties Inflation Adjustment Act of 1990); and Pub. L. 114–74 at § 701.

■ 81. In § 825.104, revise paragraph (b) to read as follows:

§ 825.104 Covered employer.

* * * * *

(b) The terms commerce and industry affecting commerce are defined in accordance with section 501(1) and (3) of the Labor Management Relations Act of 1947 (LMRA) (29 U.S.C. 142(1) and (3)), as set forth in the definitions at § 825.102 of this part. For purposes of the FMLA, employers who meet the 50-employee coverage test are deemed to be engaged in commerce or in an industry or activity affecting commerce.

* * * * *

■ 82. In § 825.209, revise paragraph (a) to read as follows:

§ 825.209 Maintenance of employee benefits.

(a) During any FMLA leave, an employer must maintain the employee's coverage under any group health plan (as defined in the Internal Revenue Code of 1986 at 26 U.S.C. 5000(b)(1) on the same conditions as coverage would have been provided if the employee had been continuously employed during the entire leave period. All employers covered by FMLA, including public agencies, are subject to the Act's requirements to maintain health coverage. The definition of group health plan is set forth in § 825.102. For purposes of FMLA, the term group health plan shall not include an insurance program providing health coverage under which employees purchase individual policies from insurers provided that:

(1) No contributions are made by the employer;

(2) Participation in the program is completely voluntary for employees;

(3) The sole functions of the employer with respect to the program are, without endorsing the program, to permit the insurer to publicize the program to employees, to collect premiums through payroll deductions and to remit them to the insurer;

(4) The employer receives no consideration in the form of cash or otherwise in connection with the program, other than reasonable compensation, excluding any profit, for administrative services actually rendered in connection with payroll deduction; and,

(5) The premium charged with respect to such coverage does not increase in the event the employment relationship terminates.

* * * * *

■ 83. In § 825.401, revise paragraph (a) to read as follows:

§ 825.401 Filing a complaint with the Federal Government.

(a) A complaint may be filed in person, by mail or by telephone, with the Wage and Hour Division, U.S. Department of Labor. A complaint may be filed at any local office of the Wage and Hour Division; the address and telephone number of local offices may be found in telephone directories or on the Department's Web site.

* * * * *

[FR Doc. 2016–31293 Filed 1–6–17; 8:45 am]

BILLING CODE 4510–27–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 22 and 124

[FRL–9956–53–OARM]

Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation/Termination or Suspension of Permits; Procedures for Decisionmaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule revises the Environmental Protection Agency's (''EPA'') Consolidated Rules of Practice governing the administrative assessment

of civil penalties and various other administrative adjudicatory hearings. These revisions simplify the administrative processing of cases by removing inconsistencies, codifying electronic filing and service procedures, and streamlining the procedures in cases initiated at EPA Headquarters. This rule also corrects some punctuation typographical errors found in the Consolidated Rules of Practice. This rule similarly revises EPA's procedures governing decisionmaking in permit appeals. These amendments are procedural in nature and none of these changes are intended to substantively alter the Agency's administrative enforcement actions or review of permit appeals.

DATES: This rule is effective on March 10, 2017.

FOR FURTHER INFORMATION CONTACT: Michael B. Wright, Office of Administrative Law Judges, U.S. Environmental Protection Agency, Ronald Reagan Building, Room M1200, 1300 Pennsylvania Ave. NW., Washington, DC 20004, phone number (202) 564–3247 or by email at *wright.michaelb@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is the EPA issuing this rule in final form without first issuing a proposal?

Today's final rule is limited to procedural requirements for administrative adjudicatory hearings and appeals from such hearings and from permit decisions. Under the Administrative Procedure Act, an agency may issue ''rules of agency organization, procedure, or practice'' without first proposing such rules for public comment. 5 U.S.C. 553(b). Accordingly, public comment is not required.

II. Does this action apply to me?

This action affects parties involved in EPA administrative adjudicatory proceedings for the assessment of civil penalties, issuance of various compliance orders, and termination or suspension of certain permits, under part 22 of title 40 of the CFR. *See* 40 CFR 22.1. This action also affects parties involved in appeal of EPA permits under part 124 of title 40 of the CFR.

III. Summary of Rule

A. Background: The EPA's Consolidated Rules of Practice in Part 22 and the EPA's Rules for Procedures for Decisionmaking on Permits in Part 124

Part 22 of Title 40 of the CFR establishes procedures governing administrative adjudicatory proceedings to assess administrative civil penalties, to issue various compliance orders, and to terminate or suspend certain permits. 40 CFR 22.1. These proceedings are conducted under a variety of environmental statutes, including the Clean Air Act, the Clean Water Act, the Solid Waste Disposal Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, among others. Such cases are generally heard by the Administrative Law Judges (ALJs) within the EPA's Office of Administrative Law Judges or Regional Judicial Officers. The part 22 regulations are titled the ''Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation/Termination or Suspension of Permits'' (''Rules of Practice'').

The EPA promulgated the Rules of Practice to establish uniform procedural rules for administrative proceedings required to be held on the record after opportunity for a hearing in accordance with section 554 of the Administrative Procedure Act, 5 U.S.C. 551 *et seq., see* 40 CFR part 22, subparts A–G, and administrative enforcement proceedings not governed by section 554, *id.* part 22, subpart I. Consolidated Rules of Practice, 45 FR 24360 (Apr. 9, 1980). The Rules of Practice also establish supplementary rules that recognize the unique procedural requirements of certain environmental statutes within the EPA's jurisdiction. *See* 40 CFR part 22, subpart H. Finally, the Rules of Practice establish procedures for appeals from decisions of the ALJs and Regional Judicial Officers to the Environmental Appeals Board. *See id.* part 22, subpart F.

Part 124 of Title 40 of the CFR establishes rules governing the EPA's issuance, modification, and revocation of permits under the Resource Conservation and Recovery Act, the Underground Injection Control program of the Safe Drinking Water Act, the Prevention of Significant Deterioration program of the Clean Air Act, and the National Pollutant Discharge Elimination System program of the Clean Water Act. These permit rules include procedures for appealing permit decisions by the EPA's regional offices to the Environmental Appeals Board. *See* 40 CFR 124.19.

B. Amendments to Part 22 Procedures

This action makes several minor changes to part 22 procedures. Many of these changes pertain to the electronic filing and service of documents.

Filing and service. The EPA has amended the filing and service requirements to clarify how these requirements apply to electronic transmission of documents and to otherwise clarify filing and service requirements and make them more consistent with similar requirements in part 124.

Section 22.5(a) currently allows a Presiding Officer or the Environmental Appeals Board to ''authorize'' filing of documents by ''facsimile or electronic filing.'' 40 CFR 22.5(a). The EPA is amending this section to also allow a Presiding Officer or the Environmental Appeals Board to ''require'' filing by ''facsimile or an electronic filing system.'' Both the Office of the Administrative Law Judges and the Environmental Appeals Board have an operational electronic filing system. This section is also being amended to standardize the Environmental Appeals Board filing methods under part 22 with those currently in the EPA's permit regulations in part 124.

Section 22.5(b)(2) is modified to allow parties to agree with other parties to service by facsimile or other electronic means, including but not necessarily limited to email. A party's consent to such methods of service must be in writing and the party must file acknowledgement of such consent with the Clerk for the Presiding Officer or the Environmental Appeals Board, whichever is appropriate. This section is also modified to allow the Presiding Officer or the Environmental Appeals Board to authorize or require that the parties serve each other by facsimile or other electronic means, including but not necessarily limited to email. To facilitate electronic service, § 22.5(b)(4) is modified to require that a party include an email address in the first document it files in a proceeding.

The EPA emphasizes that the rules on electronic delivery of documents differ depending on whether the document is being *filed* with an EPA adjudicatory tribunal or *served* on a party to the proceeding. In the case of filing a document in an EPA administrative proceeding, the Presiding Officer or the Environmental Appeals Board has the sole authority to authorize or require electronic filing, and only these entities may authorize or require electronic filing by facsimile or an electronic filing system. As to service of documents between parties, not only may the Presiding Officer or the Environmental Appeals Board authorize or require service by either facsimile or other electronic means, including but not necessarily limited to email, but the parties may agree to such forms of electronic service.

Additionally, the EPA is revising § 22.5(b) to clarify that in cases before the Environmental Appeals Board, documents a party files with the Board need not also be served on the Board.

Section 22.6 is amended to allow the Regional Hearing Clerk, the Headquarters Hearing Clerk, or the Clerk of the Environmental Appeals Board to serve rulings, orders, decisions, or other documents by electronic means (including but not necessarily limited to facsimile and email).

Section 22.7(c) addresses when service is considered complete and includes a provision allowing an additional period of time for response to documents served using certain procedures. *Id.* § 22.7(c). The EPA has amended this section to specify that when documents are served by facsimile or other electronic means, the service will be complete upon transmission. This approach is similar to that in Rule 5(b) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 5(b).

The EPA has also modified the so-called ''mailbox rule'' in § 22.7(c) providing for additional days to respond to documents served using certain procedures. As modified, the revised mailbox rule in § 22.7(c) allows an additional three days to the time allowed for response to documents served by U.S. mail, the EPA's internal mail,[1] or commercial delivery service. Three additional days are not allowed for a response when a document to be responded to is served by personal delivery or electronic means (*e.g.,* facsimile or email). This change allows additional days where needed, but recognizes that extra days for delivery are not needed where same-day delivery is utilized. Further, this change makes part 22 consistent with the Federal Rules of Civil Procedure, including changes made to the Rules effective December 1, 2016. Rule 6(d) of the Federal Rules of Civil Procedure currently grants an additional three days when service is effectuated by U.S. mail, an agreed-to delivery service, or an electronic means. However, an amendment to Rule 6(d) that was effective December 1, 2016, removes electronic service from the types of service to which the additional three-day rule applies. Order (S. Ct. Apr. 28, 2016). This change was based on the conclusion that electronic service has become sufficiently reliable method of providing instantaneous delivery. Fed. R. Civ. P. 6(d) advisory committee's note to 2016 amendment.

Presiding officer prior to respondent filing answer. Generally, the Presiding Officer in part 22 proceedings is an Administrative Law Judge except for proceedings under subpart I, which are not governed by section 554 of the Administrative Procedure Act. *See* 40 CFR 22.3 (definition of ''Presiding Officer'') & subpart I. Regional Judicial Officers are the Presiding Officer under subpart I proceedings. *Id.* § 22.51. The Environmental Appeals Board hears appeals from interlocutory orders and initial decisions of a Presiding Officer. *Id.* § 22.29–22.30.

However, sections 22.4(a) and 22.16(c) currently specify, among other things, that the Environmental Appeals Board will act as Presiding Officer in proceedings under part 22 commenced at EPA Headquarters until the respondent files an answer. *Id.* §§ 22.4(a), 22.16(c). In such proceedings, an Administrative Law Judge replaces the Environmental Appeals Board as the Presiding Officer once an answer is filed. *Id.* § 22.16(c).

This rule amendment modifies § 22.4(a) and § 22.16(c) to authorize an Administrative Law Judge to serve as the Presiding Officer in part 22 proceedings commenced at EPA Headquarters from the time a complaint is filed. The Environmental Appeals Board will no longer be assigned as a Presiding Officer for the period between the filing of a complaint and the filing of an answer. Rather, an Administrative Law Judge will serve as the Presiding Officer both prior to and after the filing of the answer. Removing the Environmental Appeals Board from the initial stage of enforcement proceedings will enhance the efficiency of proceedings commenced at EPA Headquarters because a single entity will exercise the role of Presiding Officer. This also eliminates the possibility that the Environmental Appeals Board could be asked to review on appeal its own decision on a preliminary motion (filed before an answer is filed).

Other changes. Section 22.28 addresses motions to reopen a hearing. This rule modifies § 22.28 to clarify the effect of filing such a motion and to expand the section to apply to motions to set aside a default order. The revised language clarifies that the filing of a motion to reopen a hearing tolls not only the time by when an initial decision becomes final or by when an appeal of an initial decision to the Environmental Appeals Board must be filed but also the time by which the Board must decide whether it is going to exercise its authority to hear the case on its own initiative. The revised language also applies similar requirements to a motion to set aside a default order.

Additionally, the EPA is making a series of changes to § 22.30 to clarify various issues relating to appeals to the Environmental Appeals Board. *See id.* § 22.30. Section 22.30 is modified to (1) explain how attachments to a notice of appeal, appellate brief, or response brief should be identified (§ 22.30(a)(1)(iii) and (2)); (2) impose word/page limitations for briefs and motions (§ 22.30(a)(3)); (3) provide more consistency between § 22.30(a)(1)(iii) and § 124.19(a)(4)(ii) pertaining to the need for parties' briefs to contain specific citations or other appropriate references (*e.g.,* by including the document name and page number) (§ 22.30(a)(1)(iii) and (2)); (4) clarify that when the Board initiates review of an initial decision, it will identify any issues to be briefed and a schedule for briefing in its initial order of its intent to review or in a subsequent order (§ 22.30(b)); (5) clarify that the Board may request oral argument on its own initiative, how a party must request oral argument, and that the Board may establish additional oral argument procedures by order (§ 22.30(d)); (6) make explicit that the Board may act on a motion without awaiting a response (§ 22.30(e)(2)); and (7) explain the procedure for parties to request an extension of time (§ 22.30(e)(3)).

C. Amendments to Part 124 Procedures

Most of the revisions to part 124 also concern filing and service issues. Section 124.19(i) addresses filing and service requirements in permit appeal proceedings before the Environmental Appeals Board. This section has been modified to add language clarifying when service is complete. Specifically, service is complete upon mailing for U.S. mail and EPA internal mail, when placed in the custody of a reliable commercial deliver service, or upon transmission for facsimile or email. This new language is similar to that in Rule 5(b)(2) of the Federal Rules of Civil Procedure and Environmental Appeals Board decisions. Fed. R. Civ. P. 5(b)(2); s*ee In re Beckman Prod. Servs.,* 5 E.A.D. 10, 15 (EAB 1994) (''When the Region serves a final permit decision by mail, service occurs upon mailing.''). The EPA has revised the language in § 124.19(i)(3) to clarify that parties may agree to electronic service by facsimile, email, or other electronic means. The EPA has also revised § 124.19(i)(3) to require that parties that consent to

[1] EPA has specifically included ''EPA internal mail'' in this revision to the mailbox rule because the Environmental Appeals Board previously ruled that a prior version of this provision referencing ''certified mail'' did not cover a document served by EPA internal mail. *In re Outboard Marine Corp.,* 6 E.A.D. 194, 197 (EAB 1995).

service by electronic means file acknowledgement of that consent with the Environmental Appeals Board.

The EPA has also made several changes to part 124 on service and filing that duplicate the changes made to part 22: (1) Requiring that a party's first filing contain an email address (§ 124.19(i)(3)(i)); (2) authorizing the Environmental Appeals Board to require that parties file documents by facsimile or through use of the Board's electronic filing system (§ 124.19(i)(2)); (3) allowing the Environmental Appeals Board to authorize or require that the parties serve each other by facsimile or other electronic means, including email (§ 124.19(i)(3)(ii)); and (4) authorizing the Board to serve rulings, orders, and decisions on the parties by electronic means (including but not necessarily limited to facsimile and email). (§ 124.19(i)(3)(iii).

Section 124.19(b)(1) and (2) are modified so that the deadlines for filing a response to a petition for review are based on the date the petition is served, rather than filed. This provides for appropriate notice of the petition for review in advance of the deadline for a response.

Similar to the changes made in the mailbox rule in § 22.7(c), discussed above, the EPA has modified § 124.20(d) to specify that three days are added to a prescribed period of time to act when service is made by U.S. mail, the EPA's internal mail, or a reliable, commercial delivery service. Three days are not added to the prescribed time to act when service is made by personal delivery or electronic transmission (*e.g.,* facsimile or email).

The EPA has also added word/page limitations to § 124.19(f) for motions mirroring the word/page limitations added to § 22.30. Finally, the EPA has amended § 124.19(a)(4)(ii) and (b) to further clarify that parties are to provide in their briefs appropriate reference to the administrative record (*e.g.,* by including the document name and page number) as to each issue raised.

IV. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget (OMB) because it is limited to agency organization, management, or personnel matters.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the PRA. This action will modify the EPA's procedural regulations governing administrative adjudicatory proceedings and appeals of adjudicatory proceedings and permit decisions to allow flexibility in the methods of serving and issuing documents and to promote efficiency in allocation of judicial resources. Specifically, the modifications to the Rules of Practice will codify the electronic service of documents between parties and by EPA adjudicative bodies. In addition, the modifications will facilitate the efficient issuance of rulings on motions by substituting an Administrative Law Judge for the Environmental Appeals Board to serve as the presiding officer in civil penalty cases initiated at EPA Headquarters before an answer is filed.

C. Regulatory Flexibility Act

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule pertains to agency management or personnel, which the APA expressly exempts from notice and comment rulemaking requirements under 5 U.S.C. 553(a)(2).

D. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. This action will modify the EPA's procedural regulations governing administrative adjudicatory proceedings and appeals of adjudicatory proceedings and permit decisions to allow flexibility in the methods of serving and issuing documents and to promote efficiency in allocation of judicial resources. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action will modify the EPA's procedural regulations governing administrative adjudicatory proceedings and appeals of adjudicatory proceedings and permit decisions to allow flexibility in the methods of serving and issuing documents and to promote efficiency in allocation of judicial resources.

K. Congressional Review Act

This rule is exempt from the CRA because it is a rule relating to agency management or personnel.

List of Subjects

40 CFR Part 22

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Hazardous waste, Penalties, Pesticides and pests, Poison prevention, Water pollution control.

40 CFR Part 124

Environmental protection, Administrative practice and procedures.

Dated: December 20, 2016.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, 40 CFR parts 22 and 124 are amended as follows:

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION/TERMINATION OR SUSPENSION OF PERMITS

■ 1. The authority citation for part 22 is revised to read as follows:

Authority: 7 U.S.C. 1361; 15 U.S.C. 2615; 33 U.S.C. 1319, 1342, 1361, 1415 and 1418; 42 U.S.C. 300g–3(g), 6912, 6925, 6928, 6991e and 6992d; 42 U.S.C. 7413(d), 7524(c), 7545(d), 7547, 7601 and 7607(a), 9609, and 11045.

Subpart A—General

■ 2. In § 22.4, revise the first sentence of paragraph (a)(1) to read as follows:

§ 22.4 Powers and duties of the Environmental Appeals Board, Regional Judicial Officer and Presiding Officer; disqualification, withdrawal, and reassignment.

(a) *Environmental Appeals Board.* (1) The Environmental Appeals Board rules on appeals from the initial decisions, rulings and orders of a Presiding Officer in proceedings under these Consolidated Rules of Practice, and approves settlement of proceedings under these Consolidated Rules of Practice commenced at EPA Headquarters. * * *

* * * * *

■ 3. In § 22.5, revise the section heading and paragraphs (a)(1), (b) introductory text, (b)(2), and (c)(4) to read as follows:

§ 22.5 Filing, service by the parties, and form of all filed documents; business confidentiality claims.

(a) *Filing of documents.* (1) The original and one copy of each document intended to be part of the record shall be filed with the Headquarters or Regional Hearing Clerk, as appropriate, when the proceeding is before the Presiding Officer, or filed with the Clerk of the Board when the proceeding is before the Environmental Appeals Board. A document is filed when it is received by the appropriate Clerk. When a document is required to be filed with the Environmental Appeals Board, the document shall be sent to the Clerk of the Board by U.S. Mail, delivered by hand or courier (including delivery by U.S. Express Mail or by a commercial delivery service), or transmitted by the Environmental Appeal Board's electronic filing system, according to the procedures specified in 40 CFR 124.19 (i)(2)(i), (ii), and (iii). The Presiding Officer or the Environmental Appeals Board may by order authorize or require filing by facsimile or an electronic filing system, subject to any appropriate conditions and limitations.

* * * * *

(b) *Service of documents.* Unless the proceeding is before the Environmental Appeals Board, a copy of each document filed in the proceeding shall be served on the Presiding Officer and on each party. In a proceeding before the Environmental Appeals Board, a copy of each document filed in the proceeding shall be served on each party.

* * * * *

(2) *Service of filed documents other than the complaint, rulings, orders, and decisions.* All documents filed by a party other than the complaint, rulings, orders, and decisions shall be served by the filing party on all other parties. Service may be made personally, by U.S. mail (including certified mail, return receipt requested, Overnight Express and Priority Mail), by any reliable commercial delivery service, or by facsimile or other electronic means, including but not necessarily limited to email, if service by such electronic means is consented to in writing. A party who consents to service by facsimile or email must file an acknowledgement of its consent (identifying the type of electronic means agreed to and the electronic address to be used) with the appropriate Clerk. In addition, the Presiding Officer or the Environmental Appeals Board may by order authorize or require service by facsimile, email, or other electronic means, subject to any appropriate conditions and limitations.

(c) * * *

(4) The first document filed by any person shall contain the name, mailing address, telephone number, and email address of an individual authorized to receive service relating to the proceeding on behalf of the person. Parties shall promptly file any changes in this information with the Headquarters or Regional Hearing Clerk or the Clerk of the Board, as appropriate, and serve copies on the Presiding Officer and all parties to the proceeding. If a party fails to furnish such information and any changes thereto, service to the party's last known address shall satisfy the requirements of paragraph (b)(2) of this section and § 22.6.

* * * * *

■ 4. Revise § 22.6 to read as follows:

§ 22.6 Filing and service of rulings, orders and decisions.

All rulings, orders, decisions, and other documents issued by the Regional Administrator or Presiding Officer shall be filed with the Headquarters or Regional Hearing Clerk, as appropriate, in any manner allowed for the service of such documents. All rulings, orders, decisions, and other documents issued by the Environmental Appeals Board shall be filed with the Clerk of the Board. The Clerk of the Board, the Headquarters Hearing Clerk, or the Regional Hearing Clerk, as appropriate, must serve copies of such rulings, orders, decisions and other documents on all parties. Service may be made by U.S. mail (including by certified mail or return receipt requested, Overnight Express and Priority Mail), EPA's internal mail, any reliable commercial delivery service, or electronic means (including but not necessarily limited to facsimile and email).

■ 5. In § 22.7, revise paragraph (c) to read as follows:

§ 22.7 Computation and extension of time.

* * * * *

(c) *Completion of service.* Service of the complaint is complete when the return receipt is signed. Service of all other documents is complete upon mailing, when placed in the custody of a reliable commercial delivery service, or for facsimile or other electronic means, including but not necessarily limited to email, upon transmission. Where a document is served by U.S. mail, EPA internal mail, or commercial delivery service, including overnight or same-day delivery, 3 days shall be added to the time allowed by these Consolidated Rules of Practice for the filing of a responsive document. The time allowed for the serving of a responsive document is not expanded by 3 days when the served document is served by personal delivery, facsimile, or other electronic means, including but not necessarily limited to email.

Subpart C—Prehearing Procedures

■ 6. In § 22.16, revise paragraph (c) to read as follows:

§ 22.16 Motions.

* * * * *

(c) *Decision.* The Regional Judicial Officer (or in a proceeding commenced at EPA Headquarters, an Administrative Law Judge) shall rule on all motions filed or made before an answer to the complaint is filed. Except as provided in §§ 22.29(c) and 22.51, an Administrative Law Judge shall rule on all motions filed or made after an answer is filed and

before an initial decision becomes final or has been appealed. The Environmental Appeals Board shall rule as provided in § 22.29(c) and on all motions filed or made after an appeal of the initial decision is filed, except as provided pursuant to § 22.28.

■ 7. Revise the subpart E heading to read as follows:

Subpart E—Initial Decision, Motion To Reopen a Hearing, and Motion To Set Aside a Default Order

■ 8. Revise § 22.28 to read as follows:

§ 22.28 Motion to reopen a hearing or to set aside a default order.

(a) *Motion to reopen a hearing*—(1) *Filing and content.* A motion to reopen a hearing to take further evidence must be filed no later than 20 days after service of the initial decision and shall state the specific grounds upon which relief is sought. Where the movant seeks to introduce new evidence, the motion shall: State briefly the nature and purpose of the evidence to be adduced; show that such evidence is not cumulative; and show good cause why such evidence was not adduced at the hearing. The motion shall be made to the Presiding Officer and filed with the Headquarters or Regional Hearing Clerk, as appropriate. A copy of the motion shall be filed with the Clerk of the Board in the manner prescribed by § 22.5(a)(1).

(2) *Disposition of motion to reopen a hearing.* Within 15 days following the service of a motion to reopen a hearing, any other party to the proceeding may file with the Headquarters or Regional Hearing Clerk, as appropriate, and serve on all other parties a response. A reopened hearing shall be governed by the applicable sections of these Consolidated Rules of Practice. The timely filing of a motion to reopen a hearing shall automatically toll the running of the time periods for an initial decision becoming final under § 22.27(c), for appeal under § 22.30, and for the Environmental Appeals Board to elect to review the initial decision on its own initiative pursuant to § 22.30(b). These time periods begin again in full when the Presiding Officer serves an order denying the motion to reopen the hearing or an amended decision. The Presiding Officer may summarily deny subsequent motions to reopen a hearing filed by the same party if the Presiding Officer determines that the motion was filed to delay the finality of the decision.

(b) *Motion to set aside default order*—(1) *Filing and content.* A motion to set aside a default order must be filed no later than 20 days after service of the initial decision and shall state the specific grounds upon which relief is sought. The motion shall be made to the Presiding Officer and filed with the Headquarters or Regional Hearing Clerk, as appropriate. A copy of the motion shall be filed with the Clerk of the Board in the manner prescribed by § 22.5(a)(1).

(2) *Effect of motion to set aside default.* The timely filing of a motion to set aside a default order automatically tolls the running of the time periods for an initial decision becoming final under § 22.27(c), for appeal under § 22.30(a), and for the Environmental Appeals Board to elect to review the initial decision on its own initiative pursuant to § 22.30(b). These time periods begin again in full when the Presiding Officer serves an order denying the motion to set aside or an amended decision. The Presiding Officer may summarily deny subsequent motions to set aside a default order filed by the same party if the Presiding Officer determines that the motion was filed to delay the finality of the decision.

Subpart F—Appeals and Administrative Review

■ 9. In § 22.30, revise paragraphs (a), (b), (c), (d), and (e) to read as follows:

§ 22.30 Appeal from or review of initial decision.

(a) *Notice of appeal and appeal brief*—(1) *Filing an appeal*—(i) *Filing deadline and who may appeal.* Within 30 days after the initial decision is served, any party may file an appeal from any adverse order or ruling of the Presiding Officer.

(ii) *Filing requirements.* Appellant must file a notice of appeal and an accompanying appellate brief with the Environmental Appeals Board as set forth in § 22.5(a). One copy of any document filed with the Clerk of the Board shall also be served on the Headquarters or Regional Hearing Clerk, as appropriate. Appellant also shall serve a copy of the notice of appeal upon the Presiding Officer. Appellant shall simultaneously serve one copy of the notice and brief upon all other parties and non-party participants.

(iii) *Content.* The notice of appeal shall summarize the order or ruling, or part thereof, appealed from. The appellant's brief shall contain tables of contents and authorities (with appropriate page references), a statement of the issues presented for review, a statement of the nature of the case and the facts relevant to the issues presented for review (with specific citation or other appropriate reference to the record (*e.g.,* by including the document name and page number)), argument on the issues presented, a short conclusion stating the precise relief sought, alternative findings of fact, and alternative conclusions regarding issues of law or discretion. If any appellant includes attachments to its notice of appeal or appellate brief, the notice of appeal or appellate brief shall contain a table that provides the title of each appended document and assigns a label identifying where it may be found in the record.

(iv) *Multiple appeals.* If a timely notice of appeal is filed by a party, any other party may file a notice of appeal and accompanying appellate brief on any issue within 20 days after the date on which the first notice of appeal was served or within the time to appeal in paragraph (a)(1)(i) of this section, whichever period ends later.

(2) *Response brief.* Within 20 days of service of notices of appeal and briefs under paragraph (a)(1) of this section, any other party or non-party participant may file with the Environmental Appeals Board an original and one copy of a response brief responding to arguments raised by the appellant, together with specific citation or other appropriate reference to the record, initial decision, and opposing brief (*e.g.,* by including the document name and page number). Appellee shall simultaneously serve one copy of the response brief upon each party, non-party participant, and the Regional Hearing Clerk. Response briefs shall be limited to the scope of the appeal brief. If any responding party or non-party participant includes attachments to its response brief, the response brief shall contain a table that provides the title of each appended document and assigns a label identifying where it may be found in the record. Further briefs may be filed only with leave of the Environmental Appeals Board.

(3) *Length*—(i) *Briefs.* Unless otherwise ordered by the Environmental Appeals Board, appellate and response briefs may not exceed 14,000 words, and all other briefs may not exceed 7000 words. Filers may rely on the word-processing system used to determine the word count. As an alternative to this word limitation, filers may comply with a 30-page limit for appellate and response briefs, or a 15-page limit for replies. Headings, footnotes, and quotations count toward the word limitation. The table of contents, table of authorities, table of attachments (if any), statement requesting oral argument (if any), statement of compliance with the word limitation, and any attachments do not count toward the word or page-length limitation. The Environmental

Appeals Board may exclude any appeal, response, or other brief that does not meet word or page-length limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board to file a longer brief. Such requests are discouraged and will be granted only in unusual circumstances.

(ii) *Motions.* Unless otherwise ordered by the Environmental Appeals Board, motions and any responses or replies may not exceed 7000 words. Filers may rely on the word-processing system used to determine the word count. As an alternative to this word limitation, filers may comply with a 15-page limit. Headings, footnotes, and quotations count toward the word or page-length limitation. The Environmental Appeals Board may exclude any motion that does not meet word limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board. Such requests are discouraged and will be granted only in unusual circumstances.

(b) *Review initiated by the Environmental Appeals Board.* Whenever the Environmental Appeals Board determines to review an initial decision on its own initiative, it shall issue an order notifying the parties and the Presiding Officer of its intent to review that decision. The Clerk of the Board shall serve the order upon the Regional Hearing Clerk, the Presiding Officer, and the parties within 45 days after the initial decision was served upon the parties. In that order or in a later order, the Environmental Appeals Board shall identify any issues to be briefed by the parties and establish a time schedule for filing and service of briefs.

(c) *Scope of appeal or review.* The parties' rights of appeal shall be limited to those issues raised during the course of the proceeding and by the initial decision, and to issues concerning subject matter jurisdiction. If the Environmental Appeals Board determines that issues raised, but not appealed by the parties, should be argued, it shall give the parties written notice of such determination to allow preparation of adequate argument. The Environmental Appeals Board may remand the case to the Presiding Officer for further proceedings.

(d) *Argument before the Environmental Appeals Board.* The Environmental Appeals Board may, at its discretion in response to a request or on its own initiative, order oral argument on any or all issues in a proceeding. To request oral argument, a party must include in its substantive brief a statement explaining why oral argument is necessary. The Environmental Appeals Board may, by order, establish additional procedures governing any oral argument before the Environmental Appeals Board.

(e) *Motions on appeal*—(1) *General.* All motions made during the course of an appeal shall conform to § 22.16 unless otherwise provided. In advance of filing a motion, parties must attempt to ascertain whether the other party(ies) concur(s) or object(s) to the motion and must indicate in the motion the attempt made and the response obtained.

(2) *Disposition of a motion for a procedural order.* The Environmental Appeals Board may act on a motion for a procedural order at any time without awaiting a response.

(3) *Timing on motions for extension of time.* Parties must file motions for extensions of time sufficiently in advance of the due date to allow other parties to have a reasonable opportunity to respond to the request for more time and to provide the Environmental Appeals Board with a reasonable opportunity to issue an order.

* * * * *

PART 124—PROCEDURES FOR DECISIONMAKING

■ 10. The authority citation for part 124 continues to read as follows:

Authority: Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.;* Safe Drinking Water Act, 42 U.S.C. 300f *et seq.;* Clean Water Act, 33 U.S.C. 1251 *et seq.;* Clean Air Act, 42 U.S.C. 7401 *et seq.*

Subpart A—General Program Requirements

■ 11. In § 124.19:

■ a. Revise the first sentence of paragraph (a)(4)(ii), and paragraph (b).

■ b. Redesignate paragraph (f)(5) as paragraph (f)(6).

■ c. Add a new paragraph (f)(5).

■ d. Revise paragraphs (i) introductory text, (i)(2) introductory text, and (3).

The addition and revisions read as follows:

§ 124.19 Appeal of RCRA, UIC, NPDES and PSD Permits.

(a) * * *

(4) * * *

(ii) Petitioners must demonstrate, by providing specific citation or other appropriate reference to the administrative record (*e.g.,* by including the document name and page number), that each issue being raised in the petition was raised during the public comment period (including any public hearing) to the extent required by § 124.13. * * *

(b) *Response(s) to a petition for review.* (1) In a PSD or other new source permit appeal, the Regional Administrator must file a response to the petition for review, a certified index of the administrative record, and the relevant portions of the administrative record within 21 days after the service of the petition. The response brief must respond to arguments raised by the appellant, together with specific citation or other appropriate reference to the record (*e.g.,* by including the document name and page number).

(2) In all other permit appeals under this section, the Regional Administrator must file a response to the petition, a certified index of the administrative record, and the relevant portions of the administrative record within 30 days after the service of a petition.

* * * * *

(f) * * *

(5) *Length.* Unless otherwise ordered by the Environmental Appeals Board, motions and any responses or replies may not exceed 7000 words. Filers may rely on the word-processing system used to determine the word count. In lieu of a word limitation, filers may comply with a 15-page limit. Headings, footnotes, and quotations count toward the word or page-length limitation. The Environmental Appeals Board may exclude any motion that does not meet word limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board. Such requests are discouraged and will be granted only in unusual circumstances.

* * * * *

(i) *Filing and service requirements.* Documents filed under this section, including the petition for review, must be filed with the Clerk of the Environmental Appeals Board. A document is filed when it is received by the Clerk of the Environmental Appeals Board at the address specified for the appropriate method of delivery as provided in paragraph (i)(2) of this section. Service of a document between parties to an appeal or by the Environmental Appeals Board on a party is complete upon mailing for U.S. mail or EPA internal mail, when placed in the custody of a reliable commercial delivery service, or upon transmission for facsimile or email.

* * * * *

(2) *Method of filing.* Unless otherwise permitted under these rules, documents

must be filed either by using the Environmental Appeals Board's electronic filing system, by U.S. mail, or by hand delivery. In addition, a motion or a response to a motion may be submitted by facsimile if the submission contains no attachments. Upon filing a motion or response to a motion by facsimile, the sender must, within one business day, submit the original copy to the Clerk of the Environmental Appeals Board either electronically, by mail, or by hand-delivery. The Environmental Appeals Board may by order require filing by facsimile or the Board's electronic filing system, subject to any appropriate conditions and limitations.

* * * * *

(3) *Service*—(i) *Service information.* The first document filed by any person shall contain the name, mailing address, telephone number, and email address of an individual authorized to receive service relating to the proceeding. Parties shall promptly file any changes in this information with the Clerk of the Environmental Appeals Board, and serve copies on all parties to the proceeding. If a party fails to furnish such information and any changes thereto, service to the party's last known address shall satisfy the requirements of paragraph (i)(3) of this section.

(ii) *Service requirements for parties.* Petitioner must serve the petition for review on the Regional Administrator and the permit applicant (if the applicant is not the petitioner). Once an appeal is docketed, every document filed with the Environmental Appeals Board must be served on all other parties. Service must be by first class U.S. mail, by any reliable commercial delivery service, or, if agreed to by the parties, by facsimile or other electronic means, including but not necessarily limited to or email. A party who consents to service by facsimile or other electronic means must file an acknowledgement of its consent (identifying the type of electronic means agreed to and the electronic address to be used) with the Clerk of the Environmental Appeals Board. The Environmental Appeals Board may by order authorize or require service by facsimile, email, or other electronic means, subject to any appropriate conditions and limitations.

(iii) *Service of rulings, orders, and decisions.* The Clerk of the Environmental Appeals Board must serve copies of rulings, orders, and decisions on all parties. Service may be made by U.S. mail (including by certified mail or return receipt requested, Overnight Express and Priority Mail), EPA's internal mail, any reliable commercial delivery service, or electronic means (including but not necessarily limited to facsimile and email).

* * * * *

■ 12. In § 124.20, revise paragraph (d) to read as follows:

§ 124.20 Computation of time.

* * * * *

(d) When a party or interested person may or must act within a prescribed period after being served and service is made by U.S. mail, EPA's internal mail, or reliable commercial delivery service, 3 days shall be added to the prescribed time. The prescribed period for acting after being served is not expanded by 3 days when service is made by personal delivery, facsimile, or email.

[FR Doc. 2016–31638 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2015–0402; FRL–9957–27–Region 1]

Approval and Promulgation of Implementation Plans; Rhode Island; Clean Air Act Infrastructure State and Federal Implementation Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is removing several obsolete Federal Implementation Plans (FIPs) for the State of Rhode Island. These FIPs address Clean Air Act (CAA) infrastructure State Implementation Plan (SIP) requirements that have since been addressed by Rhode Island in its SIP. Therefore, EPA is removing from the Code of Federal Regulations (CFR) the corresponding FIPs. This action is being taken in accordance with the CAA.

DATES: This rule is effective on February 8, 2017.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2015–0402. All documents in the docket are listed on the *http://www.regulations.gov* Web site, although some information, such as confidential business information or other information whose disclosure is restricted by statute is not publically available. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that, if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Richard P. Burkhart, Air Quality Planning Unit, Air Programs Branch (Mail Code OEP05–02), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912; (617) 918–1664; *burkhart.richard@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background and Purpose
II. Public Comments
III. Final Action
IV. Statutory and Executive Order Reviews

I. Background and Purpose

This rulemaking addresses infrastructure SIP submissions from the State of Rhode Island for the 1997 fine particle matter ($PM_{2.5}$), 2006 $PM_{2.5}$, 2008 lead (Pb), 2008 ozone, 2010 nitrogen dioxide (NO_2), and 2010 sulfur dioxide (SO_2) National Ambient Air Quality Standards (NAAQS). The state submitted these infrastructure SIPs on the following dates: 1997 $PM_{2.5}$—September 10, 2008; 2006 $PM_{2.5}$—November 6, 2009; 2008 Pb—October 26, 2011; 2008 ozone—January 2, 2013; 2010 NO_2—January 2, 2013; and 2010 SO_2—June 27, 2014. Details of Rhode Island's submittals and EPA evaluation of those submittals can be found in our Notice of Proposed Rulemaking (NPR) (81 FR 10168; February 29, 2016).

On April 20, 2016, EPA took final action on the vast majority of the elements included in these submittals (see 81 FR 23175). In today's action, EPA is taking final action on its proposal to remove the following sections from the Code of Federal Regulations (CFR): 40 CFR 52.2073(b); 52.2075(b); and 52.2078(b). As discussed in detail in the NPR, these sections related to the public

availability of emissions data and enforcement procedures are no longer necessary and have become obsolete since EPA has approved the relevant infrastructure SIP elements. Removal of Federal Implementation language is reserved for the Administrator, and has not been delegated to the Regional Administrator, who signed the April 20, 2016 final rulemaking referenced above.

II. Public Comments

EPA did not receive any comments in response to the NPR.

III. Final Action

EPA is removing the following sections from the CFR: 40 CFR 52.2073(b); 52.2075(b); and 52.2078(b). The Federal Implementation Plan requirements in these sections are no longer necessary since EPA has since approved the relevant Clean Air Act infrastructure SIP revisions submitted by Rhode Island (see 81 FR 23175; April 20, 2016). A detailed discussion of the rationale for our action is included in the NPR (see 81 FR 10168; February 29, 2016).

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under EOs 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. Entities potentially affected directly by this rule include state, local and tribal governments and none of these governments are small governments. Other types of small entities are not directly subject to the requirements of this rule.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in E.O. 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in E.O. 13175. These regulation revisions do not affect the relationship or distribution of power and responsibilities between the federal government and Indian tribes.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets E.O. 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the E.O. has the potential to influence the regulation. This action is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to E.O. 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under E.O. 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to E.O. 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is a procedural change and does not have any impact on human health or the environment.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C section 804(2). This rule will be effective *February 8, 2017.*

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *March 10, 2017.* Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 15, 2016.

Gina McCarthy,

Administrator.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart OO—Rhode Island

§ 52.2073 [Removed and Reserved]

■ 2. Section 52.2073 is removed and reserved.

§ 52.2075 [Removed and Reserved]

■ 3. Section 52.2075 is removed and reserved.

§ 52.2078 [Removed and Reserved]

■ 4. Section 52.2078 is removed and reserved.

[FR Doc. 2016–31444 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2016–0287; FRL–9957–64–Region 9]

Approval of Arizona Air Plan Revisions; Ajo and Morenci, Arizona; Second 10-Year Sulfur Dioxide Maintenance Plans and Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule and technical correction.

SUMMARY: The Environmental Protection Agency (EPA) is approving the second 10-year maintenance plans for the Ajo and Morenci areas in Arizona for the 1971 National Ambient Air Quality Standards (NAAQS or ''standards'') for sulfur dioxide (SO_2), and correcting an error in the description of the Ajo SO_2 maintenance area in the Code of Federal Regulations. Elsewhere in this **Federal Register**, we are proposing approval and soliciting written comment on these actions. If we receive adverse comments on this direct final rule, resulting in withdrawal of the entire rule or any part(s) of it, we will address those comments when we finalize the proposal. The EPA does not plan to institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: This rule is effective March 10, 2017, without further notice, unless we receive adverse comments by February 8, 2017. If the EPA receives adverse comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that some or all of the provisions in this direct final rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0287 at *http://www.regulations.gov,* or via email to Wienke Tax, Air Planning Office at *tax.wienke@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

You may inspect and copy the rulemaking docket for this notice at the following location during normal business hours: Environmental Protection Agency, Region IX, Air Division, Air Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, CA 94105–3901. Copies of the State Implementation Plan materials are also available for inspection at the address listed here: Arizona Department of Environmental Quality, 1110 W. Washington Street, First Floor, Phoenix, AZ 85007, Phone: (602) 771–4335.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, EPA Region IX, (415) 947–4192, *tax.wienke@epa.gov.*

SUPPLEMENTARY INFORMATION: Elsewhere in this **Federal Register**, we are proposing approval and soliciting written comment on this action. Throughout this document, the words ''we,'' ''us,'' or ''our'' mean EPA.

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I. Summary of Action

We are approving the second 10-year maintenance plans for the Ajo and Morenci, Arizona SO_2 maintenance areas and correcting an error in the boundary description of the Ajo maintenance area in the Code of Federal Regulations (CFR).[1] [2]

II. Background

A. What National Ambient Air Quality Standards are considered in this rulemaking?

Sulfur dioxide (SO_2) is the pollutant that is the subject of this action. The NAAQS are health-based and welfare-based standards for certain ambient air pollutants. SO_2 is among the ambient air pollutants for which we have established a health-based standard. SO_2 causes adverse health effects by reducing lung function, increasing respiratory illness, altering the lung's defenses and aggravating existing cardiovascular disease. Children, the elderly, and people with asthma are the most vulnerable. SO_2 has a variety of additional impacts, including acidic deposition, damage to crops and vegetation, and corrosion of natural and man-made materials.

In 1971, the EPA established both short- and long-term primary NAAQS

[1] For the definition of the Ajo maintenance area, see 40 CFR 81.303. Ajo is a town located in northwestern Pima County, in the southwestern portion of Arizona. The EPA designated the entire area of Pima County as nonattainment for SO_2 on March 3, 1978 for lack of a State recommendation. The EPA approved the State's request that the SO_2-affected portion of Pima County be limited to the townships surrounding Ajo on April 10, 1979 (44 FR 21261). Townships T11S, R6W; T11S, R5W; T12S, R6W; T12S, R5W; and T13S, R6W comprised the nonattainment area. Townships T11S, R7W; T12S, R7W; T13S, R5W; and T13S, R7W were designated as ''cannot be classified.'' At the time of our redesignation, we incorrectly identified the maintenance area as all townships and ranges T11S–13S, R5W–R6W as ''better than national standards.'' However, T11S, R7W; T12S, R7W; T13S, R7W; and T13S, R5W were originally designated as ''cannot be classified'' and should have remained such. Today, we are correcting that error.

[2] For the definition of the Morenci maintenance area, see 40 CFR 81.303. Morenci is a town in eastern Greenlee County near the border of Arizona and New Mexico. The EPA designated the entire area of Greenlee County as nonattainment for SO_2 on March 3, 1978 for lack of a State recommendation. The EPA approved the State's request that the SO_2-affected portion of Greenlee County be limited to the townships surrounding Morenci on April 10, 1979 (44 FR 21261). Within Greenlee County, Townships T3S, R28E; T3S, R29E; T3S, R30E; T4S, R28E; T4S, R29E; T4S, R30E; T5S, R28E; and T5S, R29E comprise the maintenance area. Township T5S, R30E is designated as ''cannot be classified.''

for SO_2. The short-term (24-hour) standard of 0.14 parts per million (ppm) was not to be exceeded more than once per year. The long-term standard specifies an annual arithmetic mean not to exceed 0.030 ppm.[3] *See* 40 CFR 50.4.

In 2010, the EPA revised the primary SO_2 NAAQS by establishing a new 1-hour standard of 75 parts per billion (ppb). The EPA revoked the existing 1971 primary standards at that time because they would not provide additional public health protection. *See* 75 FR 35550 (June 22, 2010). This action relates only to the revoked 1971 NAAQS. The State has requested that we take action on these maintenance plans.[4]

B. What is a State Implementation Plan?

The Clean Air Act (CAA or ''Act'') requires states to attain and maintain ambient air quality equal to or better than the NAAQS. The state's commitments for attaining and maintaining the NAAQS are outlined in the State Implementation Plan (SIP) for that state. The SIP is a planning document that, when implemented, is designed to ensure the achievement of the NAAQS. The Act requires that SIP revisions be made periodically as necessary to provide continued compliance with the standards.

SIPs include, among other things, the following: (1) An inventory of emission sources; (2) statutes and regulations adopted by the state legislature and executive agencies; (3) air quality analyses that include demonstrations that adequate controls are in place to meet the NAAQS; and (4) contingency measures to be undertaken if an area fails to attain the standard or make reasonable progress toward attainment by the required date, or a contingency plan if the area fails to maintain the NAAQS once redesignated. The state must make the SIP available for public review and comment through a public hearing and the SIP must be adopted by the state and submitted to us by the governor or her/his designee.

The EPA takes action on the SIP submittal, thus rendering the rules and regulations federally enforceable. The approved SIP serves as the state's commitment to take actions that will reduce or eliminate air quality problems. Any subsequent revisions to the SIP must go through the formal SIP revision process specified in the Act.

C. What is the background for this action?

1. When were the nonattainment areas established?

Ajo

Ajo is located in northwestern Pima County. On March 3, 1978, at 43 FR 8968, for lack of a State recommendation, we designated Pima County as a primary SO_2 nonattainment area based on monitored violations of the primary SO_2 NAAQS in the area between 1975 and 1977. At the request of the Arizona Department of Environmental Quality (ADEQ), the nonattainment area was subsequently reduced to five townships in and around Ajo. *See* 44 FR 21261 (April 10, 1979). As a result, townships T11S, R6W; T11S, R5W; T12S, R6W; T12s, R5W; and T13S, R6W made up the nonattainment area. Townships T11S, R7W; T12S, R7W; T13S, R7W; and T13S, R5W were classified as ''cannot be classified'' areas.

Morenci

Morenci is a town in eastern Greenlee County near the border of Arizona and New Mexico. On March 3, 1978, at 43 FR 8968, for lack of a state recommendation, we designated Greenlee County as a primary SO_2 nonattainment area based on monitored violations of the primary SO_2 NAAQS in the area between 1975 and 1977. At the request of the ADEQ, the nonattainment area was subsequently reduced to the townships in and around Morenci. *See* 44 FR 21261 (April 10, 1979). As a result, within Greenlee County townships T3S, R28E; T3S, R29E; T3S, R30E; T4S, R28E; T4S, R29E; T4S, R30E; T5S, R28E; and T5S, R29E made up the nonattainment area. Township T5S, R30E was classified as a ''cannot be classified'' area.

On the date of enactment of the 1990 CAA Amendments, SO_2 areas meeting the conditions of section 107(d) of the Act were designated nonattainment for the SO_2 NAAQS by operation of law. Section 107(d) describes the processes by which nonattainment areas are designated, including the pre-existing SO_2 nonattainment areas. Thus, the Ajo and Morenci areas remained nonattainment for the primary SO_2 NAAQS following enactment of the 1990 CAA Amendments on November 15, 1990.

2. When were the Ajo and Morenci areas redesignated for SO_2?

In 2004, we redesignated the Ajo and Morenci areas under the criteria used for areas with shut-down smelters and discontinued monitoring described in a memorandum from John Seitz to Regional Office Air Division Directors titled ''Redesignation of Sulfur Dioxide Nonattainment Areas in the Absence of Monitored Data,'' dated October 18, 2000 (''Seitz Memo'').[5]

Ajo

Phelps Dodge Mining Company's Ajo Incorporated (PDAI) operation was the largest point source in the Ajo SO_2 nonattainment area. On April 4, 1985, the PDAI smelter was permanently deactivated. Dismantling of the Ajo facility began in 1995. By February 1996, the facility was completely dismantled. On October 15, 1997, ADEQ confirmed that the facility was dismantled and no longer existed at the former site. On November 3, 2003, the EPA finalized approval of the maintenance plan and redesignation request for the Ajo area, effective January 2, 2004 (*see* 68 FR 62239). At that time, we incorrectly identified the maintenance area as townships and ranges T11S–T13S, R5W–R6W as ''better than national standards.'' However, T13S, R5W was originally designated as ''cannot be classified'' and should have remained such. Additionally, townships T13S, R5W; T11S, R7W; T12S, R7W; and T13S, R7W were dropped from the CFR, and should be listed in 40 CFR 81.303 as ''cannot be classified,'' as they were upon Ajo's original designation in 1979. Today, we are correcting those errors.

Morenci

The Phelps Dodge Morenci Incorporated (PDMI) operation was the largest SO_2 point source in the Morenci nonattainment area during its operation. PDMI was located next to the Morenci copper mine, one of the largest copper producing operations in North America. PDMI was located close to the community of Morenci, in eastern Greenlee County, near the Arizona/New Mexico border.

On December 31, 1984, the PDMI smelter was permanently deactivated. Dismantling of the Morenci facility began in 1995 and was complete by December 1996. On October 29, 1997, ADEQ confirmed that the facility was dismantled and no longer existed at the former site. On April 26, 2004, the EPA finalized approval of the maintenance

[3] Secondary NAAQS are promulgated to protect welfare. The secondary 1971 SO_2 NAAQS (3-hour) of 0.50 ppm is not to be exceeded more than once per year. The Ajo and Morenci areas are not classified nonattainment for the secondary standard, and this action relates only to the primary 1971 SO_2 NAAQS.

[4] This action is consistent with the CAA's anti-backsliding provisions. EPA's proposed rule on revocation of the 1971 SO_2 NAAQS discussed that maintenance SIPs would continue being implemented by states until such time as they are subsumed by new planning and control requirements associated with the revised NAAQS. *See* 74 FR 64810, 64863 (December 8, 2009).

[5] *See* 68 FR 62239 (November 3, 2003) for Ajo and 69 FR 22447 (April 26, 2004) for Morenci.

plan and redesignation request for the Morenci area, effective June 25, 2004 (*see* 69 FR 22447).

3. What is the current status of the areas?

The Ajo and Morenci areas remain sparsely settled, and only minor industrial or commercial activities that produce small quantities of SO_2 emissions are located in or near the nonattainment areas.

Ajo

In Ajo, the only remaining SO_2 point sources consist of emergency generators run by Freeport-McMoRan Corporation and Minerals Research and Recovery, which have a potential to emit (PTE) of 0.374 tons per year (tpy) of SO_2.[6] The 50 kilometer (km) buffer area required to be evaluated by the Seitz Memo includes an Arizona Public Service emergency generator, a paper mill, the Gila Bend Air Force Auxiliary Field, and a cotton gin, with a combined PTE of 7.388 tpy.[7]

Currently, no ambient SO_2 monitors operate in the Ajo area. However, we do not expect the cumulative impact of the sources in and around Ajo to cause a violation of the NAAQS because the area's emissions are so low. No significant new sources have located in the area since our redesignation of the area to attainment in 2003.

Morenci

Minor industrial or commercial activities such as Freeport-McMoRan mining operations and emergency generators for the Morenci wastewater treatment plant operate in the area. The 50 km area around the nonattainment area also contains a construction company, well fields, and several other sources that all still have active permits and together produce about 135 tpy of SO_2 emissions.[8]

Currently, no ambient SO_2 monitors operate in the Morenci area. However, we do not expect the cumulative impact of the sources in and around Morenci to cause a violation of the NAAQS. No significant new sources have located in the area, and the smelter was the cause of past violations.

D. What are the applicable provisions for second 10-year maintenance plans for SO_2?

1. What are the statutory provisions?

Section 175A of the CAA provides the general framework for maintenance plans. The initial 10-year maintenance plan must provide for maintenance of the NAAQS for at least 10 years after redesignation, including any additional control measures as may be necessary to ensure such maintenance. In addition, maintenance plans are to contain such contingency provisions as we deem necessary to assure the prompt correction of a violation of the NAAQS that occurs after redesignation. The contingency measures must include, at a minimum, a requirement that the state will implement all control measures contained in the nonattainment SIP prior to redesignation.

Section 175A(b) of the CAA requires states to submit a subsequent maintenance plan revision (second 10-year maintenance plan) eight years after redesignation. The Act requires only that this second 10-year maintenance plan maintain the applicable NAAQS for ten years after the expiration of the first 10-year maintenance plan. Beyond these provisions, however, section 175A of the CAA does not define the content of a second 10-year maintenance plan.

2. What general EPA guidance applies to SO_2 maintenance plans?

Our primary general guidance on maintenance plans and redesignation requests is a September 4, 1992 memo from John Calcagni, titled ''Procedures for Processing Requests to Redesignate Areas to Attainment'' (''Calcagni Memo''). Specific guidance on SO_2 redesignations also appears in a January 26, 1995 memo from Sally L. Shaver, titled ''Attainment Determination Policy for Sulfur Dioxide Nonattainment Areas'' (''Shaver Memo'').

Guidance on SO_2 maintenance plan requirements for an area lacking monitored ambient data, if the area's historic violations were caused by a major point source that is no longer in operation, is found in the Seitz Memo at section II.C.2 and footnote 4. The Seitz Memo exempts eligible areas from the maintenance plan requirements of continued ambient air quality monitoring.

While the Seitz Memo primarily addresses redesignations, we find it is appropriate to apply the Seitz Memo to second 10-year maintenance plans for areas that were redesignated in accordance with the memo and continue to experience similar conditions to those at the time of redesignation.

3. What are the requirements for maintenance plans for single-source SO_2 nonattainment areas in the absence of monitored data?

Our historic redesignation policy for SO_2 has called for eight quarters of clean ambient air quality data as a necessary prerequisite to redesignation of any area to attainment. The Seitz Memo provides guidance on SO_2 maintenance plan requirements for an area lacking monitored ambient data, if the area's historic violations were caused by a major point source that is no longer in operation. To allow for these areas to qualify for redesignation to attainment, this policy requires that the maintenance plan address otherwise applicable provisions, and include:

(1) Emissions inventories representing actual emissions when violations occurred; current emissions; and emissions projected to the 10th year after redesignation; all three inventories should include estimates of emissions in a 50 km buffer zone around the nonattainment area;

(2) dispersion modeling showing that no NAAQS violations will occur over the next 10 years and that the shut-down source was the dominant cause of the high concentrations in the past;

(3) evidence that if the shut-down source resumes operation, it would be considered a new source and be required to obtain a permit under the Prevention of Significant Deterioration (PSD) provisions of the CAA; and

(4) a commitment to resume monitoring before any major SO_2 source commences operation.

III. The EPA's Evaluation of the Arizona State Submittals

A. Did the State meet the CAA procedural requirements?

Ajo

On February 22, 2013, ADEQ submitted to the EPA the ''Final Arizona State Implementation Plan Revision, Maintenance Plan for the Ajo Sulfur Dioxide Planning Area (1971 NAAQS)'' (''2013 Ajo Maintenance Plan''). The State verified that it had adhered to its SIP adoption procedures in Appendix E to the 2013 Ajo Maintenance Plan, which includes the notice of public hearing, the agenda for the February 7, 2013 public hearing, the sign in sheet, the public hearing officer certification and transcript of the hearing, and the State's responsiveness summary.

On August 22, 2013, the 2013 Ajo Maintenance Plan was deemed complete by operation of law. See 40

[6] Final Arizona State Implementation Plan Revision, Maintenance Plan for the Ajo Sulfur Dioxide Planning Area (1971 NAAQS) (2013 Ajo Maintenance Plan), page (p.) 23, Table 4.6.

[7] 2013 Ajo Maintenance Plan, p. 24, Table 4.7.

[8] Proposed Arizona State Implementation Plan Revision, Maintenance Plan for the Morenci Sulfur Dioxide Planning Area (1971 NAAQS), p. 20, active permits only.

CFR part 51, appendix V, for the EPA's completeness criteria, which must be satisfied before EPA formal review.

Morenci

On December 18, 2014, ADEQ submitted to the EPA the ''Proposed Arizona State Implementation Plan Revision, Maintenance Plan for the Morenci Sulfur Dioxide Planning Area (1971 NAAQS)'' (''2014 Morenci Maintenance Plan''). The State verified that it had adhered to its SIP adoption procedures in Appendix E to the 2014 Morenci Maintenance Plan, which includes the notice of public hearing, the agenda for the December 15, 2014 public hearing, the sign in sheet, the public hearing officer certification and transcript of the hearing, and the State's responsiveness summary.

On May 10, 2015, the 2014 Morenci Maintenance Plan was deemed complete by operation of law. See 40 CFR part 51, appendix V, for the EPA's completeness criteria, which must be satisfied before EPA formal review.

B. Has the State met the substantive maintenance plan requirements?

1. Were the area's violations caused by a major point source of SO_2 emissions that is no longer in operation?

As discussed above, the only major source of SO_2 emissions within the Ajo nonattainment area was the Phelps Dodge Mining Company's PDAI copper smelter, which ceased operation in 1985 and was completely dismantled by February 1996. The last recorded 24-hour or annual average exceedances of the primary NAAQS at PDAI occurred in 1984. During the monitoring network's history, annual average SO_2 levels were generally half of the current NAAQS (0.030 ppm). *See* 2013 Ajo Maintenance Plan, page (p.) 17. ADEQ removed the SO_2 monitor in 1985, and the smelter operating permits expired. The smelting equipment was removed over a period of years, and the smelter was completely dismantled by February 1996. No new sources of SO_2 of the magnitude of PDAI have located in the area. Thus, Ajo meets this criterion for review under the Seitz Memo.

As discussed above, the only major source of SO_2 emissions within the Morenci nonattainment area was the Phelps Dodge Mining Company's PDMI copper smelter, which was permanently deactivated by December 31, 1984 and was completely dismantled by December 1996. The last recorded 24-hour or annual average exceedances of the primary NAAQS at PDMI occurred in 1984. During the monitoring network's history, annual average SO_2 levels were generally half of the current NAAQS (0.030 ppm). *See* 2014 Morenci Maintenance Plan, p. 15–16. ADEQ removed the SO_2 monitors in 1985, and the smelter operating permits expired. The smelting equipment was removed over a period of years, and the smelter was completely dismantled by December 1996. No new sources of SO_2 of the magnitude of PDMI have located in the area. Thus, Morenci meets this criterion for review under the Seitz Memo.

2. Has the state met the requirements for second 10-year maintenance plans?

The 2013 Ajo Maintenance Plan and 2014 Morenci Maintenance Plan both extend the maintenance period for ten years after the expiration of the first 10-year maintenance plans, as required by Section 175A(b) of the CAA. As discussed below, the State has addressed the requirements in the Seitz Memo for emissions inventories, modeling, permitting of major new sources, and agreement to commence monitoring if a new major source locates in either the Ajo or Morenci areas. Therefore, the State has met the specific criteria in the Seitz Memo for approval of maintenance plans and redesignation requests where a single source was the historic cause of violations and the source is now shut down. We provide more details on each requirement and how the 2013 Ajo Maintenance Plan and the 2014 Morenci Maintenance Plan meet each requirement in the following sections.

Ajo

a. Emissions Inventories

In addition to reproducing the emissions inventories in the Ajo Sulfur Dioxide Nonattainment Area State Implementation Plan and Maintenance Plan (June 18, 2002) (''2002 Ajo maintenance plan''), the 2013 Ajo Maintenance Plan includes new emissions inventories for 2008, representing an updated ''current'' emissions inventory (the most recent National Emissions Inventory (NEI) available at the time), 2010, 2015, 2020, and 2025 for the second 10-year maintenance period.[9] Continued maintenance of the Ajo area for 10 years following the initial 10-year maintenance period is demonstrated in part by showing that future SO_2 emissions in the area are not expected to exceed the level of the attainment emissions inventory.

The emissions inventories in the 2013 Ajo Maintenance Plan include estimates of SO_2 from all relevant source categories, which the 2013 Plan divides among stationary, and area and mobile. Point source information was received from the Pima County Department of Environmental Quality (PDEQ) and the Maricopa County Air Quality Division's annual emissions inventory data. The Ajo maintenance area contains two point sources (*i.e.,* Freeport-McMoRan Corporation Childs Well Field Emergency Generator, and Minerals Research and Recovery, Inc.), which together emit less than 1 tpy SO_2. The 50 km buffer area contains four point sources, including a cotton gin, a paper mill, an Air Force auxiliary field, and an emergency generator. The 2013 Ajo Maintenance Plan includes a description of current facility types, emitting equipment, permitted emissions limits, operating rates, and emissions calculation methods.

Area and mobile sources in ADEQ's 2008 and subsequent year inventories were derived from the EPA's NEI and local agency records. Historical and 2008 emissions inventories demonstrate that no significant area or mobile sources existed in the Ajo area prior to or subsequent to the smelter operation, which closed in 1985.

Based on our review of the emissions inventories in the 2013 Ajo Maintenance Plan and the supporting information in Appendix C, we conclude that the inventories are complete, accurate, and consistent with applicable CAA provisions and the Seitz Memo.

b. Dispersion Modeling

Past EPA policy memoranda on SO_2 redesignations all recommend dispersion modeling to show that the NAAQS is met and will be maintained. The Seitz Memo recommends dispersion modeling of all point sources within 50 km of the nonattainment area boundary. Screening modeling can be used to conservatively show that non-smelter sources have only an insignificant contribution to average SO_2 concentrations in a nonattainment area.

[9] The State provided the three emissions inventories specified in the Seitz Memo for the sources in, and within 50 kilometers of, the Ajo nonattainment area in the 2002 Ajo maintenance plan. For a representative year when the copper smelter was in operation (1981), direct SO_2 emissions from smelting operations were 39,596 tpy. ADEQ's 2002 submittal identified only a single existing point source within the Ajo Area, the Phelps Dodge Generator Station. Phelps Dodge has since shut down the generators and no longer uses them as emergency/back up electric supply. *See* 2013 Ajo Maintenance Plan, p. 32 and Appendix C–1.

For the 2002 Ajo Maintenance Plan, screening dispersion modeling was performed using the SCREEN3 model run with conservative assumptions about source parameters and meteorology. At the time of the 2002 Ajo Maintenance Plan, the Ajo nonattainment area had one minor point source of SO_2 emissions (*i.e.,* Phelps-Dodge Generating Station) and one permitted minor point source in the 50 km buffer (*i.e.,* the proposed Gila Bend Regional Landfill). The model predicted that the impact from these two sources would not exceed 66% of the 1971 SO_2 NAAQS, even assuming constant worst-case conditions about high-sulfur content fuel use.

The Seitz Memo also requires a modeling analysis that shows that the point sources that were shutdown were the dominant sources contributing to high SO_2 concentrations in the airshed. Since the emissions of non-smelter sources in the area had changed relatively little since the time that emission controls were placed on the smelter, this same screening modeling was used to show that the non-smelter sources were insignificant in the past, and thus the smelter was the dominant source contributing to past high SO_2 concentrations.

ADEQ did not conduct a new modeling analysis for the 2013 Ajo Maintenance Plan. As described above, the modeling for the 2002 Ajo Maintenance Plan modeled the existing two sources at maximum projected emissions rates from 2004 to 2015 and showed the area would not exceed 66% of the NAAQS. Since that modeling analysis was conducted, the Phelps-Dodge Generating Station has shut down, the Gila Bend Regional Landfill was never constructed, and the permit for the landfill was allowed to expire.

Currently, only two sources operate within the nonattainment area (*i.e.,* Freeport-McMoRan Incorporated Childs Well Field Emergency Generator, and Minerals Research and Recovery), and they are permitted to emit less than 1% of the emissions modeled in the 2002 Ajo Maintenance Plan. Point sources within the 50 km buffer surrounding the nonattainment area emit about 25% of emissions modeled in the 2002 Ajo Maintenance Plan. 2025 projections show that these low emissions are expected to persist through the second 10-year maintenance period. *See* 2013 Ajo Maintenance Plan, pp. 33 and 34.

ADEQ proposes, and we concur, that because current emissions in the maintenance area and the 50 km buffer are a small fraction of modeled emissions from 2002, the ambient SO_2 modeling requirement for second 10-year maintenance plans is met by the prior modeling, and the State has demonstrated that the 1971 SO_2 NAAQS is adequately protected.

c. Treatment of New Sources of SO_2 Emissions

In nonattainment areas, section 172(c)(5) of the CAA requires New Source Review (NSR) permits prior to the construction and operation of new major stationary sources and major modifications at existing major stationary sources. However, in attainment areas, section 165 of the CAA requires major sources and major modifications to obtain PSD permits. The PSD program requires stationary sources to apply the best available control technology and ensure that projects will not cause or contribute to a violation of a NAAQS or maximum allowable increase.

ADEQ and the PDEQ have PSD permitting programs (*i.e.,* Arizona Administrative Code (A.A.C.) R18–2–406 and Pima County Code 17.16.590) that were established to preserve the air quality in areas where ambient standards have been met. The State's updated PSD program was approved into the SIP on November 2, 2015 (80 FR 67319). PDEQ's PSD program is not SIP-approved, but the federal PSD permitting program at 40 CFR 52.21 was delegated to PDEQ effective April 14, 1994.

The PSD program has applied to any major source or major modification in the Ajo area since the area was redesignated to attainment for SO_2 in 2003, except for coarse particulate (PM_{10}), for which the area is designated nonattainment. Under section 172(c)(5) of the CAA, major sources and major modifications of PM_{10} in the Ajo area remain subject to the nonattainment NSR program, while all other NSR regulated pollutants are subject to the PSD program. Thus the existing ADEQ and PDEQ PSD and NSR programs satisfy the preconstruction permit provision of the Seitz Memo as one of the prerequisites to redesignation for the Ajo SO_2 nonattainment area.

d. Commitment to Resume Monitoring

ADEQ commits to resume monitoring before any major source of SO_2 commences to operate in the Ajo maintenance area. *See* 2013 Ajo Maintenance Plan, p. 38. This addresses the monitoring provision of the Seitz Memo.

Morenci

a. Emissions Inventory

The 2014 Morenci Maintenance Plan includes historical inventories that were submitted as part of the Morenci Sulfur Dioxide Nonattainment Area State Implementation Plan and Maintenance Plan (submitted June 21, 2002) (''2002 Morenci maintenance plan'') as well as a current-year inventory for 2011 (the most recent NEI available at the time), and projected inventories for 2015, 2020, 2025, and 2030 for the second 10-year maintenance period.[10]

The emissions inventories in the 2014 Morenci Maintenance Plan include estimates of SO_2 emissions from all relevant source categories, which are divided among stationary, area, and mobile source categories. Additional information on how the inventories were developed, including activity data and emissions calculations, is provided in Appendix C of the 2014 Morenci Maintenance Plan. Point source information was developed by ADEQ from permit information and the NEI. The 2011 inventory identifies two existing point sources within the Morenci maintenance area: The Freeport-McMoRan Morenci mine with 2011 actual emissions of 48.5 tpy SO_2, and the Morenci Townsite Wastewater Treatment Plant Emergency Generators with 2011 actual emissions of 0.003 tpy SO_2. In 2011, 13 point additional sources with actual emissions of 38.05 tpy SO_2 were located within 50 km of the Morenci maintenance area boundary. As of 2014, six of these sources had terminated their permits, resulting in slightly lower emissions.

Area and mobile source emissions in ADEQ's 2011 and subsequent year inventories were derived from the NEI. The year 2011 was a historically high wildfire year, and included the largest wildfire in Arizona history (*i.e.,* the Wallow fire), which burned in Greenlee County and surrounding areas.[11] ADEQ

[10] In the 2002 Morenci Maintenance Plan, the State provided the three emissions inventories specified in the Seitz Memo for the sources in, and within 50 kilometers of, the Morenci nonattainment area. For a representative year when the copper smelter was in operation (1984), direct actual SO_2 emissions from smelting operations were 82,432 tpy. During its operation, the Morenci primary copper smelter was the only major point source in the area. The 2002 Morenci Maintenance Plan included inventories for 1984 (a year the smelter was in operation), 1999 (a year the area was attaining the SO_2 standard), and 2015 (the projected inventory for the horizon year of the maintenance period). Sources in the 50 km buffer around the Morenci area were estimated to emit 186.5 tpy in 1999, based on PTE, but had actual emissions significantly lower, at 1.2 tpy. *See* 2014 Morenci Maintenance Plan, p. 18.

[11] National Interagency Fire Center's Web site at *https://www.nifc.gov/fireInfo/fireInfo_statistics.html,* ''Historical year-end statistics by state,'' and *https://en.wikipedia.org/wiki/List_of_Arizona_wildfires.* Acres burned in 2011 in Arizona were more than 10 times higher than 2010 acres burned in Arizona due to wildfires, and about five

Continued

assumed the 2011 wildfire emissions remained constant when projecting emissions into the future.

Based on our review of the emissions inventories in the 2014 Morenci Maintenance Plan and the supporting information in Appendix C, we conclude that the inventories are complete, accurate, and consistent with applicable CAA provisions and the Seitz Memo.

b. Dispersion Modeling

The EPA policy memoranda on SO_2 redesignations recommend dispersion modeling to show that the NAAQS is met and will be maintained. The Seitz Memo recommends dispersion modeling of all point sources within 50 km of the nonattainment area boundary. For the 2002 Morenci Maintenance Plan, screening dispersion modeling was performed using the SCREEN3 model, which was run with conservative assumptions about source parameters and meteorology. The modeling results indicated that the impact of existing sources on concentrations within the nonattainment area would not exceed 25 percent of the 1971 SO_2 NAAQS.

The Seitz Memo also requires a modeling analysis that shows point sources that were shutdown were the dominant sources contributing to high SO_2 concentrations in the airshed. The screening modeling described above was used in the 2002 Morenci Maintenance Plan to show that the non-smelter sources have an insignificant contribution, and thus the smelter was the dominant source contributing to past high SO_2 concentrations.

For the 2014 Morenci Maintenance Plan, ADEQ conducted a modeling analysis similar to the analysis in the 2002 Morenci Maintenance Plan. The two largest sources in the maintenance area and within the 50 km buffer area were modeled. The two sources are Freeport-McMoRan Morenci Mine (FMMM) in the maintenance area, with a PTE of 88 tpy SO_2, and the Freeport-McMoRan Safford Mine (FMSM) in the 50 km buffer area, with a PTE of 81 tpy SO_2. Other point sources were not modeled because of their small or negligible emissions.

The EPA dispersion model AERSCREEN (version 11126) was used to conservatively estimate the impact of FMMM and FMSM on maintenance in the Morenci planning area.[12] The results of the AERSCREEN modeling indicated that the impact of these existing sources would have a cumulative potential impact of 42–53% of the 1971 annual and 24-hour SO_2 NAAQS respectively. *See* 2014 Morenci Maintenance Plan, p. 29. Projections for 2030 show that this low level of emissions is expected to persist through the second maintenance period. *See* 2014 Morenci Maintenance Plan, p. 32. We therefore conclude that the State has demonstrated that the 1971 SO_2 NAAQS is adequately protected.

c. Treatment of New Sources of SO_2 Emissions

In nonattainment areas, section 172(c)(5) of the CAA requires NSR permits prior to the construction and operation of new major stationary sources and major modifications at existing major stationary sources. However, in attainment areas, section 165 of the CAA requires major sources and major modifications to obtain PSD permits. The PSD program requires stationary sources to apply the best available control technology and ensure projects will not cause or contribute to a violation of a NAAQS or maximum allowable increase.

ADEQ has a PSD permitting program (*i.e.,* A.A.C. R18–2–406) that was established to preserve the air quality in areas where ambient standards have been met. The State's updated PSD program was approved into the SIP on November 2, 2015 (80 FR 67319). The PSD program has applied to any major source or major modification in the Morenci area since the area was redesignated to attainment for SO_2 in 2004. Thus the ADEQ's existing PSD program satisfies the preconstruction permit provision of the Seitz Memo as one of the prerequisites to redesignation for the Morenci SO_2 nonattainment area.

d. Commitment To Resume Monitoring

ADEQ commits to resume monitoring before any major source of SO_2 commences to operate. *See* 2014 Morenci Maintenance Plan, p. 16. This addresses the monitoring provision of the Seitz Memo.

3. Other CAA Requirements

a. Contingency Plan

As discussed above, section 175A of the CAA sets forth the statutory requirements for maintenance plans, and the Calcagni, Seitz and Shaver Memos cited above contain specific EPA guidance. The only maintenance plan element not covered by the Seitz Memo is the contingency provisions. Section 175A(d) of the CAA requires that maintenance plans contain contingency provisions deemed necessary by the Administrator to assure that the state will promptly correct any violation of the standard which occurs after the redesignation of the area as an attainment area.

Ajo

The 2013 Ajo Maintenance Plan includes the State's commitment to continue to track maintenance of the SO_2 NAAQS through updates to the emissions inventory. Additionally, ADEQ commits to reestablish an appropriate air quality monitoring network before any major source of SO_2 begins operations in the Ajo maintenance area. *See* 2013 Ajo Maintenance Plan, p. 38.

Since the primary cause of future violations of the 1971 SO_2 NAAQS in the area would be from modified or new point sources, ADEQ's current operating permit program places limits on SO_2 emissions from existing sources. Should a new facility be constructed in the Ajo area or an existing facility want to upgrade or increase SO_2 emissions, the facility would also be subject to PSD as required in the Calcagni Memo.

The Calcagni Memo emphasizes the importance of specific contingency measures, schedules for adoption, and action levels to trigger implementation of the contingency plan. Since there are no remaining sources of SO_2 emissions of the magnitude of the PDAI smelter, and there is no SO_2 monitoring in the Ajo area, we agree with the State that the level of specificity recommended in the Calcagni Memo is not necessary, and we conclude that the State's commitment satisfactorily addresses the CAA provisions. We find that the State's commitment to continue to track maintenance of the SO_2 NAAQS through updates to the emissions inventory and the State's PSD permitting programs are sufficient to assure that the Ajo area will not violate the NAAQS.

Morenci

The 2014 Morenci Maintenance Plan includes the State's commitment to continue to demonstrate maintenance of the SO_2 NAAQS through updates to the emissions inventory. Additionally, ADEQ commits to reestablish an appropriate air quality monitoring network before any major source of SO_2 begins operations in the Morenci maintenance area. *See* 2014 Morenci Maintenance Plan, p. 32.

Since the primary cause of future violations of the 1971 SO_2 NAAQS in

times higher than acres burned in Arizona in 2012 due to wildfires.

[12] AERSCREEN has replaced SCREEN3 as the EPA's preferred screening model. *See* Memorandum dated April 11, 2011, from Tyler Fox to the EPA Regional Modeling Contacts, ''AERSCREEN Released as EPA Recommended Screening Model'' in the docket for this action. SCREEN3 was used for the 2002 Morenci Maintenance Plan.

the area would be from modified or new point sources, ADEQ's current operating permit program places limits on SO_2 emissions from existing sources. Should a new facility be constructed in the Morenci area or an existing facility want to upgrade or increase SO_2 emissions, the facility would also be subject to PSD as required in the Calcagni Memo.

The Calcagni Memo emphasizes the importance of specific contingency measures, schedules for adoption, and action levels to trigger implementation of the contingency plan. Since there are no remaining sources of SO_2 emissions of the magnitude of the PDMI smelter, and there is no SO_2 monitoring in the Morenci area, we agree with the State that the level of specificity recommended in the Calcagni Memo is not necessary, and we conclude that the State's commitment satisfactorily addresses the CAA provisions. We find that the State's commitment to continue to track maintenance of the SO_2 NAAQS through updates to the emissions inventory and the State's PSD permitting programs are sufficient to assure that the Morenci area will not violate the NAAQS.

b. Transportation and General Conformity

Conformity is required under section 176(c) of the CAA to ensure that federal actions are consistent with (''conform to'') the purpose of the SIP. Conformity to the purpose of the SIP means that federal activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Conformity applies to areas that are designated nonattainment and to maintenance areas. The requirement to determine conformity applies to transportation plans, programs and projects developed, funded, or approved under Title 23 U.S.C. and the Federal Transit Act (''Transportation conformity'') as well as to other federally supported or funded projects (''general conformity'').

Transportation conformity applies to projects that require Federal Highway Administration or Federal Transit Administration funding. 40 CFR part 93 describes the requirements for federal actions related to transportation plans, programs, and projects to conform to the purposes of the SIP. Because the EPA does not consider SO_2 a transportation-related criteria pollutant,[13] only the requirements related to general conformity apply to the Ajo and Morenci areas.

Section 176(c)(4) of the CAA establishes the framework for general conformity. Besides ensuring that federal actions not covered by the transportation conformity rule will not interfere with the SIP, the general conformity regulations encourage consultation between the federal agency and the state or local air pollution control agencies before and during the environmental review process, as well as public notification of and access to federal agency conformity determinations, and allows for air quality review of individual federal actions.

Section 176(c) of the CAA required the states to revise their SIPs to establish criteria and procedures to ensure that federally supported or funded projects in nonattainment and maintenance areas ''conform'' to the air quality planning goals in the applicable SIP. SIP revisions intended to meet the conformity requirements in section 176(c) are referred to as ''conformity SIPs.'' In 2005, Congress amended section 176(c), and under the amended conformity provisions, states are no longer required to submit conformity SIPs for general conformity, and the conformity SIP requirements for transportation conformity have been reduced to include only those relating to consultation, enforcement, and enforceability. CAA section 176(c)(4)(E).

The EPA believes it is reasonable to interpret the conformity SIP requirements as not applying for purposes of a redesignation request under section 107(d)(3)(E)(v) because state conformity rules are still required after redesignation and Federal conformity rules apply where state rules have not been approved. *See Wall* v. *EPA*, 265 F. 3d 426 (6th Cir. 2001), upholding this interpretation. Because both Ajo and Morenci have already been redesignated for this standard, we believe it is reasonable to apply the interpretation of conformity SIP requirements as not applying for the purposes of redesignation to the approval of second ten-year maintenance plans.

Criteria for making determinations and provisions for general conformity are contained in Arizona Administrative Code R18–2–1438. Arizona has an approved general conformity SIP.[14]

Ajo

ADEQ commits in the 2013 Ajo Maintenance Plan to review and comment, as appropriate, on any federal agency draft general conformity determination it receives consistent with 40 CFR 93.155 for any federal plans or actions in this planning area, although none are currently planned for the area. *See* 2013 Ajo Maintenance Plan, p. 13.

Morenci

ADEQ commits in the 2014 Morenci Maintenance Plan to review and comment, as appropriate, on any federal agency draft general conformity determination it receives consistent with 40 CFR 93.155 for any federal plans or actions in this planning area, although none are currently planned for the area. *See* 2014 Morenci Maintenance Plan, p. 11.

IV. Technical Correction

A. History of the Ajo Nonattainment and Maintenance Area Boundary

On November 3, 2003, the EPA finalized approval of the maintenance plan and redesignation request for the Ajo area, effective January 2, 2004 (*see* 68 FR 62239). To codify this rulemaking, we amended 40 CFR 81.303 that lists the designations for air quality planning areas in Arizona, but we incorrectly identified the Ajo maintenance area in the Arizona SO_2 table by dropping township T13S, R5W from the maintenance area, and inadvertently deleted other townships and ranges in the ''cannot be classified'' description. Township T13S, R5W as well as townships T11S, R7W; T12S, R7W; and T13S, R7W should have remained ''cannot be classified.''

Section 110(k)(6) of the CAA provides that when the EPA's action approving any plan or plan revision (or part thereof), area designation, redesignation, classification, or reclassification was in error, the EPA may in the same manner revise such action. Under the EPA's authority under section 110(k)(6) of the Act, we are taking direct final action to amend the Arizona-SO_2 table in 40 CFR 81.303 by re-codifying and correcting the previous detailed descriptions of the Ajo maintenance area and townships identified as ''cannot be classified.''

The maintenance area consists of townships T11S, R6W; T11S, R5W; T12S, R6W; T12S, R5W; and T13S, R6W. In addition, townships T13S, R5W; T11S, R7W; T12S, R7W; and T13S, R7W are listed in 40 CFR 81.303 as ''cannot be classified,'' as they were upon the Ajo area's original designation in 1979.

V. Final Action

We are approving the second 10-year SO_2 maintenance plans for the Ajo and Morenci areas in Arizona under sections 110 and 175A of the CAA and correcting

[13] 40 CFR 93.102(b)(1).

[14] 64 FR 19916, April 23, 1999.

an error made in the description of the Ajo maintenance area and in the identification of townships as ''cannot be classified'' in the CFR when we redesignated the area in 2003. As authorized in section 110(k)(3) of the Act, the EPA is fully approving the submitted SIPs because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted SIPs. If we receive adverse comments by February 8, 2017, we will publish a timely withdrawal in the **Federal Register** to notify the public that some or all of the provisions of the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on March 10, 2017. This will incorporate these SIPs into the federally enforceable SIP.

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 10, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: December 15, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart D—Arizona

■ 2. Section 52.120 in paragraph (e), table 1 is amended by:

■ a. Adding an entry for '' 'Arizona State Implementation Plan Revision, Maintenance Plan for the Ajo Sulfur Dioxide Area (1971 NAAQS), (February 2013) excluding Appendix C, ''Overview of Point Source Emissions Limits and Potential to Emit'' after the heading ''Part D Elements and Plans (Other than for the Metropolitan Phoenix and Tucson Areas)' ''; and

■ b. Adding an entry for ''Arizona State Implementation Plan Revision, Maintenance Plan for the Morenci Sulfur Dioxide Area (1971 NAAQS), (December 2014)'' after the entry for ''Final Miami Sulfur Dioxide Nonattainment Area State Implementation and Maintenance Plan (June 2002)(revised May 26, 2004), excluding appendix A (''SIP Support Information''), sections A.1 (''Pertinent

Sections of the Arizona Administrative Code'') and A.2 (''Information Regarding Revisions to AAC R18–2–715 and R18–2–715.01, 'Standards of Performance for Primary Copper Smelters: Site Specific Requirements; Compliance and Monitoring'''); and appendix D (''SIP Public Hearing Documentation'')''.

The additions read as follows:

§ 52.120 Identification of plan.

* * * * *

(e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively] [1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
*	*	*	*	*
Part D Elements and Plans (Other than for the Metropolitan Phoenix or Tucson Areas)				
Arizona State Implementation Plan Revision, Maintenance Plan for the Ajo Sulfur Dioxide Area (1971 NAAQS), (February 2013), excluding Appendix C, ''Overview of Point Source Emissions Limits and Potential to Emit''.	Ajo Sulfur Dioxide Air Quality Planning Area.	February 22, 2013	1/9/2017, [Insert **Federal Register** citation].	Adopted by the Arizona Department of Environmental Quality on February 22, 2013. Fulfills requirements for second ten-year maintenance plans. The SIP includes a request to correct the maintenance area boundary.
*	*	*	*	*
Arizona State Implementation Plan Revision, Maintenance Plan for the Morenci Sulfur Dioxide Area (1971 NAAQS), (December 2014).	Morenci Sulfur Dioxide Air Quality Planning Area.	December 18, 2014	January 9, 2017, [Insert **Federal Register** citation].	Adopted by the Arizona Department of Environmental Quality on December 18, 2014. Fulfills requirements for second ten-year maintenance plans.
*	*	*	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. Section 81.303 is amended in the table for ''Arizona—1971 Sulfur Dioxide NAAQS (Primary and Secondary)'' by revising the entry for ''Ajo'' to read as follows:

§ 81.303 Arizona.

* * * * *

ARIZONA—1971 SULFUR DIOXIDE NAAQS

[Primary and secondary]

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Ajo:				
T11S, R5W				X
T11S, R6W				X
T12S, R5W				X
T12S, R6W				X
T13S, R6W				X
T11S, R7W			X	
T12S, R7W			X	
T13S, R5W			X	
T13S, R7W			X	
*	*	*	*	*

* * * * *

[FR Doc. 2016–31637 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

46 CFR PART 503

[Docket No. 16–18]

RIN 3072–AC66

Amendments to Regulations Governing Access to Commission Information and Records; Freedom of Information Act

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission amends its regulations for processing requests for information and records under the Freedom of Information Act (FOIA). The regulations are being revised to incorporate changes brought by amendments to the FOIA under the FOIA Improvement Act of 2016. The Act requires agencies to review their FOIA regulations and issue regulations implementing the amendments no later than 180 days after enactment.

DATES: This rule is effective January 30, 2017.

FOR FURTHER INFORMATION CONTACT: *Mail:* Rachel E. Dickon, Assistant Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION: On June 30, 2016, the President signed into law the FOIA Improvement Act of 2016. The Act prescribes a range of procedural requirements that affect the Commission's FOIA regulations, and which this final rule implements, including requirements that the Commission:

- Provide publically available documents and its FOIA Annual Reports in an electronic format;
- provide FOIA requesters the right to seek dispute resolution services from the Commission's FOIA Public Liaison and/or the Office of Government Information Services during the FOIA process;
- provide a minimum of 90 days for FOIA requesters to file an administrative appeal; and
- not apply the deliberative process privilege to records created 25 years or more before the date on which the records were requested.

Regulatory Analysis and Notices

Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act requires an agency to review regulations to assess their impact on small entities and prepare an initial regulatory flexibility analysis, unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. This final rule will affect only persons who file FOIA requests, and therefore, the Commission certifies that this final rule will not have a significant or negative economic impacts on a substantial number of small entities.

Paperwork Reduction Act (PRA)

The Paperwork Reduction Act of 1995 requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before making most requests for information if the agency is requesting information from more than ten persons. 44 U.S.C. 3507. The agency must submit collections of information in proposed rules to OMB in conjunction with the publication of the proposed rulemaking. 5 CFR 1320.11. This final rule does not impose any collections of information, as defined by 44 U.S.C. 3502(3) and 5 CFR 1320.3(c).

National Environmental Policy Act (NEPA)

This final rule will have no physical impact upon the environment, and therefore, will not require any further review under NEPA.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document may be used to find this action in the Unified Agenda, available at *http://www.reginfo.gov/public/do/eAgendaMain.*

List of Subjects in 46 CFR Part 503

Administrative practices and procedures, Archives and records, Classified information, Confidential business information, Freedom of information, Information, Privacy, Records, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set forth in the preamble, the Federal Maritime Commission amends 46 CFR part 503 as follows:

PART 503—PUBLIC INFORMATION

■ 1. The authority citation for part 503 continues to read as follows:

Authority: 5 U.S.C. 552, 552a, 552b, 553; 31 U.S.C. 9701; E.O. 13526, 75 FR 707, 3 CFR, 2010 Comp., p. 298.

Subpart C—Records, Information and Materials Generally Available to the Public Without Resort to Freedom of Information Act Procedures

■ 2. Amend § 503.21 by revising paragraphs (a) introductory text and (c) introductory text to read as follows:

§ 503.21 Mandatory public records.

(a) The Commission, as required by the Freedom of Information Act, 5 U.S.C. 552, is responsible for determining which of its records must be made publicly available, for identifying additional records of interest to the public that are appropriate for public disclosure, for posting and indexing such records, and for reviewing and updating posted records and indices on an ongoing basis. The Commission makes the following materials available for public inspection in electronic format on its Web site at *www.fmc.gov:*

* * * * *

(c) The Commission maintains and makes available for public inspection in an electronic format, a current log or index providing identifying information for the public as to any matter which is issued, adopted, or promulgated, and which is required by paragraph (a) of this section to be made available or published.

* * * * *

Subpart D—Requests for Records Under the Freedom of Information Act

■ 3. Amend § 503.32 by revising paragraphs (a)(1) and (2), (a)(3)(i)(B), and (b)(3) to read as follows:

§ 503.32 Procedures for responding to requests made under the Freedom of Information Act.

(a) * * *

(1) Such determination shall be made by the Secretary within twenty (20) business days after receipt of such request, except as provided in paragraphs (b) and (e)(4) of this section, and the Secretary shall immediately notify the requester of:

(i) Such determination and the reasons therefor;

(ii) The right of such person to seek assistance from the agency's FOIA Public Liaison; and

(iii) In the case of an adverse determination, the right of such

requester to appeal to the Chairman no less than 90 days after the date of such adverse determination, and the right of such requester to seek dispute resolution services from the agency's FOIA Public Liaison or the Office of Government Information Services.

(2) Upon granting a request, the Secretary shall promptly make records available to the requestor. Upon denial of such a request the Secretary shall promptly notify the requestor of the determination, explain the reason for denial, give an estimate of the volume of matter denied, and set forth the names and titles or positions of each person responsible for the denial of the request.

(3)(i) * * *

(B) Be filed not later than 90 days following receipt of notification of full or partial denial of records requested.

* * * * *

(b) * * *

(3) If the time limit is extended as prescribed under this section, and the request cannot be processed within the extended time limit, the Secretary shall notify the requestor, and either provide the requestor with an opportunity to limit the scope of the request so that it may be processed within the time limit, or provide the requestor an opportunity to arrange with the Secretary an alternative time frame for processing the request or a modified request. To aid the requester, the Commission will make available its FOIA Public Liaison, who shall assist in the resolution of any dispute between the requester and the Commission, and notify the requester of the right of the requester to seek dispute resolution services from the Office of Government Information Services.

* * * * *

■ 4. Amend § 503.33 by revising paragraph (a)(5) and adding paragraphs (a)(8) and (9) to read as follows:

§ 503.33 Exceptions to availability of records.

(a) * * *

(5) Inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the Commission, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

* * * * *

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

* * * * *

■ 5. Amend § 503.34 by revising paragraph (b) to read as follows:

§ 503.34 Annual report of public information request activity.

* * * * *

(b) Each such report shall be made available to the public in electronic format.

By the Commission.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–31891 Filed 1–6–17; 8:45 am]

BILLING CODE 6731–AA–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 516 and 552

[Change 81; GSAR Case 2015–G513; Docket No. 2016–0021; Sequence No. 1]

RIN 3090–AJ79

General Services Administration Acquisition Regulation (GSAR); Fair Opportunity Complaints on GSA Contracts

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is issuing a final rule amending the General Services Administration Acquisition Regulation (GSAR) to clarify that the ordering-agency task and delivery order Ombudsman has jurisdiction and responsibility to review and resolve fair opportunity complaints on tasks and delivery orders placed against GSA multiple-award contracts.

DATES: *Effective:* January 9, 2017.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Dana Davis, General Services Acquisition Policy Division, GSA, by telephone at 202–357–9652 or by email at *dana.munson@gsa.gov.* For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite GSAR case 2015–G513.

SUPPLEMENTARY INFORMATION:

I. Discussion of Changes

The General Services Administration (GSA) is issuing a final rule amending the General Services Administration Acquisition Regulation (GSAR) part 552, Solicitation Provisions and Contract Clauses at 552.216–74 Task and Delivery Orders. The final rule clarifies that the jurisdiction and responsibility to review and resolve fair opportunity complaints placed against GSA multiple-award contracts lies with the ordering-agency task and delivery order Ombudsman. Also, the final rule requires the ordering agency to include contact information for their task and delivery order Ombudsman when placing task or delivery orders against GSA multiple-award contracts. Finally, so that GSA can maintain insight into fair opportunity complaints that arise on orders other agencies place against these contracts, the final rule requires the contractor to provide a copy of its complaint to the GSA Procurement Ombudsman for informational purposes, at the same time the contractor files its complaint to the ordering agency for action.

II. Public Comments Not Required

41 U.S.C. 1707, Publication of proposed regulations, applies to the publication of the General Services Administration Acquisition Regulation. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including amendment or modification thereof) must be published for public comment if it has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment because it does not have a significant impact on the public, contractors or offerors. This rule brings internal GSAR policy up-to-date with FAR policy. The change clarifies internal operating procedures by the Government by clarifying GSA's jurisdiction regarding fair opportunity complaints. The proposed rule comment period is impracticable as the FAR has already directed specific regulatory action.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives; and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant

regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant GSAR revision and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

This final rule does not contain any information collection that requires additional approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

List of Subjects in 48 CFR Parts 516 and 552

Government procurement.

Dated: December 29, 2016.

Nicholas West,

Acting Senior Procurement Executive, Acting Director, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, GSA amends 48 CFR parts 516 and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 516 and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 516—TYPES OF CONTRACTS

■ 2. Amend section 516.506 by—

■ a. Revising paragraph (b);

■ b. Redesignate paragraph (d) as paragraph (e); and

■ c. Adding a new paragraph (d).

The revision and addition reads as follows:

516.506 Solicitation provisions and contract clauses.

* * * * *

(b) In solicitations and contracts for multiple-award contracts where GSA is the only ordering activity, or for GSA orders placed against a GSA multiple-award contract, insert clause 552.216–74, GSA Task-Order and Delivery-Order Ombudsman. This clause shall not be included in GSA-awarded contracts available for multiple agency use (*i.e.,* Governmentwide Acquisition Contracts, Multi-Agency Contracts); instead, see paragraph (d) of this section.

* * * * *

(d) Insert clause 552.216–76, Ordering Agency Task-Order and Delivery-Order Ombudsman in all GSA-awarded contracts available for multiple agency use (*i.e.,* Governmentwide Acquisition Contracts, Multi-Agency Contracts).

* * * * *

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Amend section 552.216–74 by revising the date of the clause and paragraph (c) to read as follows:

552.216–74 GSA Task-Order and Delivery-Order Ombudsman.

* * * * *

GSA Task-Order and Delivery-Order Ombudsman JAN 2017)

* * * * *

(c) The GSA Task-Order and Delivery-Order Ombudsman is located at the General Services Administration (GSA), Office of Government-wide Policy (OGP), Office of Acquisition Policy (MV). Contact information for the GSA Task-Order and Delivery-Order Ombudsman can be found at: *http://www.gsa.gov/ombudsman.*

(End of Clause)

■ 4. Add section 552.216–76 to read as follows:

552.216–76 Ordering Agency Task-Order and Delivery-Order Ombudsman.

As prescribed in 516.506(d), insert the following provision:

Ordering Agency Task-Order and Delivery-Order Ombudsman (JAN 2017)

(a) *Ordering Agency Task-Order and Delivery-Order Ombudsman.* The Ordering Agency shall designate a Task-Order and Delivery-Order Ombudsman to review complaints from contractors and ensure that they are afforded a fair opportunity for consideration in the award of task or delivery orders placed against GSA Indefinite Delivery/Indefinite Quantity (ID/IQ) contracts, consistent with the procedures in the contract. The contact information for the Ordering Agency Task-Order and Delivery-Order Ombudsman shall be made available to contractors.

(b) *Submission of Complaints.* When a contractor submits a complaint to the Ordering Agency's designated Task-Order and Delivery-Order Ombudsman, the contractor shall also send a copy of the complaint to the GSA Procurement Ombudsman, for informational purposes. The GSA Procurement Ombudsman is located at the General Services Administration, Office of Governmentwide Policy (OGP), Office of Acquisition Policy (MV). Contact information for the GSA Procurement Ombudsman can be found at: *http://www.gsa.gov/ombudsman.*

(c) If the contractor is not satisfied with the resolution of its complaint by the Ordering Agency Task-Order and Delivery-Order Ombudsman, the contractor may follow the procedures outlined in FAR subpart 33.1, as applicable (*e.g.,* FAR 16.505(a)(10).

(End of Clause)

[FR Doc. 2016–31932 Filed 1–6–17; 8:45 am]

BILLING CODE 6820–61–P

Proposed Rules

Federal Register
Vol. 82, No. 5
Monday, January 9, 2017

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

12 CFR Part 1805

Announcement Type: Notice and Request for Information

SUMMARY: The Community Development Financial Institutions Fund (CDFI Fund), Department of the Treasury, requests comments from the public regarding the current policies and procedures to certify an organization as a Community Development Financial Institution (CDFI). Capitalized terms found in this notice are defined in the regulations that govern the CDFI Program, in our regulations.

DATES: Written comments must be received on or before March 10, 2017 to be assured of consideration.

ADDRESSES: Submit your comments via email to David Meyer, Certification, Compliance Monitoring and Evaluation (CCME) Manager, CDFI Fund, at *cdfihelp@cdfi.treas.gov.*

FOR FURTHER INFORMATION CONTACT: David Meyer, CCME Manager, CDFI Fund, 1500 Pennsylvania Avenue NW., Washington, DC 20220 or email to *cdfihelp@cdfi.treas.gov.* Information on CDFI Certification may be obtained on the CDFI Fund's Web site at *https://www.cdfifund.gov/programs-training/certification/Pages/default.aspx.*

SUPPLEMENTARY INFORMATION: Pursuant to the CDFI Fund's authorizing statute (the Community Development and Regulatory Improvement Act of 1994, 12 U.S.C. 4701 *et seq.*) (the Act) and the regulations that govern the CDFI Program (12 CFR part 1805), a community development financial institution (CDFI) is a legal entity that: (i) Has a primary mission of promoting community development; (ii) serves an investment area or targeted population; (iii) provides development services in conjunction with equity investments or loans, directly or through a subsidiary or affiliate; (iv) maintains, through representation on its governing board or otherwise, accountability to residents of its investment area or targeted population; and (v) is not an agency or instrumentality of the United States, or of any State or political subdivision of a State.

In accordance with the statutory definition, the CDFI Fund has established seven tests, described below, to certify an Applicant financial entity as a CDFI. Applicants provide legal documentation, narratives and financial data to demonstrate their ability to meet the certification criteria. Applications are accepted on a rolling basis and may be submitted more than once, if declined. Certified CDFIs must complete an annual recertification process to update the financial and organization data contained in the original certification application. CDFI certification application and supplemental information can be found on the CDFI Fund Web site.

With this Request for Information (RFI), the CDFI Fund is embarking on a review of its CDFI certification tests to ensure that they continue to meet the statutory and regulatory requirements and the evolving nature of an industry that has changed significantly since the CDFI Fund's establishment in 1994. Since the first CDFIs were certified, the universe of certified CDFIs has grown from 196 in 1997 to over a 1,000 in number today, with over $100 billion in total assets and headquarters in all fifty states and several territories. It is a goal of the CDFI Fund to foster a diversity of CDFI types, activities, and geographies, and to enable market-driven solutions to emerge in a constantly changing economic environment.

In addition, the significance of CDFI certification has increased over the years. While CDFI certification continues to make an entity eligible for various programs at the CDFI Fund (CDFI Program, Native American CDFI Assistance Program, Capital Magnet Fund, and the CDFI Bond Guarantee Program), because it is seen as indicating a strong community development mission, it also has come to serve as a qualifier for other Federal government programs and benefits. These include, among others, the Small Business Administration's Community Advantage program and Federal Home Loan Bank membership, as well as consideration for certain investments under the Community Reinvestment Act and, pursuant to 12 CFR 1026.43(a)(3)(v)(A), an exemption from the Consumer Financial Protection Bureau's ''Ability to Repay'' rule. The CDFI Fund believes that it is important that certification remain a mark of confidence in an organization's commitment to a community development mission.

It also is imperative that CDFI certification criteria continue to support, rather than inhibit, the growth and reach of CDFIs, especially as it relates to their ability to take advantage of new technologies. These new technologies create the potential for mission-driven organizations like CDFIs to extend their reach and impact in order to improve access to financial products and services for underserved communities and populations wherever they are. This raises questions, however, of whether CDFI certification—particularly in terms of a CDFI's ability to define a Target Market and demonstrate accountability to that Target Market—is currently designed to enable such scope, which was neither possible nor envisioned when the criteria were first established.

Through this RFI, the CDFI Fund seeks feedback from the public on certain aspects of the certification criteria and process, as listed in Sections I and II. We also seek any additional information beyond these questions that members of the public believe would assist in updating the CDFI Fund's certification policies. The CDFI Fund intends to consider the feedback received through this RFI as it reexamines its current criteria and proposes any revisions to its CDFI certification policies. In making any changes to the existing criteria, the CDFI Fund will seek to ensure that certification continues to foster a diversity of CDFI types, activities, and geographies; allows for innovation that supports the growth and reach of CDFIs; and signifies confidence in a strong community development mission.

I. Certification Criteria

A. *Legal Entity:* To satisfy the legal entity test, the CDFI Fund requires evidence of an Applicant's incorporation/organization/establishment, such as IRS documentation, establishing documents filed with appropriate authorities, or

charter numbers for Insured Depository Institutions and Credit Unions at the time of certification application.

1. The statute does not indicate how long an organization must be in existence to be considered a ''person (other than an individual).'' Should there be a minimum period of time an organization should be in existence before applying for CDFI certification? If so, how long? If not, why not?

2. Is there additional documentation, beyond an organization's establishing documents filed with State jurisdictions, that should be accepted to demonstrate that an organization is a legal entity?

B. *Primary Mission:* The statute states that a CDFI must have ''a primary mission of promoting community development,'' but specifies few criteria for meeting that test. The CDFI Fund currently allows Applicants for certification to meet this test by providing board-approved organizational documents that demonstrate that the Applicant has a primary mission of promoting community development along with a narrative statement describing how the Applicant's mission is consistent with the CDFI Fund's and a brief description of Financial Products offered. Insured Credit Unions that have received a Low Income Designation from the National Credit Union Administration are deemed to have met this criterion by virtue of their designation.

1. Should the currently required board-approved documentation and narrative statement be sufficient to demonstrate an Applicant's primary mission, or should the CDFI Fund apply a more prescriptive primary mission test? For example, should the CDFI Fund provide a more explicit, possibly quantitative, definition of what it means to ''promote community development'' that Applicants would be required to meet? If so, what should be the definition and what test should be applied? Are there criteria that the CDFI Fund should not consider and why?

2. Should there be different standards for meeting the primary mission test for nonprofit versus for-profit organizations, particularly for-profits that are not Insured Depository Institutions? If so, what different standards should be applied?

3. What evidence can the CDFI Fund use to confirm an Applicant's adherence to a stated community development mission? For example, how can the CDFI Fund distinguish between an organization that is fully committed to a community development mission and one that targets the same communities or populations as a CDFI and claims a community development mission, but whose actions do not demonstrate intent to create community development and/or are predatory in nature?

4. To what extent should the CDFI Fund evaluate the Financial Products and/or Financial Services offered by an Applicant to determine its ability to meet the primary mission test? What test would the CDFI Fund apply in any such evaluation of Financial Products and/or Financial Services?

5. Currently, by statute, Depository Institution Holding Companies wishing to be certified as CDFIs must provide documentation that their parent, Subsidiaries, and Affiliate organizations collectively meet the primary mission test. Should the CDFI Fund also make this a requirement for Non-Regulated CDFIs, for example, a Non-Regulated for-profit financial institution? Why or why not?

C. *Financing Entity:* Insured Depository Institutions and Credit Unions are deemed to automatically meet this criterion. Non-Regulated CDFIs must demonstrate that they engage in direct financial activity (*e.g.,* the provision of Financial Products, Financial Services, and Development Services) as reflected on financial statements and executed notes, and must dedicate a predominance of their assets to Financial Products, Development Services, and/or similar financing.

1. The CDFI Fund does not currently define the term ''predominance,'' but in practice accepts a plurality of assets as meeting this criterion. Should the term ''predominance'' be defined more specifically, and if so, how?

2. Should entities that provide less than a plurality of financing activity ever be considered Financing Entities? If so, under what circumstances and is there a minimum level of activity that should be required?

3. Currently, the amount of assets and staff time dedicated to financing activities are used to measure the level of a CDFI's financing activity. How else could a CDFI's level of financing activity be measured?

4. For Non-Regulated CDFIs, is the current ''predominance of assets'' test appropriate, or should alternatives or additional considerations be permitted?

5. Should Non-Regulated CDFIs be permitted to include the financing or Financial Services activity of a mission-driven Subsidiary as part of the assessment of the parent CDFI's financing activities?

6. Should Non-Regulated CDFIs be permitted to rely upon the financing or Financial Services activity of a parent CDFI as part of the assessment of the Subsidiary's or Affiliate's financing activities?

7. Should an organization applying for CDFI certification be required to transact a minimum number or dollar amount of loan or equity investments to be considered a financing entity? Should the Applicant be required to have at least one or more years of loan or equity investment origination? If so, what should those rules be?

8. Should an organization that only services loans or Equity Investments or has very few transactions be considered a financing entity?

9. Should certified CDFIs be required to offer loans or Equity Investments each year, in order to maintain certification status?

10. Currently, non-arms-length transactions do not contribute to meeting the financing entity criteria. For example, transactions made with Subsidiaries and/or Affiliates are not considered to be arms-length transactions. Should some transactions with Affiliates be permissible as evidence of an organization being a financing entity? If so, which ones? How should an ''arms-length transaction'' be defined?

11. Should Applicants be required to disclose the expected amount and types of lending that may be made to Affiliates and Insiders in their certification applications? Should such transactions be limited as a condition of certification? Why or why not?

12. Current CDFI Program regulations use the term ''similar financing activities'' in its definition of the term ''Financial Products.'' How should the CDFI Fund determine what is included in ''similar financing activities?''

D. *Serves an Investment Area or Targeted Population:* Applicants for certification must identify the Investment Area(s) and/or Targeted Population(s) they intend to serve as their Target Market.

1. Threshold Target Market Test: Although no threshold level of service is indicated in the statute or regulation, current CDFI Fund policy requires that an organization must serve at least one eligible Target Market and must direct at least 60 percent of all of its Financial Product activities to one or more eligible Target Market to qualify for certification. In general, both the number and dollar amount of the organization's Financial Product activities should be at least 60 percent of all of its Financial Product activities in the most recent fiscal year. If an organization does not meet the 60 percent threshold in terms of either number or dollar amount of transactions (but not both), the organization can

provide an argument as to why the figure is less than 60 percent and the CDFI Fund reserves the right to accept or reject the explanation.

a. Is the current standard that 60 percent of a CDFI's Financial Product activities must be in qualified Target Markets the right standard? If not, what percentage of transactions should be in and/or to a qualified Target Market to demonstrate that an organization serves that Target Market and why?

b. Should there be different thresholds for different institution types (*i.e.,* Insured Depository Institutions and Credit Unions, nonprofit loan funds, and venture capital funds)?

c. The CDFI Fund currently relies on self-reported summary data submitted by Applicants to demonstrate that they meet the Target Market threshold test. Should statistical sampling of transactions be required to establish a current baseline of activity and document the Target Markets that they are serving?

d. The August 31, 2015 Interim CDFI Program Regulations added the provision of Financial Services as a means of demonstrating that an applicant serves a Target Market. However, the CDFI Fund does not currently have a method of recognizing or applying the provision of Financial Services toward the current 60 percent threshold test for certification. In addition to the level of Financial Products provided by an Applicant, how should an Applicant receive credit for the provision of Financial Services toward meeting any threshold test? How should this be measured? If an Applicant requests credit for providing Financial Services, should there be a separate minimum level of Financial Products that must be provided by the Applicant?

e. The CDFI Fund currently first considers an Applicant's financial activity during its most recent fiscal year in determining whether it meets the threshold test. Is this the appropriate time period to consider, or should a longer period of time be considered? If so, should the applicant be required to meet the threshold in each year of the test, for a time period, or should an average be considered? Should the CDFI Fund consider an Applicant's portfolio of loans outstanding?

2. Investment Areas: The statute requires that an Investment Area must meet at least one of the economic distress criteria (poverty rate greater than 20 percent; Median Family Income (MFI) at 80 percent or below specific MFI benchmarks; unemployment rate 1.5 times the national average) and has significant unmet needs for Financial Products and Services, or is wholly located within an Empowerment Zone or Enterprise Community.

a. The CDFI Fund's current practice is to define Investment Areas that are composed of one or more units of geography that meet certain distress criteria. Units include but are not limited to counties, census tracts, and Indian Reservations. Should the CDFI Fund change this practice? If so, how?

b. Currently the CDFI Fund allows Investment Areas to be composed of a set of contiguous geographic units that may include a small portion of units that individually do not qualify as Investment Areas. Should the CDFI Fund continue this practice, or should all units within the Investment Area meet the Investment Area qualifications?

3. Targeted Populations: Targeted Populations include Low Income Targeted Populations (LITP) and Other Targeted Populations (OTP) for a specific geographic unit. LITP, for a specified geographic unit, by statute includes individuals whose family income (adjusted for family size) is 80 percent of the area MFI (for metropolitan areas). LITP in non-Metropolitan Areas is the greater of 80 percent of the area MFI; or 80 percent of the statewide non-Metropolitan Area MFI. The CDFI Fund currently includes, for a specific geographic unit(s), African-Americans, Hispanics, Native Americans, Native Alaskans, Native Hawaiians, and Other Pacific Islanders among the groups automatically considered eligible for an OTP Target Market. Applicants are permitted to seek OTP recognition for other populations by demonstrating that the group lacks access to capital.

a. Should the Targeted Populations be expanded to automatically accept more specifically defined Other Targeted Populations that are eligible for other Federal programs that support economic development in Low-Income communities? If so, which ones and why?

b. CDFIs currently are approved to serve Targeted Populations within a defined geographic unit at below and up to a national level. Should all Applicants proposing to serve Targeted Populations be approved to serve such Target Markets nationally?

4. National Target Markets: Currently, in order to be certified with a Target Market national in geographic scope, CDFIs need to show that they have conducted their financing activities broadly across the variously defined regions of the country, (*e.g.* Northeast, West, Midwest, South, Southeast, etc.)

a. Given that it is unlikely that most CDFIs that work broadly across the nation will complete transactions in every State every year, how can organizations demonstrate that they serve a national Target Market, whether for an Investment Area or for a Targeted Population? Should there be a certain minimum geographic dispersion of actual investments?

b. Some CDFIs serve multiple markets that are part of a multi-State region or are comprised of geographically unconnected markets. When should the CDFI Fund recognize these practices as constituting a national Target Market?

E. *Development Services:* A CDFI directly, through an Affiliate, or through a contract with another provider, must have a track record of providing Development Services in conjunction with its Financial Products and/or Financial Services. Development Services means activities undertaken by a CDFI, its Affiliate or contractor that promote community development and shall prepare or assist current or potential borrowers or investees to use the CDFI's Financial Products or Financial Services. For example, such activities include, but are not limited to, financial or credit counseling; homeownership counseling; and business planning and management assistance.

1. Should the CDFI Fund more explicitly define Development Services? If so, how should it be defined?

2. Should the CDFI Fund require CDFIs to provide a corresponding Development Service for each Financial Product and Financial Service?

3. Should a certified CDFI be required to offer each Development Service each year to maintain certification status?

F. *Accountability:* The CDFI Fund currently requires that a CDFI maintain accountability to its Target Market through representation on its governing board and/or advisory boards. Prior to recent changes in the regulation, a CDFI could demonstrate accountability through other mechanisms such as focus groups, community meeting, and/or customer surveys.

1. What percentage of a CDFI's board members should satisfy accountability rules? Should different percentages apply to different types of boards, *i.e.* governing vs. advisory boards?

2. Is representation on an advisory board sufficient to demonstrate accountability?

3. Should CDFIs be able to demonstrate accountability through means other than board membership? If so, how?

4. Is a business plan and a stratified, statistically significant random sample

of lending by asset class and location sufficient to document accountability? Under what circumstances?

5. Should accountability requirements differ based on a CDFI's type of Target Market, and if so, how?

6. How should the CDFI Fund assess accountability if a CDFI's Target Market includes borrowers or investees who are not members of a Targeted Population themselves (*e.g.,* small businesses, micro businesses, and affordable housing developers, charter schools), but whose ''end-beneficiaries'' are?

7. How should a CDFI demonstrate accountability to a national Target Market, in particular an Investment Area national in scope? Should there be a requirement to have local accountability to supplement a national governing or advisory board? In this context, how should the term ''local'' be defined?

8. How should an Applicant that utilizes a web-based lending platform, especially one that serves a national Target Market, demonstrate accountability?

G. *Non-Governmental Entity:* By statute, a CDFI Shall not be an agency or instrumentality of the United States, or any State or political subdivision thereof. An entity that is created by, or that receives substantial assistance from, one or more government entities may be a CDFI provided it is not controlled by such entities and maintains independent decision-making power over its activities. In the CDFI Certification application, the Applicant must respond to a series of questions designed to surface/discover issues or circumstances that may prevent an Applicant from meeting this criteria.

1. Are the current standards for establishing that an Applicant is not owned or controlled by a governmental entity sufficient?

2. Are there additional or alternative questions and/or documentation the CDFI Fund should require to determine if an Applicant is an agency or instrumentality of a Federal, State or local government?

II. Certification Policy and Procedures

A. Should the CDFI Fund request information on the reason for applying for certification and intended use (*e.g.,* funding requirement, marketing)?

B. Are there additional sources of data collected by other federal agencies that can be used to meet any of the seven certification tests? If so, please describe.

III. General Certification Questions for Public Comment: Through This RFI, the CDFI Fund Invites Comments and Responses to the Following Questions Regarding CDFI Certification

A. ''Community-based'' is a term often used to describe CDFIs. How should ''community-based'' be defined and what does it mean for CDFIs to be ''community-based?''

B. Although not defined in statute, the CDFI Fund allows Applicants that serve Native communities to self-designate themselves as Native CDFIs and apply for Financial Assistance and Technical Assistance through the Native CDFI Program. Applicants that self-designate as a Native CDFI must attest to providing 50 percent or more of their products and services to Native lands or Native populations. Should the CDFI Fund continue to allow Applicants to self-designate as Native CDFIs or should there be more defined standards that the CDFI Fund should verify? If so, what should they be?

C. Should CDFIs be allowed to be composed of multiple legal entities (Subsidiaries and/or Affiliates)? And if so, must a CDFI include all of its Subsidiaries and/or Affiliates for consideration?

D. Should CDFI certification standards have more ''bright-line'' tests, *i.e.* specific thresholds and benchmarks that are, where possible, quantitative in nature, or should the CDFI Fund maintain flexibility to evaluate Applicants on a case by case basis, even at the expense of certainty for applicants?

E. In addition to earlier questions regarding potentially different Primary Mission or Target Market standards based on institution type, are there other CDFI certification criteria standards that should vary based on institution type or the type of CDFI?

F. Should ''start-up'' entities be able to be certified? How should the term ''start-up'' be defined?

G. Are there additional areas of CDFI certification policy or the CDFI certification application review process that could use improvement? If so, how?

Authority: 12 U.S.C. 4701 *et seq.;* 12 CFR 1805.

Mary Ann Donovan,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2017–00013 Filed 1–6–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 160907827–6827–01]

RIN 0648–BG02

Mallows Bay—Potomac River National Marine Sanctuary; Notice of Proposed Rulemaking and Availability of Draft Environmental Impact Statement and Management Plan

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Proposed rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) proposes to designate approximately 52 square miles of waters encompassing and surrounding Maryland's Mallows Bay as the Mallows Bay—Potomac River National Marine Sanctuary (MPNMS or sanctuary). NOAA also proposes regulations to implement the sanctuary designation and establish the sanctuary's terms of designation to protect historical, archeological, and cultural resources of national significance. A draft environmental impact statement (DEIS) and draft management plan (DMP) have also been prepared for this proposed action. The purpose of this action is to supplement and complement current Maryland state regulations and resource protection efforts to ensure long term protection of the nationally significant collection of historic shipwrecks and other maritime cultural heritage resources. NOAA is soliciting public comment on the proposed rule, draft environmental impact statement, and draft management plan. NOAA will also begin consultations under Section 106 of the National Historic Preservation Act (NHPA) and solicit public comments specifically related to the identification and assessment of the historic properties within the affected area in compliance with Section 106 review process.

DATES: NOAA will consider all comments received by March 31, 2017. Public meetings will be held on the following dates:

(1) March 7, 2017, 6:00 p.m. to 9:00 p.m., La Plata, MD, and

(2) March 9, 2017, 6:00 p.m. to 9:00 p.m., Arnold, MD.

ADDRESSES: You may submit comments on this document, identified by NOAA–

NOS–2016–0149, by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0149,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Paul Orlando, Regional Coordinator, Northeast and Great Lakes Region, 410 Severn Ave., Suite 207–A, Annapolis, MD 21403.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NOAA will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the proposed rule, DEIS, and DMP can be downloaded or viewed on the internet at *www.regulations.gov* (search for docket # NOAA–NOS–2016–0149) or at *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0149.* Copies can also be obtained by contacting the person identified under **FOR FURTHER INFORMATION CONTACT**.

The public meeting locations are:

(1) La Plata, MD: Charles County Government Building, 200 Baltimore St., La Plata, MD 20646 (March 7, 2017)

(2) Arnold, MD: Anne Arundel Community College, Center for Applied Learning and Technology (CALT) Building, Room 100, 101 College Pkwy., Arnold, MD 21012 (March 9, 2017)

FOR FURTHER INFORMATION CONTACT: Paul Orlando, Regional Coordinator, Northeast and Great Lakes Region at (240) 460–1978, *paul.orlando@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce (Secretary) to designate and protect as national marine sanctuaries areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or esthetic qualities. Day-to-day management of national marine sanctuaries has been delegated by the Secretary to NOAA's Office of National Marine Sanctuaries (ONMS). The primary objective of the NMSA is to protect the sanctuary system's biological and cultural resources, such as coral reefs, marine animals, historical shipwrecks, historic structures, and archaeological sites.

NOAA is considering the Mallows Bay area of the tidal Potomac River for designation as a national marine sanctuary. The area is 40 miles south of Washington, DC, located off the Nanjemoy Peninsula of Charles County, Maryland. This is an area of national significance featuring unique historical, archaeological, cultural, ecological, and esthetic resources and qualities, which offer opportunities for conservation, education, recreation, and research. Its maritime landscape is home to a diverse collection of historic shipwrecks that date back to the Civil War and potentially date to the American Revolutionary War, totaling nearly 200 known vessels including the remains of the largest ''Ghost Fleet'' of World War I, wooden steamships built for the U.S. Emergency Fleet. The fleet was constructed at more than 40 shipyards in 17 states as part of the massive national wartime preparation. The area's archaeological and cultural resources cover centuries of history from the earliest American Indian presence in the region about 12,000 years ago to the Revolutionary, Civil and two World Wars, as well as successive regimes of Potomac fishing industries.

The Maryland Department of Natural Resources (DNR), Maryland Historical Trust, Maryland Department of Tourism, and Charles County, MD, have worked together with community partners to initiate conservation and compatible public access strategies in and around Mallows Bay, consistent with numerous planning and implementation documents. In 2010, DNR purchased a portion of land adjacent to Mallows Bay and made it available to Charles County to create and manage Mallows Bay County Park, the main launch point for access to the historic shipwrecks. Pursuant to the NHPA, Maryland Historical Trust has stewardship and oversight responsibility for the shipwrecks, along with hundreds of other historic sites around the state. DNR manages the waterbody and associated ecosystem resources, including land use, resource conservation and extraction activities. The lands on either side of Mallows Bay County Park are held by the U.S. Department of Interior's Bureau of Land Management and a private citizen.

On September 16, 2014, pursuant to section 304 of the National Marine Sanctuaries Act and the Sanctuary Nomination Process (SNP; 79 FR 33851), a coalition of community groups submitted a nomination asking NOAA to designate Mallows Bay—Potomac River as a national marine sanctuary. The nomination cited conservation goals to protect and conserve the fragile remains of the Nation's cultural heritage as well as the opportunities to expand public access, recreation, tourism, research, and education to the area. The nomination was endorsed by a diverse coalition of organizations and individuals at local, state, regional, and national levels including elected officials, businesses, Native American, environmental, recreation, conservation, fishing, tourism, museums, historical societies, and education groups. The nomination identified opportunities for NOAA to protect, study, interpret, and manage the area's unique resources, including by building on existing local, county, and State of Maryland efforts to manage the area for the protection of shipwrecks. NOAA's review of the nomination against the criteria and considerations of the SNP, including the requirement for broad-based community support indicated strong merit in proposing this area as a national marine sanctuary. Therefore, NOAA completed its review of the nomination and, on January 12, 2015, added the area to the inventory of nominations that are eligible for designation. All nominations submitted to NOAA can be found at: *http://www.nominate.noaa.gov/nominations/.*

NOAA began the sanctuary designation process for Mallows Bay—Potomac River National Marine Sanctuary on October 7, 2015 with the publication of a notice of intent (NOI; 80 FR 60634) to prepare a DEIS and the initiation of a public process, as required under the NMSA and the National Environmental Policy Act (NEPA). The DEIS evaluates alternatives related to the proposed designation of Mallows Bay—Potomac River National Marine Sanctuary, including a no action alternative. The NOI also announced NOAA's intent to fulfill its responsibilities under the requirements of the NHPA.

B. Need for Action

The proposed designation would allow NOAA to complement current state-led efforts to conserve and manage the nationally significant maritime cultural heritage resources while

enhancing public awareness and appreciation, and facilitating to the extent compatible with the primary objective of resource protection, all public and private uses including recreation and tourism, as directed by the NMSA. The threats to these resources are related to actions or conditions that result in the damage or loss of the historic resources. Over time direct damage both intentionally and unintentional has occurred from breaking, redistribution of shipwrecks and artifacts, defacing and physical alteration, burning, and removal from the area. Additionally, indirect damage to the resources has occurred from the accumulation and entanglement of trash and marine debris around the resources and from weather-related processes such as wind, flood, and ice events.

The proposed sanctuary would concentrate on the protection, access and interpretation of the maritime cultural features of the area, including the Ghost Fleet, other vessels of historic significance, and related maritime infrastructure. The State of Maryland currently has a comprehensive set of management measures for the protection of the natural environment, including wildlife, fish, birds, water quality, and habitat. As such, NOAA's proposed sanctuary regulations would focus only on the protection of the shipwrecks and associated maritime cultural heritage resources.

NOAA's proposed management actions will be primarily non-regulatory in nature with a concise set of regulations focused on protecting the maritime cultural heritage resources. Although the Maryland Submerged Archeological Historic Property Act (Md. Code Ann., State Fin. & Proc. sections 5A–333 *et seq.*) provides a basic level of protection for maritime cultural heritage resources in Mallows Bay and adjacent areas of the Potomac River, the proposed action would allow NOAA's management under the NMSA to supplement and complement the existing authority and the current management framework in the area. The proposed national marine sanctuary would address ongoing threats to the maritime cultural heritage resources while providing opportunities for research, education, recreation, and tourism through coordinated and comprehensive management and conservation the resources in collaboration with the State of Maryland and Charles County. NOAA is also proposing to carry out education, science, and interpretative programs that describe for visitors and user communities the relationship between the shipwreck structures and their interplay with the natural system.

C. Designation Process

National Marine Sanctuary Designation Process

The National Marine Sanctuaries Act authorizes NOAA to identify, designate, and protect areas of the marine and Great Lakes environment with special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archaeological, educational, or aesthetic qualities as national marine sanctuaries. NOAA may identify areas to consider for national marine sanctuary designation through the community-based Sanctuary Nomination Process as described in the final rule (79 FR 33851) establishing the process. The NMSA process for designating a new national marine sanctuary has four steps:

Scoping: NOAA announces its intent to designate a new national marine sanctuary and asks the public for input on potential boundaries, resources that could be protected, issues NOAA should consider and any information that should be included in the detailed resource analysis in a draft environmental impact statement.

Sanctuary Proposal: NOAA prepares draft designation documents including a DMP, DEIS that analyzes a range of alternatives, proposed regulations, and proposed boundaries.

Public Review: The public, agency partners, tribes, and other stakeholders provide input on the draft documents. The public review step also includes the formal consultations required under NEPA, the NMSA, the NHPA, and other relevant statutes. NOAA considers all input and determines appropriate changes.

Sanctuary Designation: NOAA makes a final decision and prepares final documents. Before the designation becomes effective, the Governor reviews the documents. Congress also has the opportunity to review the documents.

Public Scoping Process

On October 7, 2015, NOAA initiated the public scoping process with the publication of a NOI in the **Federal Register** (80 FR 60634) asking for public input on the proposed designation and informing the public that NOAA intended to prepare a DEIS evaluating alternatives related to the proposed designation of Mallows Bay—Potomac River National Marine Sanctuary under the NMSA. That announcement initiated a 90-day public comment period during which NOAA would solicited additional input related to the scale and scope of the proposed sanctuary, including ideas presented in the community nomination. The NOI also announced NOAA's intent to fulfill its responsibilities under the requirements of the NHPA.

During the public comment period, NOAA solicited input on the range of issues to be considered in an environmental impact statement to designate this area as a national marine sanctuary. NOAA specifically asked for information that would assist in the development of alternatives including proposed regulations and boundaries. NOAA accepted public comments through a web-based portal and by mail from October 7, 2015 through January 15, 2016, and hosted two public scoping meetings. During the scoping comment period, NOAA received approximately 264 comments from individuals, businesses, organizations, and local, state, and federal agencies. The first scoping meeting was held on November 4, 2015 in La Plata, MD, where approximately 125 people attended and 51 oral and written comments were received. The second meeting was held on November 10, 2015 in Annapolis, MD. Approximately 100 people attended that meeting, and 23 oral and written comments were received.

The written comments received included 141 from individuals, nine from businesses, 46 from organizations, two from local agencies, two from state agencies, and four from federal agencies. Comments were also submitted by U.S. Representative Steny Hoyer and U.S. Senator Ben Cardin. All comments are available for review online at *https://www.regulations.gov/#!docketDetail;D=NOAA-NOS-2015-0111.*

The majority of comments received during the scoping period generally support the proposed sanctuary designation based on the considerable value and significance of the natural, maritime, archaeological, and cultural resources within the area including those related to Native American history and activities, the immense potential for ecological and archaeological research of the area's resources, and the economic and educational benefits of increased tourism and public access and awareness. The public comments also identified several additional potential benefits, including restoration of the Chesapeake watershed, economic revitalization of the local area, and promoting heritage and ecotourism.

Several comments opposed the nomination predominantly citing opposition to the possibility of increased government intervention, specifically regarding fossil collection and fishing activities that could

potentially be impacted by a sanctuary designation.

The comments also identified boundary alternatives for consideration during the designation process. Several comments supported the boundary proposed in the sanctuary nomination package, intended to align with the boundary of the Mallows Bay—Widewater Archaeological and Historic District submitted by the State of Maryland (National Register Listing Number 15000173, April 24, 2015). However, the majority of comments supported an expanded boundary. Several comments supported a northward expansion to Mattawoman Creek, but most of the comments supported a larger boundary extending from Chapman Park in the North to Chapel point in the South. One comment suggested an even larger northern boundary extending to Piscataway Creek. Most of the support for the expanded boundaries was based on the benefits of the additional protection that the commenters felt a larger boundary would provide to the significant natural and maritime cultural heritage resources in the area.

Several comments did not support a boundary expansion citing issues related to management, local impact, and government overreach. Some comments expressed concerns regarding how the boundaries would affect the Commonwealth of Virginia's interests and one comment noted that Virginia should be excluded from the sanctuary boundary.

Additional comments addressed regulatory frameworks, access issues, migratory bird protections, designation timeline goals, intergovernmental collaboration, infrastructure, education and outreach programing, and interpretation plans.

NOAA used these public comments to inform the preparation of the draft management plan, draft environmental impact statement, and the proposed sanctuary regulations. The proposed designation reflects the general public support for the protection of all nationally significant maritime cultural heritage resources in the area. It also incorporates the need for enhanced recreation and access to the proposed sanctuary to support tourism and the local economy.

In this proposed rule, NOAA is proposing to regulate damage to the maritime cultural heritage resources in a 52-square mile area of Maryland waters of the Potomac River as described below. The proposed boundaries were expanded beyond the initially nominated area and the National Register Historic District based on public comments, additional research conducted related to the historical and archaeological resources of the area, and input from Maryland Department of Natural Resources, Maryland Historical Trust, and Charles County.

The environmental effects of this proposed designation and alternatives are analyzed in a DEIS published concurrently with this proposed rule summary statement. NOAA has also developed an associated draft management plan describing comprehensive proposed management framework envisioned for the area, including non-regulatory programs and activities actions and strategies to promote opportunities for research, education, and recreation in the area. NOAA is seeking public comment on the proposed rule, DEIS, and draft management plan, which are available at *http://sanctuaries.noaa.gov/mallows-bay/* or may be obtained by contacting the individual listed under the heading **FOR FURTHER INFORMATION CONTACT**.

II. Summary of the Proposed Regulations

1. Adding New Subpart S and Reserving Subpart T

NOAA is proposing to amend 15 CFR part 922 by adding a new subpart (subpart S) that contains site-specific regulations for MPNMS. This subpart would include the proposed boundary, contain definitions of common terms used in the new subpart, provide a framework for co-management of the sanctuary, identify prohibited activities and exceptions, and establish procedures for certification of existing uses, permitting otherwise prohibited activities, and emergency regulation procedures. Several conforming changes would also be made to the national regulations as described detail below.

NOAA is concurrently working on designating a separate new national marine sanctuary in Wisconsin's Lake Michigan waters as part of a separate rulemaking process, and those regulations would be published in their own new subpart (subpart T). As such, in this rulemaking, NOAA proposes to add and reserve subpart T for any future site-specific regulations that might be issued. NOAA would later harmonize the regulations for the Wisconsin Lake Michigan designation process with any final rule associated with this action.

2. Proposed Sanctuary Name

NOAA has proposed to name the sanctuary the ''Mallows Bay—Potomac River National Marine Sanctuary (MPNMS)'' based on the nomination submitted by the community. The name aptly identifies the area where the proposed sanctuary is located. NOAA has also selected the acronym of ''MPNMS'' to avoid having a longer acronym, such as ''MBPRNMS,'' and avoid duplication with an acronym already in use within the national marine sanctuary system, such as ''MBNMS'' used for Monterey Bay National Marine Sanctuary. NOAA is asking for public input on this proposed name. The public may also suggest an alternative name and state the reasons for suggesting an alternative name.

3. Proposed Sanctuary Boundary

NOAA is proposing to designate an area of approximately 52 square miles of the Potomac River as MPNMS. The northern boundary of the area would extend approximately 200 yards upstream of the Dominion Power lines near Ben Doane Road, Maryland to Possum Nose, Virginia. The southern boundary would extend from the end of Owens Drive east of Chotank Creek, Virginia to Benny Gray Point, Maryland. The boundary would encompass all tidal waters within this boundary from mean high tide in Maryland to mean low tide in Virginia, which serves as the boundary between Maryland and Virginia. Areas where the Virginia state line is otherwise delineated, the Quantico exclusion zone, and the area around the Quantico marina would be excluded from the sanctuary. The detailed legal boundary description is included in section 922.200 and the coordinates are located in 15 CFR part 922, subpart S, appendix A. A map of the area is shown in the DEIS.

The proposed MPNMS would include all of the known WWI-era U.S. Emergency Fleet Corporation vessels in Maryland waters, as well as a number of historically, archaeologically, and recreationally significant shipwrecks not currently included in the National Register Historic District that is located within the proposed area. The area incorporates marine battlescapes such as the land-sea engagements in the Civil War, among the first in that conflict, and one Revolutionary War battlescape; the site of the first military balloon launch from a purpose built ''aircraft carrier'' in history; the site of two major amphibious invasion operations: Butler's attack from Budd's Ferry to Quantico Creek on March 9, 1861, and the Liverpool Point to Aquia Creek crossings during the Fredericksburg Campaign; several wharves, landings, navigational aids of historic note; Confederate communications and contraband water routes during the Civil War, and the overall scene of the

Union's Potomac River blockade, 1861–1865.

The proposed boundary was developed based on the nomination submitted by the State of Maryland and expanded based on additional information and suggestions received during the public comment period. NOAA's adjustments include moving both the northern and southern boundary lines to incorporate additional maritime culture heritage resources.

4. Definitions

a. Define MPNMS Sanctuary Resources

NOAA is proposing to narrowly define ''sanctuary resources'' for MPNMS to include only the maritime cultural heritage resources of the sanctuary area in accordance with the purpose of the proposed designation. The definition would not include biological and ecological resources of the area already managed by the State of Maryland. Creating this new site-specific definition requires NOAA to modify the national definition of ''sanctuary resource'' in the national regulations at section 922.3 to add an additional sentence that defines the term for MPNMS at section 922.201(a). This is similar to the approach taken for other national marine sanctuaries that do not share the full ''sanctuary resource'' definition such as Thunder Bay National Marine Sanctuary.

Additionally NOAA would add a definition in the MPNMS regulations at section 922.201(a) for sanctuary resource that uses the national definition for ''historical resources'' and expands it to specifically provide examples of the types of resources in this sanctuary that fall within that definition. The national definition of ''historical resources'' at section 922.3 describes the resource within the definition of ''historical resource'' to include resources that possess historical, cultural, archaeological or paleontological significance, such as sites, contextual information, structures, districts, and objects significantly associated with or representative of earlier people, cultures, maritime heritage, and human activities and events. These historical resources also include ''cultural resources,'' ''submerged cultural resources,'' and also include ''historical properties,'' as defined in the National Historic Preservation Act.

The new MPNMS definition of sanctuary resources would then be defined in section 922.201 to include historical resources as defined by section 922.3. This would include any sunken watercraft and any associated rigging, gear, fittings, trappings, and equipment. It would also include personal property of the officers, crew, and passengers, and any cargo, as well as and any submerged or partially submerged prehistoric, historic cultural remains, such as docks, piers, fishing-related remains (*e.g.* weirs, fish-traps) or other cultural heritage materials. For MPNMS sanctuary resource would also mean any archaeological, historical, and cultural remains associated with or representative of historic or prehistoric American Indians and historic groups or peoples and their activities.

This proposed rule incorporates and adopts other common terms defined in the existing national regulations at section 922.3; some of those definitions include: ''Cultural resources,'' which means any historical or cultural feature, including archaeological sites, historic structures, shipwrecks, and artifacts; and ''National Marine Sanctuary'' or ''Sanctuary,'' which means an area of the marine environment of special national significance due to its resource or human-use values, which is designated as such to ensure its conservation and management.

5. Co-Management of the Sanctuary

In order to further enhance the strong engagement forged by the State of Maryland and Charles County in nominating this area as a proposed national marine sanctuary and in contributing to the development of the draft designation documents, NOAA proposes to manage the sanctuary collaboratively with the state and county. NOAA proposes to establish the framework for co-management of the sanctuary at section 922.202 and intends to work out the operational details of the collaboration in a Memorandum of Understanding (MOU). Details on the execution of sanctuary management such as activities, programs, and permitting programs would be included in the MOU and can be updated to adapt to changing conditions or threats to the sanctuary resources. Any significant changes to the regulations or management plan would not only be jointly coordinated but also subject to public review.

6. Prohibited and Regulated Activities

NOAA is proposing to supplement and complement existing management of this area by proposing three regulations to protect the sanctuary resources in section 922.203(a).

a. Damaging Sanctuary Resources

As a complement to existing protections under state law and NHPA regulations, NOAA is proposing to prohibit damaging a sanctuary resource. The proposed regulation would prohibit moving, removing, recovering, altering, destroying, possessing, or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a sanctuary resource. The sanctuary prohibition on possessing a sanctuary resources would not apply to historical resources removed from the Sanctuary before the designation is complete. However, Maryland state regulations related to the limited removal of historical resources have been in effect since July 1, 1988 currently apply to these resources and will continue to do so. In the case of sanctuary resources that are covered under the Sunken Military Craft Act (SMCA; Pub. L. 108–375, Tit. XIV; 10 U.S.C. 113 note), NOAA and the U.S. Navy would cooperate on protecting those resources using the policy and procedures described in the 2015 Memorandum of Agreement (MOA). NOAA and the Maryland Historical Trust have tentatively identified one shipwreck as covered under the SMCA. A copy of the MOA is available at: *http://www.gc.noaa.gov/moa-2014-navy-signed.pdf.*

b. Damaging Sanctuary Signs

In addition to prohibiting damage to sanctuary resources, NOAA is also proposing to prohibit damage to sanctuary signs, notices, placards, monuments, stakes, posts, buoys, or boundary markers. These materials are part of the management of the sanctuary and may contribute to education and outreach programs. The materials are also federal property and therefore NOAA proposes to prohibit damage from marking, defacing or altering the materials in any way.

c. Interfering With Investigations

NOAA is proposing a regulation to prohibit interfering with sanctuary enforcement activities. This regulation will assist in NOAA's enforcement of the sanctuary regulations and strengthen sanctuary management.

d. Exemption for Emergencies and Law Enforcement

NOAA is proposing to include an exemption from the three regulations described above for activities the respond to emergencies that threaten lives, property or the environment, or are necessary for law enforcement purposes.

e. Department of Defense Activities

NOAA is also proposing that Department of Defense (DOD) activities be carried out in a manner that avoids

damage to sanctuary resources to the maximum extent practicable. In the event that DOD activities damage a sanctuary resource, NOAA and DOD would coordinate to work out a mitigation and restoration plan. Given the definition of sanctuary resources is limited to the historical resources and does not include biological or ecological resources NOAA does not anticipate that many, if any, current DOD activities would impact the resources.

7. Emergency Regulations

As part of the proposed designation, NOAA is proposing to give the sanctuary authority to issue emergency regulations. Emergency regulations are used in limited cases and under specific conditions when there is an imminent risk to sanctuary resources and a temporary prohibition would prevent the destruction or loss of those resources. Under the NMSA, NOAA only issues emergency regulations that address an imminent risk for a fixed amount of time with a maximum of 6 months that can only be extended a single time. A full rulemaking process must be undertaken, including a public comment period, to consider making an emergency regulation permanent. NOAA would add the authority to issue emergency regulations by modifying the national regulations at section 922.44 to include MPNMS in a list of sanctuaries that have site-specific regulations related to emergency regulations, and adding detailed site-specific emergency regulations to the MPNMS regulations at section 922.204.

8. General Permits, Certifications, Authorizations, and Special Use Permits

a. General Permits

NOAA is proposing to include the authority to issue permits to allow certain activities that would otherwise violate the prohibition in MPNMS. Similar to other national marine sanctuaries, NOAA is proposing to consider these permits only for education, research, or management.

To address the above additions to the ONMS general permit authority for MPNMS, NOAA would amend regulatory text in the program-wide regulations in part 922, subpart E, to add references to subpart S, as appropriate. NOAA would also add a new section 922.205 in subpart S titled ''Permit procedures and review criteria'' that would address site-specific permit procedures for MPNMS.

b. Certifications

Because of the possibility that preexisting activities, right of subsistence use or access permitted by other federal, state, local, or tribal agencies might be occurring within the MPNMS area that would otherwise be prohibited by MPNMS regulations, NOAA would add language at section 922.206 describing the process by which it can certify existing activities within the expansion area. In compliance with the NMSA, MPNMS regulations at section 922.206 would state that certification is the process by which permitted activities existing prior to the designation of the sanctuary that violate sanctuary prohibitions may be allowed to continue, provided certain conditions are met. Applications for certifying permitted existing uses would have to be received by NOAA within 180 days of the effective date of the designation.

c. Authorizations

NOAA also proposes to provide MPNMS with the authority to consider allowing an otherwise prohibited activity if such activity is specifically authorized by any valid Federal, state, or local lease, permit, license, approval, or other authorization issued after sanctuary designation. Authorization authority is intended to streamline regulatory requirements by reducing the need for multiple permits and would apply to all proposed prohibitions at section 922.203. As such, NOAA proposes to amend the regulatory text at section 922.49 to add reference to subpart S.

d. Special Use Permits

NOAA has the authority under the NMSA to issue special use permits (SUPs) at national marine sanctuaries as established by Section 310 of the NMSA. SUPs can be used to authorize specific activities in a sanctuary if such authorization is necessary (1) to establish conditions of access to and use of any sanctuary resource; or (2) to promote public use and understanding of a sanctuary resource. The activities that qualify for a SUP are set forth in the **Federal Register** (78 FR 25957; May 3, 2013). Categories of SUPs may be changed or added to through public notice and comment. NOAA would not apply the SUP to activities in place at the time of the MPNMS designation.

SUP applications are reviewed to ensure that the activity is compatible with the purposes for which the sanctuary is designated and that the activities carried out under the SUP be conducted in a manner that do not destroy, cause the loss of, or injure sanctuary resources. NOAA also requires SUP permittees to purchase and maintain comprehensive general liability insurance, or post an equivalent bond, against claims arising out of activities conducted under the permit. The NMSA allows NOAA to assess and collect fees for the conduct of any activity under a SUP. The fees collected could be used to recover the administrative costs of issuing the permit, the cost of implementing the permit, monitoring costs associated with the conduct of the activity, and the fair market value of the use of sanctuary resources.

9. Other Conforming Amendments

The general regulations in part 922, subpart A, for general information and part 922, subpart E, for regulations of general applicability would also have to be amended so that the regulations are accurate and up-to-date. The 10 sections that will need to be updated to reflect the increased number of sanctuaries or to add subpart S to the list of sanctuaries. The modified sections to conform to adding a new sanctuary are:

- Section 922.1 Applicability of regulations
- Section 922.40 Purpose
- Section 922.41 Boundaries
- Section 922.42 Allowed activities
- Section 922.43 Prohibited or otherwise regulated activities
- Section 922.44 Emergency regulations
- Section 922.47 Pre-existing authorizations or rights and certifications of pre-existing authorizations or rights
- Section 922.48 National Marine Sanctuary permits—application procedures and issuance criteria
- Section 922.49 Notification and review of applications for leases, licenses, permits, approvals, or other authorizations to conduct a prohibited activity
- Section 922.50 Appeals of administrative action

10. Terms of Designation

Section 304(a)(4) of the National Marine Sanctuaries Act (NMSA) requires that the terms of designation include the geographic area included within the sanctuary; the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or aesthetic value; and the types of activities that will be subject to regulation by the Secretary of Commerce to protect these characteristics. Section 304(a)(4) also specifies that the terms of designation may be modified only by the same procedures by which the original designation was made. Thus, the terms of designation serve as a constitution for the Sanctuary.

NOAA is proposing to establish terms to designation that describe the geographic area, resources, and activities as described in details above. NOAA would add the terms of designation language as Appendix B to the MPNMS regulations at 15 CFR part 922, subpart S.

III. Classification

National Marine Sanctuaries Act

NOAA has determined that the designation of the Mallows Bay—Potomac River National Marine Sanctuary will not have a negative impact on the National Marine Sanctuary System and that sufficient resources exist to effectively implement sanctuary management plans and to update site characterizations. The finding for NMSA section 304(f) is published on the ONMS Web site for the Mallows Bay—Potomac River designation at *http://sanctuaries.noaa.gov/mallows-bay/.*

National Environmental Policy Act

NOAA has prepared a draft environmental impact statement to evaluate the environmental effects of the proposed rulemaking and alternatives as required by NEPA (42 U.S.C. 4321 *et seq.*) and the NMSA. Copies of the DEIS and related DMP are available at the address and Web site listed in the **ADDRESSES** section of this proposed rule. NOAA is also soliciting public comments on the DEIS and DMP. Responses to comments received on this proposed rule as well as on the DEIS and draft management plan will be published in the final environmental impact statement and preamble to the final rule.

Coastal Zone Management Act

Section 307 of the Coastal Zone Management Act (CZMA; 16 U.S.C. 1456) requires Federal agencies to consult with a state's coastal program on potential Federal regulations having an effect on state waters. Because MPNMS encompasses a portion of the Maryland State waters and is adjacent to the Commonwealth of Virginia lands and waters, NOAA intends to submit a copy of this proposed rule and supporting documents to the Maryland Coastal Zone Management Program and Virginia Coastal Zone Management Program for evaluation of Federal consistency under the CZMA. NOAA will publish the final rule and designation only after completion of the consultation requirements under the CZMA.

Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132 because NOAA supplements and complements state and local laws under the NMSA.

National Historic Preservation Act

The National Historic Preservation Act (NHPA; 16 U.S.C. 470 *et seq.*) is intended to preserve historical and archaeological sites in the United States of America. The act created the National Register of Historic Places, the list of National Historic Landmarks, and State Historic Preservation Offices. Section 106 of the NHPA requires Federal agencies to take into account the effects of their undertakings on historic properties, and afford the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment. The historic preservation review process mandated by Section 106 is outlined in regulations issued by ACHP (36 CFR part 800 *et seq.*). In fulfilling its responsibilities under the NHPA, NOAA is seeking to identify consulting parties in addition to the State Historic Preservation Officer (SHPO), and will complete the identification of historic properties and the assessment of the effects of the undertaking on such properties in scheduled consultations with those identified parties and the SHPO. By this notice NOAA seeks public input, particularly in regard to the identification of historic properties within the proposed areas of potential effect. Pursuant to 36 CFR 800.16(1)(1), historic properties includes: ''any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. The term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria.'' If you, your organization(s), or business(es) would like to be considered a ''consulting party'' under Section 106 please contact the individual listed under the heading **FOR FURTHER INFORMATION CONTACT**; include contact information for the principal representative for the consultation; and describe you or your party's interest in the proposed designation. In accordance with 36 CFR 800.3(f)(3), NOAA will consider all ''consulting party'' requests but has ultimate discretion in determining and inviting additional consulting parties.

Regulatory Flexibility Act

The Small Business Administration has established thresholds on the designation of businesses as ''small entities''. A finfish fishing businesses is considered a small business if it has annual receipts of less than $20.5 million. Scenic and Sightseeing and Recreational industries are considered small businesses if they have annual receipts not in excess of $7.5 million. According to these limits, each of the businesses potentially affected by the proposed rule would most likely be small businesses. However, as further discussed below, these regulations will not have a significant economic impact on the affected small entities, and the Chief Counsel for Regulations for the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have significant economic impact on a substantial number of small entities. Thus, NOAA is not required to and has not prepared an initial regulatory flexibility analysis.

Methodology. The analysis here is based on limited quantitative information on how much each activity occurs within the proposed sanctuary. Consequently, the result is more qualitative than quantitative.

Scales Used for Assessing Impacts. For assessing levels of impacts within an alternative, NOAA used three levels; ''negligible'', ''moderate'' and ''high'' plus ''no impacts''. For levels of impacts within the proposed alternatives being analyzed, negligible means very low benefits, costs, or net benefits (less than 1% change). Moderate impacts would be more than 1% but less than or equal to 10%, and high impacts would be more than 10%. For market economic values (revenue, costs, and profits), negligible would mean no likely impact whereas moderate and high could mean some measurable impact on market economic values at the levels noted above. NOAA analyzed the proposed national marine sanctuary described above.

Small business user groups include commercial fishing operation, recreation-tourism related businesses, and land use and development

businesses. Other user groups not included here are research and education, people who receive passive economic use value from stabilization or improvement to the proposed sanctuary resources and the U.S. Navy, none of whom are small businesses.

NOAA assessed three types of regulations included in the proposed action; (1) moving, removing, recovering, altering, inuring, etc., (2) marking, defacing or damaging etc., and (3) interfering with obstructing, etc. (see section 922.203 for full details).

Proposed Action.

Moving, Removing, etc. Regulation. Under the proposed rule, NOAA would not permit moving, removing, recovering, altering, injuring, destroying, possessing or attempting to move, remove, recover, alter, injure, destroy or possess a sanctuary resource (except where removed or possessed prior to sanctuary designation). Small businesses that could potentially be impacted include commercial fishing, recreational for-hire fishing operations, dive operations and other water recreation based operators.

The expected impact to all these business in the preferred alternative is ''no impact''. The gear likely to be used to commercially fish or recreationally fish in the sanctuary will not be impacted by this regulation. Therefore, commercial fishing operations and for-hire operations are not expected to be impacted. Education and outreach will be used to educate user groups about the location of the sanctuary resources to prevent anchor damage. Divers will still be able to use the resource, but not able to take sanctuary resources, therefore the impact for this user group is also ''no impact''.

Marking, defacing or damaging, etc. Regulation. Using the best information, there are no known businesses that rely on damaging or defacing sanctuary resources and no known businesses whose actions damage or deface sanctuary resources. Therefore, this prohibition is expected to have ''no impact'' on small businesses.

Interfering with, obstructing, delaying or preventing an investigation Regulation. This prohibition is also expected to have ''no impact'' on small businesses. There is no evidence that any small businesses in the area would be impacted by this prohibition.

All Regulations. NOAA expects the combined effects of all the regulations to have ''no impact'' on small businesses. However, it is possible that some small business may be able to leverage a sanctuary designation to increase awareness and interest in recreational opportunities within the sanctuary and sanctuary community. This could potentially improve the potential for business growth within the area. In which case, recreational operators could potentially see a positive ''moderate'' improvement. Additionally, these regulations will have no impact on personal property rights, land use and planning.

Paperwork Reduction Act

ONMS has a valid Office of Management and Budget (OMB) control number (0648–0141) for the collection of public information related to the processing of ONMS permits across the National Marine Sanctuary System. NOAA's proposal to create MPNMS would likely result in an increase in the number of requests for ONMS general permits, special use permits, certifications, and authorizations because this action proposes to add general permits and special use permits, certifications, appeals, and the authority to authorize other valid federal, state, or local leases, permits, licenses, approvals, or other authorizations. An increase in the number of ONMS permit requests would require a change to the reporting burden certified for OMB control number 0648–0141. An update to this control number for the processing of ONMS permits would be requested as part of the final rule for sanctuary expansion.

Nationwide, NOAA issues approximately 500 national marine sanctuary permits each year. Of this amount, MPNMS is expected to add 4 to 5 permit requests per year. The public reporting burden for national marine sanctuaries permits is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information.

Send comments regarding the burden estimate for this data collection requirement, or any other aspect of this data collection, including suggestions for reducing the burden, to NOAA (see **ADDRESSES**) and by email to *OIRA_submission@omb.eop.gov,* or fax to (202) 395–7285.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

IV. Request for Comments

NOAA requests comments on this proposed rule by March 31, 2017. In additional to requesting comments on this proposed rule, NOAA is also soliciting input on the DEIS and DMP. In addition NOAA would like the public comments on the proposed name for the sanctuary.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Historic preservation, Intergovernmental relations, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Wildlife.

Dated: December 22, 2016.

W. Russell Callender,

Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons discussed in the preamble, the National Oceanic and Atmospheric Administration proposes to amend 15 CFR part 922 as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for 15 CFR part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

■ 2. Revise § 922.1 to read as follows:

§ 922.1 Applicability of regulations.

Unless noted otherwise, the regulations in subparts A, D, and E of this part apply to all National Marine Sanctuaries and related site-specific regulations set forth in this part. Subparts B and C of this part apply to the sanctuary nomination process and to the designation of future Sanctuaries.

■ 3. Amend § 922.3 by revising the definition of ''Sanctuary resource'' to read as follows:

§ 922.3 Definitions.

* * * * *

Sanctuary resource means any living or non-living resource of a National Marine Sanctuary that contributes to the conservation, recreational, ecological, historical, research, educational, or aesthetic value of the Sanctuary, including, but not limited to, the substratum of the area of the Sanctuary, other submerged features and the surrounding seabed, carbonate rock, corals and other bottom formations, coralline algae and other marine plants and algae, marine invertebrates, brine-seep biota, phytoplankton, zooplankton, fish, seabirds, sea turtles and other marine reptiles, marine mammals and

historical resources. For Thunder Bay National Marine Sanctuary and Underwater Preserve, Sanctuary resource means an underwater cultural resource as defined at § 922.191. For Mallows Bay—Potomac River National Marine Sanctuary, Sanctuary resource is defined at § 922.201(a).

* * * * *

■ 4. Revise § 922.40 to read as follows:

§ 922.40 Purpose.

The purpose of the regulations in this subpart and in the site-specific subparts is to implement the designations of the National Marine Sanctuaries by regulating activities affecting them, consistent with their respective terms of designation in order to protect, preserve and manage and thereby ensure the health, integrity and continued availability of the conservation, ecological, recreational, research, educational, historical and aesthetic resources and qualities of these areas. Additional purposes of the regulations implementing the designation of the Florida Keys and Hawaiian Islands Humpback Whale National Marine Sanctuaries are found at §§ 922.160 and 922.180, respectively.

■ 5. Revise § 922.41 to read as follows:

§ 922.41 Boundaries.

The boundary for each of the National Marine Sanctuaries is set forth in the site-specific regulations covered by this part.

■ 6. Revise § 922.42 to read as follows:

§ 922.42 Allowed activities.

All activities (*e.g.,* fishing, boating, diving, research, education) may be conducted unless prohibited or otherwise regulated in the site-specific regulations covered by this part, subject to any emergency regulations promulgated under this part, subject to all prohibitions, regulations, restrictions, and conditions validly imposed by any Federal, State, or local authority of competent jurisdiction, including but not limited to, Federal, Tribal, and State fishery management authorities, and subject to the provisions of section 312 of the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1431 *et seq.*). The Assistant Administrator may only directly regulate fishing activities pursuant to the procedure set forth in section 304(a)(5) of the NMSA.

■ 7. Revise § 922.43 to read as follows:

§ 922.43 Prohibited or otherwise regulated activities.

The site-specific regulations applicable to the activities specified therein are set forth in the subparts covered by this part.

■ 8. Revise § 922.44 to read as follows:

§ 922.44 Emergency regulations.

(a) Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality, or minimize the imminent risk of such destruction, loss, or injury, any and all such activities are subject to immediate temporary regulation, including prohibition.

(b) The provisions of this section do not apply to the following national marine sanctuaries with site-specific regulations that establish procedures for issuing emergency regulations:

(1) Cordell Bank National Marine Sanctuary, § 922.112(e).

(2) Florida Keys National Marine Sanctuary, § 922.165.

(3) Hawaiian Islands Humpback Whale National Marine Sanctuary, § 922.185.

(4) Thunder Bay National Marine Sanctuary, § 922.196.

(5) Mallows Bay—Potomac River National Marine Sanctuary, § 922.204.

(6) [Reserved]

■ 9. Amend § 922.47 by revising paragraph (b) to read as follows:

§ 922.47 Pre-existing authorizations or rights and certifications of pre-existing authorizations or rights.

* * * * *

(b) The prohibitions listed in subparts F through P and R through T of this part do not apply to any activity authorized by a valid lease, permit, license, approval or other authorization in existence on the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, and issued by any Federal, State or local authority of competent jurisdiction, or by any valid right of subsistence use or access in existence on the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, provided that the holder of such authorization or right complies with certification procedures and criteria promulgated at the time of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, and with any terms and conditions on the exercise of such authorization or right imposed by the Director as a condition of certification as the Director deems necessary to achieve the purposes for which the Sanctuary was designated.

■ 10. Revise § 922.48 to read as follows:

§ 922.48 National Marine Sanctuary permits—application procedures and issuance criteria.

(a) A person may conduct an activity prohibited by subparts F through O and S and T of this part, if conducted in accordance with the scope, purpose, terms and conditions of a permit issued under this section and subparts F through O and S and T, as appropriate. For the Florida Keys National Marine Sanctuary, a person may conduct an activity prohibited by subpart P of this part if conducted in accordance with the scope, purpose, terms and conditions of a permit issued under § 922.166. For the Thunder Bay National Marine Sanctuary and Underwater Preserve, a person may conduct an activity prohibited by subpart R of this part in accordance with the scope, purpose, terms and conditions of a permit issued under § 922.195.

(b) Applications for permits to conduct activities otherwise prohibited by subparts F through O and S and T of this part, should be addressed to the Director and sent to the address specified in subparts F through O of this part, or subparts R through T of this part, as appropriate. An application must include:

(1) A detailed description of the proposed activity including a timetable for completion;

(2) The equipment, personnel and methodology to be employed;

(3) The qualifications and experience of all personnel;

(4) The potential effects of the activity, if any, on Sanctuary resources and qualities; and

(5) Copies of all other required licenses, permits, approvals or other authorizations.

(c) Upon receipt of an application, the Director may request such additional information from the applicant as he or she deems necessary to act on the application and may seek the views of any persons or entity, within or outside the Federal government, and may hold a public hearing, as deemed appropriate.

(d) The Director, at his or her discretion, may issue a permit, subject to such terms and conditions as he or she deems appropriate, to conduct a prohibited activity, in accordance with the criteria found in subparts F through O of this part, or subparts R through T of this part, as appropriate. The Director shall further impose, at a minimum, the conditions set forth in the relevant subpart.

(e) A permit granted pursuant to this section is nontransferable.

(f) The Director may amend, suspend, or revoke a permit issued pursuant to

this section for good cause. The Director may deny a permit application pursuant to this section, in whole or in part, if it is determined that the permittee or applicant has acted in violation of the terms and conditions of a permit or of the regulations set forth in this section or subparts F through O of this part, or subparts R through T of this part or for other good cause. Any such action shall be communicated in writing to the permittee or applicant by certified mail and shall set forth the reason(s) for the action taken. Procedures governing permit sanctions and denials for enforcement reasons are set forth in subpart D of 15 CFR part 904.

■ 11. Revise § 922.49 to read as follows:

§ 922.49 Notification and review of applications for leases, licenses, permits, approvals, or other authorizations to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by subparts L through P of this part, or subparts R through T of this part, if such activity is specifically authorized by any valid Federal, State, or local lease, permit, license, approval, or other authorization issued after the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary after the effective date of the regulations in subpart P, provided that:

(1) The applicant notifies the Director, in writing, of the application for such authorization (and of any application for an amendment, renewal, or extension of such authorization) within fifteen (15) days of the date of filing of the application or the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P of this part, whichever is later;

(2) The applicant complies with the other provisions of this section;

(3) The Director notifies the applicant and authorizing agency that he or she does not object to issuance of the authorization (or amendment, renewal, or extension); and

(4) The applicant complies with any terms and conditions the Director deems reasonably necessary to protect Sanctuary resources and qualities.

(b) Any potential applicant for an authorization described in paragraph (a) of this section may request the Director to issue a finding as to whether the activity for which an application is intended to be made is prohibited by subparts L through P of this part, or subparts R through T of this part, as appropriate.

(c) Notification of filings of applications should be sent to the Director, Office of National Marine Sanctuaries at the address specified in subparts L through P of this part, or subparts R through T of this part, as appropriate. A copy of the application must accompany the notification.

(d) The Director may request additional information from the applicant as he or she deems reasonably necessary to determine whether to object to issuance of an authorization described in paragraph (a) of this section, or what terms and conditions are reasonably necessary to protect Sanctuary resources and qualities. The information requested must be received by the Director within 45 days of the postmark date of the request. The Director may seek the views of any persons on the application.

(e) The Director shall notify, in writing, the agency to which application has been made of his or her pending review of the application and possible objection to issuance. Upon completion of review of the application and information received with respect thereto, the Director shall notify both the agency and applicant, in writing, whether he or she has an objection to issuance and what terms and conditions he or she deems reasonably necessary to protect Sanctuary resources and qualities, and reasons therefor.

(f) The Director may amend the terms and conditions deemed reasonably necessary to protect Sanctuary resources and qualities whenever additional information becomes available justifying such an amendment.

(g) Any time limit prescribed in or established under this section may be extended by the Director for good cause.

(h) The applicant may appeal any objection by, or terms or conditions imposed by, the Director to the Assistant Administrator or designee in accordance with the provisions of § 922.50.

■ 12. Revise § 922.50 to read as follows:

§ 922.50 Appeals of administrative action.

(a)(1) Except for permit actions taken for enforcement reasons (see subpart D of 15 CFR part 904 for applicable procedures), an applicant for, or a holder of, a National Marine Sanctuary permit; an applicant for, or a holder of, a Special Use permit issued pursuant to section 310 of the Act; a person requesting certification of an existing lease, permit, license or right of subsistence use or access under § 922.47; or, for those Sanctuaries described in subparts L through P and R through T of this part, an applicant for a lease, permit, license or other authorization issued by any Federal, State, or local authority of competent jurisdiction (hereinafter appellant) may appeal to the Assistant Administrator:

(i) The granting, denial, conditioning, amendment, suspension or revocation by the Director of a National Marine Sanctuary or Special Use permit;

(ii) The conditioning, amendment, suspension or revocation of a certification under § 922.47; or

(iii) For those Sanctuaries described in subparts L through P and R through T of this part, the objection to issuance of or the imposition of terms and conditions on a lease, permit, license or other authorization issued by any Federal, State, or local authority of competent jurisdiction.

(2) For those National Marine Sanctuaries described in subparts F through K and S and T of this part, any interested person may also appeal the same actions described in paragraphs (a)(1)(i) and (ii) of this section. For appeals arising from actions taken with respect to these National Marine Sanctuaries, the term ''appellant'' includes any such interested persons.

(b) An appeal under paragraph (a) of this section must be in writing, state the action(s) by the Director appealed and the reason(s) for the appeal, and be received within 30 days of receipt of notice of the action by the Director. Appeals should be addressed to the Assistant Administrator for Ocean Services and Coastal Zone Management, NOAA 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910.

(c)(1) The Assistant Administrator may request the appellant to submit such information as the Assistant Administrator deems necessary in order for him or her to decide the appeal. The information requested must be received by the Assistant Administrator within 45 days of the postmark date of the request. The Assistant Administrator may seek the views of any other persons. For the Monitor National Marine Sanctuary, if the appellant has requested a hearing, the Assistant Administrator shall grant an informal hearing. For all other National Marine Sanctuaries, the Assistant Administrator may determine whether to hold an informal hearing on the appeal. If the Assistant Administrator determines that an informal hearing should be held, the Assistant Administrator may designate an officer before whom the hearing shall be held.

(2) The hearing officer shall give notice in the **Federal Register** of the time, place and subject matter of the hearing. The appellant and the Director may appear personally or by counsel at the hearing and submit such material and present such arguments as deemed appropriate by the hearing officer.

Within 60 days after the record for the hearing closes, the hearing officer shall recommend a decision in writing to the Assistant Administrator.

(d) The Assistant Administrator shall decide the appeal using the same regulatory criteria as for the initial decision and shall base the appeal decision on the record before the Director and any information submitted regarding the appeal, and, if a hearing has been held, on the record before the hearing officer and the hearing officer's recommended decision. The Assistant Administrator shall notify the appellant of the final decision and the reason(s) therefore in writing. The Assistant Administrator's decision shall constitute final agency action for the purpose of the Administrative Procedure Act.

(e) Any time limit prescribed in or established under this section other than the 30-day limit for filing an appeal may be extended by the Assistant Administrator or hearing office for good cause.

■ 13. Add subpart S to read as follows:

Subpart S—Mallows Bay—Potomac River National Marine Sanctuary

Sec.
922.200 Boundary.
922.201 Definitions.
922.202 Joint management.
922.203 Prohibited or otherwise regulated activities.
922.204 Emergency regulations.
922.205 Permit procedures and review criteria.
922.206 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.
Appendix A to Subpart S of Part 922—Mallows Bay—Potomac River Marine Sanctuary Boundary Description and Coordinates of the Lateral Boundary Closures and Excluded Areas
Appendix B to Subpart S of Part 922—Mallows Bay—Potomac River Marine Sanctuary Terms of Designation

§ 922.200 Boundary.

The Mallows Bay—Potomac River National Marine Sanctuary consists of an area of approximately 39 square nautical miles (nmi 2) (52 sq. mi) of waters of the state of Maryland in the Potomac River and the submerged lands thereunder, over, around, and under the underwater cultural resources in the Potomac River. The precise boundary coordinates are listed in appendix A to this subpart. The southern and western boundary of the sanctuary approximates the border between the Commonwealth of Virginia and the State of Maryland along the western side of the Potomac River and begins at Point 1 east of Choptank Creek in King George County near Hooes, VA. From this point the boundary continues to the west passing through the points in numerical order until it reaches Point 237 at Bull Bluff on the southern side of the mouth of Potomac Creek. From this point the boundary continues north across the mouth of Potomac Creek to Point 238 near Marlboro Point in Stafford, VA. and once again follows the points in numerical order until it reaches Point 269 at the southern side of the mouth of Aquia Creek. From this point the boundary continues north across the mouth of Aquia Creek to Point 270 near Brent Point in Stafford, VA. The boundary then continues north passing through the points in numerical order until it reaches Point 312 north of Tank Creek near the restricted area in the Potomac River around Marine Base Quantico at the mouth of Chopawamsic Creek. From this point the boundary continues outside of and around the restricted area to the east and then north again passing through the points in numerical order until it reaches Point 343 south of Quantico Marina. From this point the boundary continues to the east, then north and west around the marina and then north again following the points in numerical order until it reaches Point 365 at Shipping Point on the southern side of the mouth of Quantico Creek in Quantico, VA. From this point the boundary moves to the NNE across the mouth of Quantico Creek to Possum Point near Dumfries, VA. From this point the boundary continues north passing through the points in numerical order until it reaches Point 390 SE of Southbridge, VA. From this point the boundary moves SE towards Point 391 in a straight line crossing the Potomac River until it intersects the shoreline of the river at Moss Point on the Maryland side at mean high water near Indian Head, MD just north of Goose Bay. From this intersection the boundary then follows the shoreline initially to the SW cutting across the mouths of creeks and streams along the eastern side of the Potomac River, then south past Sandy Point and around Mallows Bay. The boundary then continues following the shoreline south past Smith Point and Thomas Point where it turns to the SE and then east around Maryland Point. From here the boundary continues to follow the shoreline to the ENE past Riverside, MD until it intersects the line formed between Point 392 and Point 393 at Benny Gray Point on the western side of the mouth of Nanjemoy Creek on Tayloe Neck in Maryland. Finally, from this intersection the boundary crosses the Potomac River to the SE in a straight line and continues to Point 393 east of Choptank Creek on the Virginia side of the Potomac River.

§ 922.201 Definitions.

(a) The following terms are defined for purposes of this subpart:

(1) *Sanctuary resource* means any historical resource with the Sanctuary boundaries, as defined in § 922.3. This includes, but is not limited to, any sunken watercraft and any associated rigging, gear, fittings, trappings, and equipment; the personal property of the officers, crew, and passengers, and any cargo; and any submerged or partially submerged prehistoric, historic cultural remains, such as docks, piers, fishing-related remains (*e.g.,* weirs, fish-traps) or other cultural heritage materials. Sanctuary resource also means any archaeological, historical, and cultural remains associated with or representative of historic or prehistoric American Indians and historic groups or peoples and their activities.

(2) [Reserved]

(b) All other terms appearing in the regulations in this subpart are defined at 15 CFR 922.3, and/or in the Marine Protection, Research, and Sanctuaries Act, as amended, 33 U.S.C. 1401 *et seq.,* and 16 U.S.C. 1431 *et seq.*

§ 922.202 Joint management.

NOAA has primary responsibility for the management of the Sanctuary pursuant to the Act. However, NOAA shall co-manage the Sanctuary in collaboration with the State of Maryland and Charles County. The Director shall enter into a Memorandum of Understanding regarding this collaboration that shall address, but not be limited to, such aspects as areas of mutual concern, including Sanctuary programs, permitting, activities, development, and threats to Sanctuary resources.

§ 922.203 Prohibited or otherwise regulated activities.

(a) Except as specified in paragraphs (b) and (c) of this section, the following activities are prohibited and thus are unlawful for any person to conduct or to cause to be conducted:

(1) Moving, removing, recovering, altering, destroying, possessing, or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a Sanctuary resource. This prohibition does not apply to possessing historical resources removed from the Sanctuary area before the effective date of the Sanctuary designation.

(2) Marking, defacing, or damaging in any way, or displacing or removing or

tampering with any signs, notices, or placards, whether temporary or permanent, or with any monuments, stakes, posts, buoys, or other boundary markers related to the Sanctuary.

(3) Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation or any permit issued under the Act.

(b) The prohibitions in paragraphs (a)(1) through (3) of this section do not apply to any activity necessary to respond to an emergency threatening life, property or the environment; or to activities necessary for valid law enforcement purposes.

(c)(1) Department of Defense activities must be carried out in a manner that avoids to the maximum extent practicable any adverse impacts on Sanctuary resources.

(2) In the event of destruction of, loss of, or injury to a Sanctuary resource resulting from an incident, including but not limited to discharges, deposits, and groundings, caused by a Department of Defense activity, the Department of Defense, in coordination with the Director, must promptly prevent and mitigate further damage and must restore or replace the Sanctuary resource in a manner approved by the Director.

§ 922.204 Emergency regulations.

(a) Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource, or to minimize the imminent risk of such destruction, loss, or injury, any and all activities are subject to immediate temporary regulation, including prohibition. An emergency regulation shall not take effect without the approval of the Governor of Maryland or her/his designee or designated agency.

(b) Emergency regulations remain in effect until a date fixed in the rule or six months after the effective date, whichever is earlier. The rule may be extended once for not more than six months.

§ 922.205 Permit procedures and review criteria.

(a) *Authority to issue general permits.* The Director may allow a person to conduct an activity that would otherwise be prohibited by this subpart, through issuance of a general permit, provided the applicant complies with:

(1) The provisions of subpart E of this part; and

(2) The relevant site specific regulations appearing in this subpart.

(b) *Sanctuary general permit categories.* The Director may issue a sanctuary general permit under this subpart, subject to such terms and conditions as he or she deems appropriate, if the Director finds that the proposed activity falls within one of the following categories:

(1) Research—activities that constitute scientific research on or scientific monitoring of national marine sanctuary resources or qualities;

(2) Education—activities that enhance public awareness, understanding, or appreciation of a national marine sanctuary or national marine sanctuary resources or qualities; or

(3) Management—activities that assist in managing a national marine sanctuary.

(c) *Review criteria.* The Director shall not issue a permit under this subpart, unless he or she also finds that:

(1) The proposed activity will be conducted in a manner compatible with the primary objective of protection of national marine sanctuary resources and qualities, taking into account the following factors:

(i) The extent to which the conduct of the activity may diminish or enhance national marine sanctuary resources and qualities; and

(ii) Any indirect, secondary or cumulative effects of the activity.

(2) It is necessary to conduct the proposed activity within the national marine sanctuary to achieve its stated purpose.

(3) The methods and procedures proposed by the applicant are appropriate to achieve the proposed activity's stated purpose and eliminate, minimize, or mitigate adverse effects on sanctuary resources and qualities as much as possible.

(4) The duration of the proposed activity and its effects are no longer than necessary to achieve the activity's stated purpose.

(5) The expected end value of the activity to the furtherance of national marine sanctuary goals and purposes outweighs any potential adverse impacts on sanctuary resources and qualities from the conduct of the activity.

(6) The applicant is professionally qualified to conduct and complete the proposed activity.

(7) The applicant has adequate financial resources available to conduct and complete the proposed activity and terms and conditions of the permit.

(8) There are no other factors that would make the issuance of a permit for the activity inappropriate.

§ 922.206 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by § 922.203(a)(1) through (3) if such activity is specifically authorized by a valid Federal, state, or local lease, permit, license, approval, or other authorization, or tribal right of subsistence use or access in existence prior to the effective date of sanctuary designation and within the sanctuary designated area and complies with § 922.49 and provided that the holder of the lease, permit, license, approval, or other authorization complies with the requirements of paragraph (e) of this section.

(b) In considering whether to make the certifications called for in this section, the Director may seek and consider the views of any other person or entity, within or outside the Federal government, and may hold a public hearing as deemed appropriate.

(c) The Director may amend, suspend, or revoke any certification made under this section whenever continued operation would otherwise be inconsistent with any terms or conditions of the certification. Any such action shall be forwarded in writing to both the holder of the certified permit, license, or other authorization and the issuing agency and shall set forth reason(s) for the action taken.

(d) Requests for findings or certifications should be addressed to the Director, Office of National Marine Sanctuaries; ATTN: Sanctuary Superintendent, Mallows Bay—Potomac National Marine Sanctuary, 1305 East West Hwy., 11th Floor, Silver Spring, MD 20910. A copy of the lease, permit, license, approval, or other authorization must accompany the request.

(e) For an activity described in paragraph (a) of this section, the holder of the authorization or right may conduct the activity prohibited by § 922.203(a)(1) through (3) provided that:

(1) The holder of such authorization or right notifies the Director, in writing, within 180 days of the effective date of Sanctuary designation, of the existence of such authorization or right and requests certification of such authorization or right;

(2) The holder complies with the other provisions of this section; and

(3) The holder complies with any terms and conditions on the exercise of such authorization or right imposed as a condition of certification, by the Director, to achieve the purposes for which the Sanctuary was designated.

(f) The holder of an authorization or right described in paragraph (a) of this section authorizing an activity prohibited by § 922.203 may conduct the activity without being in violation of applicable provisions of § 922.203, pending final agency action on his or her certification request, provided the holder is otherwise in compliance with this section.

(g) The Director may request additional information from the certification requester as he or she deems reasonably necessary to condition appropriately the exercise of the certified authorization or right to achieve the purposes for which the Sanctuary was designated. The Director must receive the information requested within 45 days of the postmark date of the request. The Director may seek the views of any persons on the certification request.

(h) The Director may amend any certification made under this section whenever additional information becomes available that he/she determines justifies such an amendment.

(i) Upon completion of review of the authorization or right and information received with respect thereto, the Director shall communicate, in writing, any decision on a certification request or any action taken with respect to any certification made under this section, in writing, to both the holder of the certified lease, permit, license, approval, other authorization, or right, and the issuing agency, and shall set forth the reason(s) for the decision or action taken.

(j) The holder may appeal any action conditioning, amending, suspending, or revoking any certification in accordance with the procedures set forth in § 922.50.

(k) Any time limit prescribed in or established under this section may be extended by the Director for good cause.

Appendix A to Subpart S of Part 922—Mallows Bay—Potomac River Marine Sanctuary Boundary Description and Coordinates of the Lateral Boundary Closures and Excluded Areas

Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983.

TABLE A1—COORDINATES FOR SANCTUARY

Point ID	Latitude	Longitude
1	38.36739	−77.08823
2	38.36717	−77.08948
3	38.36704	−77.09072
4	38.36699	−77.09216
5	38.36698	−77.09295
6	38.36683	−77.09370
7	38.36674	−77.09433
8	38.36680	−77.09469
9	38.36703	−77.09430
10	38.36735	−77.09456
11	38.36761	−77.09482
12	38.36774	−77.09518
13	38.36808	−77.09629
14	38.36830	−77.09729
15	38.36870	−77.09816
16	38.36879	−77.09873
17	38.36913	−77.10063
18	38.36925	−77.10201
19	38.36947	−77.10402
20	38.36954	−77.10569
21	38.36950	−77.10722
22	38.36936	−77.10863
23	38.36900	−77.11124
24	38.36861	−77.11351
25	38.36845	−77.11467
26	38.36816	−77.11552
27	38.36818	−77.11624
28	38.36810	−77.11658
29	38.36782	−77.11717
30	38.36749	−77.11806
31	38.36709	−77.12039
32	38.36688	−77.12209
33	38.36682	−77.12429
34	38.36681	−77.12705
35	38.36690	−77.12792
36	38.36717	−77.12974
37	38.36742	−77.13146
38	38.36757	−77.13329
39	38.36764	−77.13392
40	38.36774	−77.13577
41	38.36776	−77.13724
42	38.36774	−77.13795
43	38.36753	−77.13850
44	38.36728	−77.13890
45	38.36693	−77.13928
46	38.36577	−77.14035
47	38.36475	−77.14148
48	38.36398	−77.14256
49	38.36280	−77.14402
50	38.36191	−77.14499
51	38.36031	−77.14648
52	38.35891	−77.14763
53	38.35736	−77.14879
54	38.35491	−77.15073
55	38.35391	−77.15170
56	38.35321	−77.15266
57	38.35308	−77.15292
58	38.35282	−77.15334
59	38.35248	−77.15365
60	38.35144	−77.15461
61	38.35025	−77.15589
62	38.34887	−77.15758
63	38.34760	−77.15944
64	38.34669	−77.16101
65	38.34611	−77.16212
66	38.34560	−77.16323
67	38.34525	−77.16412
68	38.34501	−77.16493
69	38.34502	−77.16541
70	38.34491	−77.16578
71	38.34483	−77.16626
72	38.34482	−77.16666
73	38.34460	−77.16748
74	38.34441	−77.16840
75	38.34444	−77.16902
76	38.34429	−77.16950
77	38.34407	−77.17030
78	38.34381	−77.17097
79	38.34350	−77.17163
80	38.34334	−77.17206
81	38.34317	−77.17263
82	38.34287	−77.17360
83	38.34209	−77.17576
84	38.34146	−77.17773
85	38.34128	−77.17854
86	38.34128	−77.17906
87	38.34138	−77.17955
88	38.34137	−77.17966
89	38.34135	−77.17980
90	38.34133	−77.18005
91	38.34131	−77.18017
92	38.34122	−77.18040
93	38.34116	−77.18079
94	38.34119	−77.18150
95	38.34120	−77.18263
96	38.34122	−77.18323
97	38.34115	−77.18430
98	38.34095	−77.18614
99	38.34079	−77.18791
100	38.34064	−77.18962
101	38.34059	−77.19086
102	38.34052	−77.19230
103	38.34053	−77.19403
104	38.34068	−77.19429
105	38.34078	−77.19441
106	38.34064	−77.19511
107	38.34055	−77.19586
108	38.34048	−77.19651
109	38.34040	−77.19799
110	38.34033	−77.19986
111	38.34040	−77.20078
112	38.34052	−77.20213
113	38.34064	−77.20333
114	38.34070	−77.20421
115	38.34043	−77.20531
116	38.34008	−77.20635
117	38.33976	−77.20698
118	38.33959	−77.20767
119	38.33960	−77.20782
120	38.33973	−77.20824
121	38.33977	−77.20867
122	38.33976	−77.20888
123	38.33973	−77.20909
124	38.33964	−77.20958
125	38.33928	−77.21080
126	38.33892	−77.21195
127	38.33854	−77.21310
128	38.33852	−77.21378
129	38.33804	−77.21485
130	38.33792	−77.21523
131	38.33761	−77.21625
132	38.33724	−77.21710
133	38.33692	−77.21799
134	38.33673	−77.21878
135	38.33658	−77.21966
136	38.33647	−77.22072
137	38.33640	−77.22109
138	38.33596	−77.22240
139	38.33567	−77.22315
140	38.33526	−77.22414
141	38.33483	−77.22528
142	38.33444	−77.22657
143	38.33408	−77.22777
144	38.33340	−77.22978
145	38.33291	−77.23116
146	38.33264	−77.23265
147	38.33231	−77.23448

TABLE A1—COORDINATES FOR SANCTUARY—Continued

Point ID	Latitude	Longitude
148	38.33227	−77.23495
149	38.33259	−77.23502
150	38.33258	−77.23529
151	38.33209	−77.23529
152	38.33180	−77.23634
153	38.33145	−77.23785
154	38.33130	−77.23898
155	38.33123	−77.23965
156	38.33112	−77.24061
157	38.33110	−77.24127
158	38.33107	−77.24231
159	38.33109	−77.24303
160	38.33109	−77.24356
161	38.33104	−77.24483
162	38.33105	−77.24512
163	38.33107	−77.24533
164	38.33107	−77.24607
165	38.33114	−77.24689
166	38.33144	−77.24694
167	38.33144	−77.24716
168	38.33121	−77.24719
169	38.33109	−77.24770
170	38.33117	−77.24806
171	38.33139	−77.24916
172	38.33133	−77.24978
173	38.33139	−77.25021
174	38.33150	−77.25141
175	38.33159	−77.25294
176	38.33150	−77.25606
177	38.33158	−77.25623
178	38.33177	−77.25646
179	38.33187	−77.25682
180	38.33184	−77.25856
181	38.33196	−77.26076
182	38.33201	−77.26171
183	38.33218	−77.26196
184	38.33233	−77.26254
185	38.33243	−77.26373
186	38.33247	−77.26524
187	38.33264	−77.26545
188	38.33289	−77.26591
189	38.33319	−77.26671
190	38.33340	−77.26757
191	38.33339	−77.26797
192	38.33377	−77.26839
193	38.33391	−77.26862
194	38.33402	−77.26888
195	38.33412	−77.26937
196	38.33416	−77.26960
197	38.33438	−77.27005
198	38.33456	−77.27032
199	38.33482	−77.27065
200	38.33546	−77.27098
201	38.33565	−77.27125
202	38.33558	−77.27149
203	38.33570	−77.27231
204	38.33583	−77.27267
205	38.33592	−77.27292
206	38.33601	−77.27324
207	38.33635	−77.27474
208	38.33656	−77.27539
209	38.33669	−77.27564
210	38.33683	−77.27572
211	38.33694	−77.27583
212	38.33708	−77.27589
213	38.33719	−77.27585
214	38.33728	−77.27637
215	38.33738	−77.27685
216	38.33768	−77.27729
217	38.33803	−77.27741
218	38.33829	−77.27725

TABLE A1—COORDINATES FOR SANCTUARY—Continued

Point ID	Latitude	Longitude
219	38.33883	−77.27803
220	38.33888	−77.27829
221	38.33863	−77.27848
222	38.33868	−77.27885
223	38.33899	−77.27960
224	38.33924	−77.28012
225	38.33939	−77.28028
226	38.33954	−77.28022
227	38.33978	−77.27993
228	38.34024	−77.27997
229	38.34082	−77.28058
230	38.34137	−77.28120
231	38.34185	−77.28191
232	38.34227	−77.28244
233	38.34255	−77.28270
234	38.34263	−77.28289
235	38.34276	−77.28333
236	38.34288	−77.28399
237	38.34287	−77.28458
238	38.35169	−77.28785
239	38.35176	−77.28762
240	38.35222	−77.28722
241	38.35296	−77.28696
242	38.35378	−77.28704
243	38.35441	−77.28734
244	38.35475	−77.28746
245	38.35571	−77.28759
246	38.35698	−77.28798
247	38.35753	−77.28814
248	38.35832	−77.28794
249	38.35873	−77.28777
250	38.35909	−77.28772
251	38.35949	−77.28810
252	38.36243	−77.29110
253	38.36281	−77.29123
254	38.36306	−77.29148
255	38.36425	−77.29288
256	38.36685	−77.29439
257	38.36867	−77.29555
258	38.36937	−77.29586
259	38.36998	−77.29646
260	38.37142	−77.29799
261	38.37293	−77.30072
262	38.37327	−77.30098
263	38.37342	−77.30149
264	38.37356	−77.30181
265	38.37371	−77.30200
266	38.37392	−77.30224
267	38.37426	−77.30275
268	38.37482	−77.30401
269	38.37519	−77.30479
270	38.39732	−77.31009
271	38.39823	−77.31030
272	38.39856	−77.31060
273	38.39887	−77.31075
274	38.39917	−77.31067
275	38.40015	−77.31074
276	38.40090	−77.31146
277	38.40139	−77.31216
278	38.40198	−77.31237
279	38.40314	−77.31278
280	38.40658	−77.31377
281	38.40984	−77.31466
282	38.41389	−77.31693
283	38.41832	−77.31913
284	38.41975	−77.31931
285	38.42352	−77.31972
286	38.42549	−77.32030
287	38.42738	−77.32081
288	38.43092	−77.32240
289	38.43163	−77.32242

TABLE A1—COORDINATES FOR SANCTUARY—Continued

Point ID	Latitude	Longitude
290	38.43351	−77.32264
291	38.43385	−77.32269
292	38.43430	−77.32265
293	38.43462	−77.32229
294	38.43498	−77.32146
295	38.43526	−77.32057
296	38.43522	−77.32040
297	38.47321	−77.31846
298	38.47434	−77.31874
299	38.47561	−77.31753
300	38.47655	−77.31686
301	38.47748	−77.31667
302	38.47821	−77.31604
303	38.47871	−77.31554
304	38.47885	−77.31564
305	38.47905	−77.31559
306	38.47922	−77.31578
307	38.47943	−77.31592
308	38.47986	−77.31592
309	38.48494	−77.31336
310	38.48878	−77.31142
311	38.49279	−77.30997
312	38.49351	−77.30981
313	38.49257	−77.30624
314	38.49509	−77.30103
315	38.49849	−77.29738
316	38.50281	−77.29424
317	38.50653	−77.29712
318	38.50663	−77.29695
319	38.50755	−77.29621
320	38.50794	−77.29610
321	38.50823	−77.29611
322	38.50858	−77.29613
323	38.50871	−77.29604
324	38.50880	−77.29604
325	38.50896	−77.29612
326	38.51029	−77.29518
327	38.51167	−77.29327
328	38.51204	−77.29382
329	38.51575	−77.29102
330	38.51736	−77.29034
331	38.51778	−77.29023
332	38.51797	−77.29006
333	38.51828	−77.28968
334	38.51867	−77.28916
335	38.51883	−77.28893
336	38.51897	−77.28886
337	38.51905	−77.28874
338	38.51902	−77.28867
339	38.51904	−77.28854
340	38.51909	−77.28843
341	38.51922	−77.28834
342	38.51935	−77.28825
343	38.51945	−77.28816
344	38.51883	−77.28626
345	38.51945	−77.28539
346	38.52021	−77.28482
347	38.52115	−77.28762
348	38.52130	−77.28757
349	38.52175	−77.28728
350	38.52193	−77.28687
351	38.52223	−77.28639
352	38.52282	−77.28636
353	38.52317	−77.28616
354	38.52390	−77.28552
355	38.52434	−77.28500
356	38.52475	−77.28427
357	38.52485	−77.28385
358	38.52498	−77.28362
359	38.52516	−77.28351
360	38.52540	−77.28331

TABLE A1—COORDINATES FOR SANCTUARY—Continued

Point ID	Latitude	Longitude
361	38.52558	−77.28310
362	38.52603	−77.28307
363	38.52706	−77.28312
364	38.52767	−77.28309
365	38.52782	−77.28322
366	38.53398	−77.27927
367	38.53458	−77.27946
368	38.53542	−77.27940
369	38.53640	−77.27899
370	38.53725	−77.27822
371	38.53714	−77.27792
372	38.53680	−77.27703
373	38.53820	−77.27624
374	38.53908	−77.27673
375	38.53962	−77.27641
376	38.54088	−77.27604
377	38.54218	−77.27594
378	38.54311	−77.27590
379	38.54345	−77.27604
380	38.54416	−77.27638
381	38.54523	−77.27670
382	38.54603	−77.27677
383	38.54678	−77.27655
384	38.54732	−77.27606
385	38.54806	−77.27536
386	38.54901	−77.27473
387	38.54986	−77.27422
388	38.55036	−77.27373
389	38.55131	−77.27265
390	38.55133	−77.27263
391*	38.52603	−77.25146
392*	38.41053	−77.12394
393	38.36739	−77.08823

Note: The coordinates in the table above marked with an asterisk (*) are not a part of the sanctuary boundary. These coordinates are landward reference points used to draw a line segment that intersects with the shoreline.

Appendix B to Subpart S of Part 922—Mallows Bay—Potomac River Marine Sanctuary Terms of Designation

Terms of Designation for the Proposed Mallows Bay—Potomac River National Marine Sanctuary

Under the authority of the National Marine Sanctuaries Act, as amended (the ''Act'' or ''NMSA''), 16 U.S.C. 1431 *et seq.,* certain waters and submerged lands located off the Nanjemoy Peninsula of Charles County, Maryland and along the tidal Potomac River and its surrounding waters are hereby designated as a National Marine Sanctuary for the purposes of providing long-term protection and management of the historical resources and recreational, research, educational, and aesthetic qualities of the area.

Article I: Effect of Designation

The NMSA authorizes the issuance of such regulations as are necessary and reasonable to implement the designation, including managing and protecting the historical resources and recreational, research, and educational qualities of the Mallows Bay—Potomac River National Marine Sanctuary (the ''Sanctuary''). Section 1 of Article IV of this Designation Document lists those activities that may have to be regulated on the effective date of designation, or at some later date, in order to protect Sanctuary resources and qualities. Listing an activity does not necessarily mean that it will be regulated; however, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original Sanctuary designation was made.

Article II: Description of the Area

The Mallows Bay—Potomac River National Marine Sanctuary consists of an area of approximately 39 square nautical miles (nmi 2) (52 sq. mi) of waters of the state of Maryland in the Potomac River and the submerged lands thereunder, over, around, and under the underwater cultural resources in the Potomac River. The southern and western boundary of the sanctuary approximates the border between the Commonwealth of Virginia and the State of Maryland for roughly 29 miles along the western side of the Potomac River and begins east of Choptank Creek in King George County near Hooes, VA. From this point the boundary approximates the border west and then north cutting across the mouths of Choptank Creek, Potomac Creek, and Aquia Creek. The boundary then continues past Widewater, VA and around the Marine Base Quantico restricted area to the east and then continues north again cutting across the mouth of Quantico Creek. From a point just north of Quantico Creek and Possum Point near Dumfries, VA the boundary crosses the Potomac to the southeast until it intersects the Maryland shoreline at Moss Point near Indian Head, MD. From this point the eastern and northern boundary of the sanctuary, approximately 21 miles in length, follows the Maryland shoreline south past Sandy Point and Mallows Bay cutting across the mouths of streams and creeks. The boundary then continues following the shoreline south past Smith Point and Thomas Point where it turns to the east around Maryland Point. From here the boundary continues to follow the shoreline past Riverside, MD to a location at Benny Gray Point on the western side of the mouth of Nanjemoy Creek on Tayloe Neck in Maryland. From here the boundary crosses the Potomac River again to the south back to its point of origin east of Choptank Creek on the Virginia side of the river. The boundary encompasses all tidal waters within this boundary from mean high tide in Maryland to mean low tide in Virginia. Excluded from the sanctuary are areas where the Virginia state line is otherwise delineated, the Quantico exclusion zone, and the area around the Quantico marina.

Article III: Special Characteristics of the Area

Mallows Bay—Potomac River National Marine Sanctuary and its surrounding waters contain a diverse collection of nearly 200 known historic shipwreck vessels dating back to the Civil War and potentially dating back to the Revolutionary War as well as archaeological artifacts dating back 12,000 years indicating the presence of some of the region's earliest American Indian cultures, including the Piscataway Indian Nation and the Piscataway Conoy Tribe of Maryland. The area is most renowned for the remains of over 100 wooden steamships, known as the ''Ghost Fleet,'' that were built for the U.S. Emergency Fleet between 1917–1919 as part of U.S. engagement in World War I. Their construction at more than 40 shipyards in 17 states reflects the massive national wartime effort that drove the expansion and economic development of communities and related maritime service industries including the present-day Merchant Marines. The area is contiguous to the Captain John Smith Chesapeake National Historic Trail, the Star Spangled Banner National Historic Trail, the Potomac Heritage National Scenic Trail and the Lower Potomac Water Trail which offer meaningful educational and recreational opportunities centered on the region's culture, heritage and history. Additionally, the structure provided by the vessels and related infrastructure serve as important habitat to thriving populations of recreational fisheries, bald eagles, and other aquatic species. The area's listing on the National Historical Register of Places in 2015 codifies the historical, archaeological and recreational significance of the Ghost Fleet and related maritime heritage sites in and around Mallows Bay—Potomac River National Marine Sanctuary.

Article IV: Scope of Regulations

Section 1. Activities Subject to Regulation. The following activities are subject to regulation, including prohibition, to the extent necessary and reasonable to ensure the protection and management of the historical resources and recreational, research and educational qualities of the area:

a. Damaging sanctuary resources.

b. Damaging sanctuary property.

c. Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation issued under the Act.

Section 2. Emergencies. Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource; or minimize the imminent risk of such destruction, loss, or injury, any activity, including those not listed in Section 1, is subject to immediate temporary regulation. An emergency regulation shall not take effect without the approval of the Governor of Maryland or her/his designee or designated agency.

Article V: Relation to Other Regulatory Program

Section 1. Fishing Regulations, Licenses, and Permits. Fishing in the Sanctuary shall not be regulated as part of the Sanctuary management regime authorized by the Act. However, fishing in the Sanctuary may be regulated by other Federal, State, Tribal and local authorities of competent jurisdiction, and designation of the Sanctuary shall have no effect on any regulation, permit, or license issued thereunder.

Section 2. Other Regulations, Licenses, and Permits. If any valid regulation issued by any Federal, state, Tribal, or local authority of

competent jurisdiction, regardless of when issued, conflicts with a Sanctuary regulation, the regulation deemed by the Director of the Office of National Marine Sanctuaries, National Oceanic and Atmospheric Administration, or designee, in consultation with the State of Maryland, to be more protective of Sanctuary resources and qualities shall govern. Pursuant to section 304(c)(1) of the Act, 16 U.S.C. 1434(c)(1), no valid lease, permit, license, approval, or other authorization issued by any Federal, State, Tribal, or local authority of competent jurisdiction, or any right of subsistence use or access, may be terminated by the Secretary of Commerce, or designee, as a result of this designation, or as a result of any Sanctuary regulation, if such lease, permit, license, approval, or other authorization, or right of subsistence use or access was issued or in existence as of the effective date of this designation. However, the Secretary of Commerce or designee, in consultation with the State of Maryland, may regulate the exercise of such authorization or right consistent with the purposes for which the Sanctuary is designated.

Section 3. Defense Activities. Department of Defense activities must be carried out in a manner that avoids to the maximum extent practicable any adverse impacts on Sanctuary resources and qualities.

Article VI. Alteration of This Designation

The terms of designation may be modified only by the same procedures by which the original designation is made, including public meetings, consultation according to the NMSA.

Subpart T—[Added and Reserved]

■ 14. Add and reserve subpart T.

[FR Doc. 2016–31742 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 160907828–6828–01]

RIN 0648–BG01

Wisconsin—Lake Michigan National Marine Sanctuary; Notice of Proposed Rulemaking and Availability of Draft Environmental Impact Statement and Management Plan

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Proposed rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is proposing to designate an area of 1,075 square miles of Wisconsin state waters as the Wisconsin—Lake Michigan National Marine Sanctuary (WLMNMS or sanctuary). NOAA also proposes regulations to implement the sanctuary designation and establish the sanctuary's terms of designation. A draft environmental impact statement and draft management plan have also been prepared for this proposed action. The purpose of this action is to supplement current Wisconsin state regulations and resource protection efforts in a way that will ensure long term protection of the nationally significant collection of historic shipwrecks and other maritime heritage resources in the area. NOAA is soliciting public comment on the proposed rule, draft environmental impact statement (DEIS), and draft management plan (DMP). NOAA will also begin consultations under Section 106 of the National Historic Preservation Act (NHPA) and solicit public comments specifically related to the identification and assessment of the historic properties within the affected area in compliance with Section 106 review process.

DATES: NOAA will consider all comments received by March 31, 2017. Public meetings will be held on the following dates:

(1) March 13, 2017, 6:30 p.m. to 8:30 p.m., Algoma, WI;

(2) March 14, 2017, 6:30 p.m. to 8:30 p.m., Manitowoc, WI;

(3) March 15, 2017, 6:30 p.m. to 8:30 p.m., Sheboygan, WI; and

(4) March 16, 2017, 6:30 p.m. to 8:30 p.m., Port Washington, WI.

ADDRESSES: You may submit comments on this document, identified by NOAA–NOS–2016–0150, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0150,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Russ Green, Regional Coordinator, Northeast and Great Lakes Region, NOAA Office of National Marine Sanctuaries, University of Wisconsin—Sheboygan, One University Drive, Sheboygan, WI 53081.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NOAA will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the proposed rule, DEIS, and DMP can be downloaded or viewed on the internet at *www.regulations.gov* (search for docket #NOAA–NOS–2016–0150) or at *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0150.* Copies can also be obtained by contacting the person identified under **FOR FURTHER INFORMATION CONTACT.**

The public meeting locations are:

(1) *Algoma, WI:* Knudson Hall, 620 Lake Street, Algoma, WI 54201 (March 13, 2017)

(2) *Manitowoc, WI:* Wisconsin Maritime Museum, 75 Maritime Dr., Manitowoc, WI 54220 (March 14, 2017)

(3) *Sheboygan, WI:* University of Wisconsin—Sheboygan, Main Building, Wombat Room (Room 2114), 1 University Drive, Sheboygan, WI 53081 (March 15, 2017)

(4) *Port Washington, WI:* Wilson House, 200 N. Franklin St., Port Washington, WI 53074 (March 16, 2017)

FOR FURTHER INFORMATION CONTACT: Russ Green, Regional Coordinator, Northeast and Great Lakes Region at (920) 459–4425 or *russ.green@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Wisconsin—Lake Michigan National Marine Sanctuary Background

The National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce (Secretary) to designate and protect as national marine sanctuaries areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or esthetic qualities. Day-to-day management of national marine sanctuaries has been delegated by the Secretary to NOAA's Office of National Marine Sanctuaries (ONMS). The primary objective of the NMSA is to protect the sanctuary system's biological and cultural resources, such as coral reefs, marine animals, historic shipwrecks, other historic structures, and archaeological sites.

The 1,075-square-mile area proposed for designation as the Wisconsin—Lake Michigan National Marine Sanctuary

encompasses the waters and bottomlands of Lake Michigan adjacent to Manitowoc, Sheboygan, and Ozaukee Counties. Principal cities in this area include Port Washington, Sheboygan, Manitowoc, Two Rivers, and Mequon. The boundary includes 80 miles of shoreline and extends 7 to 16 miles from the shoreline.

The area includes a nationally significant collection of maritime heritage resources, including 37 known shipwrecks, about 80 suspected shipwrecks, and numerous other historic maritime-related features such as historic cribs, docks, and piers. The historic shipwrecks in the proposed sanctuary are representative of the vessels that sailed and steamed this corridor, carrying grain and raw materials east as other vessels came west loaded with coal, manufactured goods, and people. Eighteen of the 37 shipwreck sites are listed on the National Register of Historic Places. Many of the shipwrecks in the proposed sanctuary retain an unusual degree of architectural integrity, with 14 vessels nearly intact. Well preserved by Lake Michigan's cold, fresh water, the shipwrecks and related maritime heritage sites in and around the proposed Wisconsin—Lake Michigan National Marine Sanctuary possess exceptional historical, archaeological and recreational value.

On December 2, 2014, pursuant to section 304 of the NMSA and the Sanctuary Nomination Process (SNP; 79 FR 33851), Wisconsin Governor Scott Walker, on behalf of the State of Wisconsin; the Cities of Two Rivers, Manitowoc, Sheboygan, and Port Washington; the Counties of Ozaukee, Sheboygan, and Manitowoc, submitted a nomination asking NOAA to consider designating this area of Wisconsin's Lake Michigan waters as a national marine sanctuary. The State of Wisconsin's selection of this geographic area for the nomination drew heavily from a 2008 report conducted by the Wisconsin History Society and funded by the Wisconsin Coastal Management Program (*Wisconsin's Historic Shipwrecks: An Overview and Analysis of Locations for a State/Federal Partnership with the National Marine Sanctuary Program, 2008, http://www.maritimetrails.org/assets/pages/Wisconsins%20Historic%20Shipwrecks.pdf*). The nomination also identified opportunities for NOAA to strengthen and expand on resource protection, education, and research programs by state of Wisconsin agencies and in the four communities along the Lake Michigan coast. NOAA completed its review of the nomination, and on February 5, 2015 added the area to the inventory of nominations that are eligible for designation. All nominations submitted to NOAA can be found at: *http://www.nominate.noaa.gov/nominations/.*

NOAA began the sanctuary designation process for Wisconsin—Lake Michigan National Marine Sanctuary on October 7, 2015 with the publication of a notice of intent (NOI; 80 FR 60631) to prepare a DEIS and the initiation of a public process, as required under the NMSA and the National Environmental Policy Act (NEPA). The DEIS evaluates alternatives related to the proposed designation of the area, including a preferred alternative. The NOI also announced NOAA's intent to fulfill its responsibilities under the requirements of the NHPA.

A duplicate version of the notice for intent was published in error two days earlier on October 5, 2015 (80 FR 60132). That publication contained the exact same content as the official version made available for public inspection and published on October 7, 2015 (80 FR 60631). Any comments received in connection with the publication in error on October 5, 2015 were accepted and considered by NOAA.

B. Need for Action

Establishing a national marine sanctuary in Wisconsin waters would complement and supplement existing state-led preservation efforts, research programs, and public outreach initiatives. Threats to the nationally significant resources in the area include both human activities and natural processes. Natural process include the damaging impacts of wind, waves, storms, and ice, as well as the impact of invasive species such as zebra and quagga mussels that today cover most of Lake Michigan's shipwrecks. Human threats to underwater cultural resources include looting and altering sanctuary shipwreck sites and damaging sites by anchoring. These processes threaten the long term sustainability of historic shipwrecks and other underwater cultural resources, and negatively impact their recreational and archaeological value. Examples of these impacts include: Anchor damage from visiting dive boats, damage due to unpermitted and poorly attached mooring lines, artifacts being looted, artifacts being moved within a shipwreck site, a remotely-operated vehicle tether entangled within a shipwreck, fishing gear entangled within a shipwreck, increased invasive mussel coverage, and the disturbance and natural deterioration of newly uncovered shipwrecks within the boundary's large swaths of shallow, sandy lakebottom.

The sanctuary would enhance and facilitate broader lake conservation efforts as well as heritage tourism within the many communities that have embraced their centuries-long maritime relationship with Lake Michigan, the Great Lakes region, and the nation. A sanctuary designation would enhance existing comprehensive management programs. The presence of a sanctuary would provide access to NOAA's extended network of scientific expertise and technological resources, enhance ongoing research, and provide an umbrella for the coordination of these activities. It would support and build on existing educational initiatives and provide programming and technology for K–12, post-graduate, and the general public across the state. A sanctuary designation, the local commitment to the sanctuary, the existing state agency interest, and NOAA's existing network of affiliated programs has the potential to create synergies that reach far beyond the proposed sanctuary boundaries.

C. Designation Process

National Marine Sanctuary Designation Process

NOAA may identify areas to consider for national marine sanctuary designation through the community-based SNP described above. The process for designating a new national marine sanctuary is described in the NMSA and has four steps:

Scoping: NOAA announces its intent to designate a new national marine sanctuary and asks the public for input on potential boundaries, resources that could be protected, issues NOAA should consider and any information that should be included in the detailed resource analysis in a draft environmental impact statement.

Sanctuary Proposal: NOAA prepares draft designation documents including a DMP, DEIS that analyzes a range of alternatives, proposed regulations and proposed boundaries.

Public Review: The public, agency partners, tribes and other stakeholders provide input on the draft documents. The public review step also includes the formal consultations required under NEPA, the NMSA, the NHPA, and other relevant statutes. NOAA considers all input and determines appropriate changes.

Sanctuary Designation: NOAA makes a final decision and prepares final documents. Before the designation becomes effective, the Governor reviews

the documents. Congress also has the opportunity to review the documents.

Public Scoping Process

On October 7, 2015 NOAA initiated the public scoping process with the publication of the NOI in the **Federal Register** (80 FR 60631) asking for public input on the proposed designation and informing the public that NOAA intended to prepare a DEIS evaluating alternatives related to the proposed designation of Wisconsin-Lake Michigan National Marine Sanctuary under NMSA. That announcement initiated a 90-day public comment period during which NOAA solicited additional input related to the scale and scope of the proposed sanctuary, including ideas presented in the community nomination. The NOI also announced NOAA's intent to fulfill its responsibilities under the requirements of NHPA.

During the public comment period, NOAA hosted three public meetings in November 2015 and provided additional opportunity for comments through a web-based portal [*https://www.regulations.gov/#!docketDetail;D=NOAA-NOS-2015-0112*] and by traditional mail until January 15, 2016. All comments received, through any of these formats, were publicly posted on the *www.regulations.gov* web portal.

During this period, approximately 135 individuals provided input. Comments were overwhelmingly supportive of the goals of sanctuary designation, including the rationale for conservation of nationally-significant resources, considerations that enhance public use and recreation, considerations that enhance tourism and the local economy, and as a venue for education, science and interpretation as described in the community nomination.

The comments underscored the need for conservation and interpretation, particularly the importance of educating users about the importance of the Great Lakes and the role that shipbuilding and shipping commerce has played in the history of the region and our nation. There was strong support from local communities, governments, and organizations supporting sanctuary designation and offering opportunities to partner for education, research, outreach and other activities.

Several commenters who otherwise supported sanctuary designation expressed concern that designation should not in any way disrupt existing lake commerce. Specific concerns focused on the need for continued ability to dredge and maintain ports and the continued ability for ships to ballast in port and in open water.

The few comments in opposition to sanctuary designation were concerned about the cost of implementation, the possibility that designation would make metal detecting illegal, and that designation would be an unneeded level of government intervention.

There were several requests that NOAA consider expanding the proposed boundaries. Several comments suggesting expansion north to include shipwrecks in Kewaunee County, and one commenter requested inclusion of Green Bay.

NOAA used the public comments submitted during the scoping process to inform the preparation of the DMP, DEIS, and the proposed sanctuary regulations. In response to many of these comments, this proposed rule proposes to provide additional protection to maritime heritage resources, particularly the nationally significant collection of historic shipwrecks. The environmental effects of these proposed designations are analyzed in a DEIS published concurrently with this proposed rule. NOAA has also developed an associated DMP describing sanctuary management activities in the area proposed for designation. NOAA is seeking public comment on the proposed rule, DEIS, and DMP, which are available at *http://sanctuaries.noaa.gov/wisconsin/* or may be obtained by contacting the individual listed under the heading **FOR FURTHER INFORMATION CONTACT**.

II. Summary of the Proposed Regulations

1. Adding New Subpart T and Reserving Subpart S

NOAA is proposing to amend 15 CFR part 922 by adding a new subpart (subpart T) that contains site-specific regulations for WLMNMS. This subpart would include the proposed boundary, contain definitions of common terms used in the new subpart, provide a framework for co-management of the sanctuary, identify prohibited activities and exceptions, and establish procedures for certification of existing uses, permitting otherwise prohibited activities, and emergency regulation procedures. Several conforming changes would also be made to the national sanctuary regulations as described below.

NOAA is concurrently working on designating a separate new national marine sanctuary in Mallows Bay—Potomac River waters as part of a separate rulemaking process, and those regulations would be published in their own new subpart (subpart S). As such, in this rulemaking, NOAA proposes to add and reserve subpart S for any future site-specific regulations that might be issued. NOAA would harmonize the regulations for the Mallows Bay-Potomac River designation process with any final rule associated with this action.

2. Proposed Sanctuary Name

NOAA has proposed to name the sanctuary the ''Wisconsin—Lake Michigan National Marine Sanctuary (WLMNMS)'' based on the nomination submitted by the community. This name aptly identifies both the lake and state where the proposed sanctuary is located. NOAA is asking for the public to provide input on this proposed name. The public may also suggest an alternative name and state the reasons for suggesting an alternative name.

3. Proposed Sanctuary Boundary

NOAA is proposing to designate a 1,075-square mile area of Lake Michigan waters off Ozaukee, Sheboygan, and Manitowoc Counties as WLMNMS. The sanctuary's shoreward boundary would be defined by the Ordinary High Water Mark as defined by the state of Wisconsin, while the lakeward boundary would be drawn to include all known shipwrecks in each county, extending 16 miles offshore at its greatest extent. The harbors and marinas of Two Rivers, Manitowoc, Sheboygan, and Port Washington would not be included in the sanctuary. The detailed legal boundary description is included in section 922.210 and the coordinates are located in 15 CFR part 922, subpart T, appendix A. A map of the area is shown in the DEIS.

Within this proposed boundary are 37 known shipwrecks, including 18 on the National Register of Historic Places. The sanctuary would provide comprehensive protection of underwater cultural resources as well as develop partnerships and resources for education, interpretation, personnel, research, and administration. This would provide enhanced management of underwater cultural resources, as well as potential economic benefits to the coastal communities from Mequon to Two Rivers.

The proposed boundary reflects the boundary the State of Wisconsin submitted to NOAA in the nomination with an adjustment based on discussions with the State of Wisconsin. The State submitted an 875-square-mile boundary in the nomination. NOAA's adjustments result in a 1,075-square-mile boundary, and includes moving the southern and northern boundary lines to

the county lines and expanding the southeast corners to include the shipwreck site of the *Senator* (its location was previously unknown), and excluding ports and harbors.

4. Definitions

NOAA is proposing a site-specific definition of ''sanctuary resources'' for the WLMNMS to be tailored to include only the underwater cultural resources found in this area in accordance with the purpose of the proposed designation. The definition would not include biological and ecological resources of the area. Creating this new site-specific definition requires NOAA to modify the national definition of ''sanctuary resource'' in the national regulations at section 922.3 to add an additional sentence that defines the term for WLMNMS at section 922.211(a). This is similar to the approach taken for other national marine sanctuaries that do not share the full ''sanctuary resource'' definition such as Thunder Bay National Marine Sanctuary.

The new WLMNMS definition of ''sanctuary resources'' would be all prehistoric, historic, archaeological, and cultural sites and artifacts within the sanctuary boundary, including but not limited to, all shipwrecks and related components.

Additionally NOAA would add a definition for ''shipwreck site'' in the WLMNMS regulations at Section 922.211(a) that would define a subset of the ''sanctuary resources.'' The definition for ''shipwreck site'' would be more narrowly focused than the broader ''sanctuary resource'' definition and would be used in one of the prohibited activities regulations. ''Shipwreck site'' is defined as any sunken watercraft, its components, cargo, contents, and associated debris field.

This proposed rule incorporates and adopts other common terms defined in the existing national regulations at section 922.3. One of the common terms adopted (without modification) is ''National Marine Sanctuary'' or ''Sanctuary,'' which means an area of the marine environment of special national significance due to its resource or human-use values, which is designated as such to ensure its conservation and management.

5. Co-Management of the Sanctuary

In order to further enhance the engagement forged by the State of Wisconsin in nominating this area to become a national marine sanctuary, NOAA is proposing to manage the sanctuary collaboratively with the State of Wisconsin. NOAA proposes to establish the framework for co-management of the sanctuary at section 922.212 and intends to work out the operational details of the collaboration in a Memorandum of Understanding (MOU). Details on the execution of sanctuary management such as activities, programs, and permitting programs would be included in the MOU and can be updated to adapt to changing conditions or threats to the sanctuary resources. Any significant changes to the regulations or management plan would not only be jointly coordinated but also subject to public review.

6. Prohibited and Regulated Activities

NOAA is proposing to supplement and complement existing management of this area by proposing three regulations to protect the sanctuary resources in section 922.213(a).

a. Damaging Sanctuary Resources

As a complement to existing protections under state law and NHPA regulations, NOAA is proposing to prohibit moving, removing, recovering, altering, destroying, possessing or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a sanctuary resource. This sanctuary prohibition would supplement the existing Wisconsin regulations that prohibit damaging shipwrecks. Since 1991 Wisconsin has had state regulations related to removing or damaging shipwrecks that currently apply to the proposed area and would continue to apply to these resources after sanctuary designation.

b. Anchoring or Grappling on a Shipwreck Site

NOAA is proposing to prohibit the use of grappling hooks and anchoring devices into shipwreck sites to protect fragile shipwrecks within the sanctuary from damage. To provide the public adequate notice of shipwreck sites, NOAA will prepare and make available sanctuary maps with known and suspected shipwreck sites. Shipwreck sites not listed on maps would still be sanctuary resources and the prohibition on anchoring and grappling would still apply. The proposed management plan includes activities related to surveying the sanctuary area and identifying additional shipwreck sites. As appropriate, and in consideration of resource management conflicts, NOAA would update the maps as new shipwreck sites are found by the sanctuary, the Wisconsin Historical Society, or other public or private groups and individuals. Because NOAA seeks to promote public access, while also ensuring sound resource protection, an initial focus of the sanctuary management plan will be the installation of permanent mooring systems at sanctuary shipwreck sites. The moorings will provide a secure and convenient anchoring point for users, eliminating the need for grappling, and providing additional notice of the location of any known shipwreck site. NOAA is proposing to publish guidelines on best practices for anchoring near shipwrecks sites to avoid violating this prohibition. An example of a best practice could include instructions on using a weighted line, with a suggested maximum weight of 15 pounds, and surface float to mark a wreck for divers to descend and ascend. But the line would not use as an anchoring line; it would need to be continuously tended and removed before the dive boat leaves the area.

c. Interfering With Investigations

NOAA is proposing a regulation to prohibit interfering with sanctuary enforcement activities. This regulation will assist in NOAA's enforcement of the sanctuary regulations and strengthen sanctuary management.

d. Exemption for Emergencies and Law Enforcement

NOAA is proposing to include an exemption from the three regulations described above for activities that respond to emergencies that threaten lives, property or the environment, or are necessary for law enforcement purposes.

7. Emergency Regulations

As part of the proposed designation, NOAA is proposing to give the sanctuary authority to issue emergency regulations. Emergency regulations are used in limited cases and under specific conditions when there is an imminent risk to sanctuary resources and a temporary prohibition would prevent the destruction or loss of those resources. Under the NMSA, NOAA only issues emergency regulations that address an imminent risk for a fixed amount of time with a maximum of 6 months that can be extended a single time. A full rulemaking process must be undertaken, including a public comment period, to consider making an emergency regulation permanent. NOAA would add the authority to issue emergency regulations by modifying the national regulations at section 922.44 to include WLMNMS in a list of sanctuaries that have site-specific regulations related to emergency

regulations, and adding detailed site-specific emergency regulations to the WLMNMS regulations at section 922.214.

8. General Permits, Certifications, Authorizations, and Special Use Permits

a. General Permits

NOAA is proposing to include the authority to issue permits to allow certain activities that would otherwise violate the prohibitions in WLMNMS regulations. Similar to other national marine sanctuaries, NOAA is proposing to consider these permits for the purposes of education, research, or management.

To address the above additions to the ONMS general permit authority for WLMNMS, NOAA would amend regulatory text in the program-wide regulations in part 922, subpart E, to add references to subpart T, as appropriate. NOAA would also add a new section 922.215 in subpart T titled ''Permit procedures and review criteria'' that would address site-specific permit procedures for WLMNMS.

b. Certifications

Because of the possibility that preexisting activities, right of subsistence use or access permitted by other federal, state, local, or tribal agencies might be occurring within the WLMNMS area that would otherwise be prohibited by WLMNMS regulations, NOAA would add language at section 922.216 describing the process by which it can certify existing activities within the WLMNMS area. In compliance with the NMSA, WLMNMS regulations at section 922.216 would state that certification is the process by which permitted activities existing prior to the designation of the sanctuary that violate sanctuary prohibitions may be allowed to continue, provided certain conditions are met. Applications for certifying permitted existing uses would have to be received by NOAA within 180 days of the effective date of the designation.

c. Authorizations

NOAA also proposes to provide WLMNMS with the authority to consider allowing an otherwise prohibited activity if such activity is specifically authorized by any valid Federal, state, or local lease, permit, license, approval, or other authorization issued after sanctuary designation. Authorization authority is intended to streamline regulatory requirements by reducing the need for multiple permits and would apply to all proposed prohibitions at section 922.213. As such, NOAA proposes to amend the regulatory text at section 922.49 to add reference to subpart T.

d. Special Use Permits

NOAA has the authority under the NMSA to issue special use permits (SUPs) at national marine sanctuaries as established by Section 310 of the NMSA. SUPs can be used to authorize specific activities in a sanctuary if such authorization is necessary (1) to establish conditions of access to and use of any sanctuary resource; or (2) to promote public use and understanding of a sanctuary resource. The activities that qualify for a SUP are set forth in the **Federal Register** (78 FR 25957; May 3, 2013). Categories of SUPs may be changed or added to through public notice and comment. NOAA would not apply the SUP to activities in place at the time of the WLMNMS designation.

SUP applications are reviewed to ensure that the activity is compatible with the purposes for which the sanctuary is designated and that the activities carried out under the SUP be conducted in a manner that do not destroy, cause the loss of, or injure sanctuary resources. NOAA also requires SUP permittees to purchase and maintain comprehensive general liability insurance, or post an equivalent bond, against claims arising out of activities conducted under the permit. The NMSA allows NOAA to assess and collect fees for the conduct of any activity under a SUP. The fees collected could be used to recover the administrative costs of issuing the permit, the cost of implementing the permit, monitoring costs associated with the conduct of the activity, and the fair market value of the use of sanctuary resources.

9. Other Conforming Amendments

The general regulations in part 922, subpart A, for general information and part 922, subpart E, for regulations of general applicability would also have to be amended so that the regulations are accurate and up-to-date. The 10 sections that will need to be updated to reflect the increased number of sanctuaries or to add subpart T to the list of sanctuaries. The modified sections to conform to adding a new sanctuary are:

- Section 922.1 Applicability of regulations
- Section 922.40 Purpose
- Section 922.41 Boundaries
- Section 922.42 Allowed activities
- Section 922.43 Prohibited or otherwise regulated activities
- Section 922.44 Emergency regulations
- Section 922.47 Pre-existing authorizations or rights and certifications of pre-existing authorizations or rights
- Section 922.48 National Marine Sanctuary permits—application procedures and issuance criteria
- Section 922.49 Notification and review of applications for leases, licenses, permits, approvals, or other authorizations to conduct a prohibited activity
- Section 922.50 Appeals of administrative action

10. Terms of Designation

Section 304(a)(4) of the National Marine Sanctuaries Act (NMSA) requires that the terms of designation include the geographic area included within the sanctuary; the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or aesthetic value; and the types of activities that will be subject to regulation by the Secretary of Commerce to protect these characteristics. Section 304(a)(4) also specifies that the terms of designation may be modified only by the same procedures by which the original designation was made. Thus, the terms of designation serve as a constitution for the Sanctuary.

NOAA is proposing to establish terms to designation that describe the geographic area, resources, and activities as described in details above. NOAA would add the terms of designation language as appendix B to the WLMNMS regulations at 15 CFR part 922, subpart T.

III. Classification

National Marine Sanctuaries Act

NOAA has determined that the designation of the Wisconsin—Lake Michigan National Marine Sanctuary will not have a negative impact on the National Marine Sanctuary System and that sufficient resources exist to effectively implement sanctuary management plans and to update site characterizations. The finding for NMSA section 304(f) is published on the ONMS Web site for Wisconsin-Lake Michigan designation at *http://sanctuaries.noaa.gov/wisconsin/*.

National Environmental Policy Act

NOAA has prepared a draft environmental impact statement to evaluate the environmental effects of the proposed rulemaking and alternatives as required by NEPA (42 U.S.C. 4321 *et seq.*) and the NMSA. Copies of the DEIS and related DMP are available at the address and Web site listed in the **ADDRESSES** section of this proposed rule. NOAA is also soliciting public

comments on the DEIS and DMP. Responses to comments received on this proposed rule as well as on the DEIS and draft management plan will be published in the final environmental impact statement and preamble to the final rule.

Coastal Zone Management Act

Section 307 of the Coastal Zone Management Act (CZMA; 16 U.S.C. 1456) requires Federal agencies to consult with a state's coastal program on potential Federal regulations having an effect on state waters. Because WLMNMS encompasses a portion of the Wisconsin State waters, NOAA intends to submit a copy of this proposed rule and supporting documents to the State of Wisconsin Coastal Zone Management Program for evaluation of Federal consistency under the CZMA. NOAA will publish the final rule and designation only after completion of the consultation requirements under the CZMA.

Executive Order 12866: Regulatory Impact

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132 because NOAA supplements and complements state and local laws under the NMSA.

National Historic Preservation Act

The National Historic Preservation Act (NHPA; 16 U.S.C. 470 *et seq.*) is intended to preserve historical and archaeological sites in the United States of America. The act created the National Register of Historic Places, the list of National Historic Landmarks, and State Historic Preservation Offices. Section 106 of the NHPA requires Federal agencies to take into account the effects of their undertakings on historic properties, and afford the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment. The historic preservation review process mandated by Section 106 is outlined in regulations issued by ACHP (36 CFR part 800 *et seq.*). In fulfilling its responsibilities under the NHPA, NOAA is seeking to identify consulting parties in addition to the State Historic Preservation Officer (SHPO), and will complete the identification of historic properties and the assessment of the effects of the undertaking on such properties in scheduled consultations with those identified parties and the SHPO. By this notice NOAA seeks public input, particularly in regard to the identification of historic properties within the proposed areas of potential effect. Pursuant to 36 CFR 800.16(l)(1), historic properties includes: ''any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. The term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria.'' If you, your organization(s), or business(es) would like to be considered a ''consulting party'' under Section 106 please contact the individual listed under the heading **FOR FURTHER INFORMATION CONTACT**; include contact information for the principal representative for the consultation; and describe you or your party's interest in the proposed designation. In accordance with 36 CFR 800.3(f)(3), NOAA will consider all ''consulting party'' requests but has ultimate discretion in determining and inviting additional consulting parties.

Regulatory Flexibility Act

This analysis seeks to fulfill the requirements of Executive Order 12866 and the Regulatory Flexibility Act. The Small Business Administration has established thresholds on the designation of businesses as ''small entities''. A finfish fishing businesses is considered a small business if it has annual receipts of less than $20.5 million. Scenic and Sightseeing and Recreational industries are considered small businesses if they have annual receipts not in excess of $7.5 million. According to these limits, each of the businesses potentially affected by the proposed rule would most likely be small businesses. However, as further discussed below, these regulations will not have a significant economic impact on the affected small entities, and the Chief Counsel for Regulations for the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have significant economic impact on a substantial number of small entities. Thus, NOAA is not required to and has not prepared an initial regulatory flexibility analysis.

Methodology. The analysis here is based on limited quantitative information on how much each activity occurs within the proposed sanctuary. Consequently, the result is more qualitative than quantitative.

Scales Used for Assessing Impacts. For assessing levels of impacts within an alternative, NOAA used three levels; ''negligible'', ''moderate'' and ''high'' plus ''no impacts''. For levels of impacts within the proposed alternatives being analyzed, negligible means very low benefits, costs, or net benefits (less than 1% change). Moderate impacts would be more than 1% but less than or equal to 10%, and high impacts would be more than 10%. For market economic values (revenue, costs, and profits), negligible would mean no likely impact whereas moderate and high could mean some measurable impact on market economic values at the levels noted above. NOAA analyzed the proposed national marine sanctuary described above.

Small business user groups include commercial fishing operation, recreation-tourism related businesses, and land use and development businesses. Other user groups not included here are research and education, people who receive passive economic use value from stabilization or improvement to the proposed sanctuary resources, none of whom are small businesses.

Proposed Action

Prohibition on damaging a sanctuary resource. Small businesses that could potentially be impacted from the proposed prohibition on damaging a sanctuary resource include commercial fishing, recreational fishing and diving. This regulation is expected to have no to minimal impact on commercial fishermen because it is coextensive with existing state law. The sanctuary will assist the state in notifying the public, including fishermen of the locations of known and suspected shipwreck sites, which will enable them to avoid snagging and damaging their gear on shipwreck sites. Lastly divers and other recreational water users will still be able to use the resource, but will not able to take sanctuary resources. Therefore the impact for this user group from this prohibition is ''no impact''.

Prohibition on anchoring or grappling into a shipwreck site. Commercial fishermen use trap nets or gill nets which are anchored down, but it is unlikely that fishermen would anchor their nets near known shipwrecks due to snagging and the potential to have their gear damaged. Thus, the expected impact to commercial fishermen is

negligible. The impact is also expected to be negligible for dive charters who would no longer be able to anchor on or grapple into a shipwreck site. NOAA is planning to add mooring buoys and provide anchoring best practices guidelines to facilitate divers to visit the shipwreck sites without damaging the fragile wrecks.

Prohibition on interfering with an investigation. There is no evidence that any small business in the area would be affected by this prohibition. Therefore, the prohibition is expected to have no impact on small businesses.

Thus, the overall expected impact to all these business in the preferred alternative is ''no impact,'' and the Chief Counsel for Regulations for the Department of Commerce has certified that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

ONMS has a valid Office of Management and Budget (OMB) control number (0648–0141) for the collection of public information related to the processing of ONMS permits across the National Marine Sanctuary System. NOAA's proposal to create WLMNMS would likely result in an increase in the number of requests for ONMS general permits, special use permits, certifications, and authorizations because this action proposes to add general permits and special use permits, certifications, appeals, and the authority to authorize other valid federal, state, or local leases, permits, licenses, approvals, or other authorizations. An increase in the number of ONMS permit requests would require a change to the reporting burden certified for OMB control number 0648–0141. An update to this control number for the processing of ONMS permits would be requested as part of the final rule for sanctuary expansion.

Nationwide, NOAA issues approximately 500 national marine sanctuary permits each year. Of this amount, WLMNMS is expected to add 4 to 5 permit requests per year. The public reporting burden for national marine sanctuaries permits is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information.

Send comments regarding the burden estimate for this data collection requirement, or any other aspect of this data collection, including suggestions for reducing the burden, to NOAA (see **ADDRESSES**) and by email to *OIRA_submission@omb.eop.gov,* or fax to (202) 395–7285. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

IV. Request for Comments

NOAA requests comments on this proposed rule by March 31, 2017. In additional to requesting comments on this proposed rule, NOAA is also soliciting input on the DEIS and DMP. In addition NOAA would like the public comments on the proposed name for the sanctuary.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Historic preservation, Intergovernmental relations, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Wildlife.

Dated: December 22, 2016.

W. Russell Callender,

Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons discussed in the preamble, the National Oceanic and Atmospheric Administration proposes to amend 15 CFR part 922 as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for 15 CFR part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

■ 2. Revise § 922.1 to read as follows:

§ 922.1 Applicability of regulations.

Unless noted otherwise, the regulations in subparts A, D, and E of this part apply to all National Marine Sanctuaries and related site-specific regulations set forth in this part. Subparts B and C of this part apply to the sanctuary nomination process and to the designation of future Sanctuaries.

■ 3. Amend § 922.3 by revising the definition of ''Sanctuary resource'' to read as follows:

§ 922.3 Definitions.

* * * * *

Sanctuary resource means any living or non-living resource of a National Marine Sanctuary that contributes to the conservation, recreational, ecological, historical, research, educational, or aesthetic value of the Sanctuary, including, but not limited to, the substratum of the area of the Sanctuary, other submerged features and the surrounding seabed, carbonate rock, corals and other bottom formations, coralline algae and other marine plants and algae, marine invertebrates, brine-seep biota, phytoplankton, zooplankton, fish, seabirds, sea turtles and other marine reptiles, marine mammals and historical resources. For Thunder Bay National Marine Sanctuary and Underwater Preserve, Sanctuary resource means an underwater cultural resource as defined at § 922.191. For Wisconsin—Lake Michigan National Marine Sanctuary, sanctuary resource is defined at § 922.211(a).

* * * * *

■ 4. Revise § 922.40 to read as follows:

§ 922.40 Purpose.

The purpose of the regulations in this subpart and in the site-specific subparts is to implement the designations of the National Marine Sanctuaries by regulating activities affecting them, consistent with their respective terms of designation in order to protect, preserve and manage and thereby ensure the health, integrity and continued availability of the conservation, ecological, recreational, research, educational, historical and aesthetic resources and qualities of these areas. Additional purposes of the regulations implementing the designation of the Florida Keys and Hawaiian Islands Humpback Whale National Marine Sanctuaries are found at §§ 922.160 and 922.180, respectively.

■ 5. Revise § 922.41 to read as follows:

§ 922.41 Boundaries.

The boundary for each of the National Marine Sanctuaries is set forth in the site-specific regulations covered by this part.

■ 6. Revise § 922.42 to read as follows:

§ 922.42 Allowed activities.

All activities (*e.g.,* fishing, boating, diving, research, education) may be conducted unless prohibited or otherwise regulated in the site-specific regulations covered by this part, subject to any emergency regulations promulgated under this part, subject to all prohibitions, regulations, restrictions, and conditions validly imposed by any Federal, State, or local authority of competent jurisdiction, including but not limited to, Federal, Tribal, and State fishery management authorities, and subject to the provisions of section 312 of the National Marine Sanctuaries Act (NMSA), (16 U.S.C. 1431 *et seq.*). The Assistant Administrator may only directly

regulate fishing activities pursuant to the procedure set forth in section 304(a)(5) of the NMSA.

■ 7. Revise § 922.43 to read as follows:

§ 922.43 Prohibited or otherwise regulated activities.

The site-specific regulations applicable to the activities specified therein are set forth in the subparts covered by this part.

■ 8. Revise § 922.44 to read as follows:

§ 922.44 Emergency regulations.

(a) Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality, or minimize the imminent risk of such destruction, loss, or injury, any and all such activities are subject to immediate temporary regulation, including prohibition.

(b) The provisions of this section do not apply to the following national marine sanctuaries with site-specific regulations that establish procedures for issuing emergency regulations:

(1) Cordell Bank National Marine Sanctuary, § 922.112(e).

(2) Florida Keys National Marine Sanctuary, § 922.165.

(3) Hawaiian Islands Humpback Whale National Marine Sanctuary, § 922.185.

(4) Thunder Bay National Marine Sanctuary, § 922.196.

(5) [Reserved]

(6) Wisconsin—Lake Michigan National Marine Sanctuary, § 922.214.

■ 9. Amend § 922.47 by revising paragraph (b) to read as follows:

§ 922.47 Pre-existing authorizations or rights and certifications of pre-existing authorizations or rights.

* * * * *

(b) The prohibitions listed in subparts F through P and R through T of this part do not apply to any activity authorized by a valid lease, permit, license, approval or other authorization in existence on the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, and issued by any Federal, State or local authority of competent jurisdiction, or by any valid right of subsistence use or access in existence on the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, provided that the holder of such authorization or right complies with certification procedures and criteria promulgated at the time of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, and with any terms and conditions on the exercise of such authorization or right imposed by the Director as a condition of certification as the Director deems necessary to achieve the purposes for which the Sanctuary was designated.

■ 10. Revise § 922.48 to read as follows:

§ 922.48 National Marine Sanctuary permits—application procedures and issuance criteria.

(a) A person may conduct an activity prohibited by subparts F through O and S and T of this part, if conducted in accordance with the scope, purpose, terms and conditions of a permit issued under this section and subparts F through O and S and T, as appropriate. For the Florida Keys National Marine Sanctuary, a person may conduct an activity prohibited by subpart P of this part if conducted in accordance with the scope, purpose, terms and conditions of a permit issued under § 922.166. For the Thunder Bay National Marine Sanctuary and Underwater Preserve, a person may conduct an activity prohibited by subpart R of this part in accordance with the scope, purpose, terms and conditions of a permit issued under § 922.195.

(b) Applications for permits to conduct activities otherwise prohibited by subparts F through O and S and T of this part, should be addressed to the Director and sent to the address specified in subparts F through O of this part, or subparts R through T of this part, as appropriate. An application must include:

(1) A detailed description of the proposed activity including a timetable for completion;

(2) The equipment, personnel and methodology to be employed;

(3) The qualifications and experience of all personnel;

(4) The potential effects of the activity, if any, on Sanctuary resources and qualities; and

(5) Copies of all other required licenses, permits, approvals or other authorizations.

(c) Upon receipt of an application, the Director may request such additional information from the applicant as he or she deems necessary to act on the application and may seek the views of any persons or entity, within or outside the Federal government, and may hold a public hearing, as deemed appropriate.

(d) The Director, at his or her discretion, may issue a permit, subject to such terms and conditions as he or she deems appropriate, to conduct a prohibited activity, in accordance with the criteria found in subparts F through O of this part, or subparts R through T of this part, as appropriate. The Director shall further impose, at a minimum, the conditions set forth in the relevant subpart.

(e) A permit granted pursuant to this section is nontransferable.

(f) The Director may amend, suspend, or revoke a permit issued pursuant to this section for good cause. The Director may deny a permit application pursuant to this section, in whole or in part, if it is determined that the permittee or applicant has acted in violation of the terms and conditions of a permit or of the regulations set forth in this section or subparts F through O of this part, or subparts R through T of this part or for other good cause. Any such action shall be communicated in writing to the permittee or applicant by certified mail and shall set forth the reason(s) for the action taken. Procedures governing permit sanctions and denials for enforcement reasons are set forth in subpart D of 15 CFR part 904.

■ 11. Revise § 922.49 to read as follows:

§ 922.49 Notification and review of applications for leases, licenses, permits, approvals, or other authorizations to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by subparts L through P of this part, or subparts R through T of this part, if such activity is specifically authorized by any valid Federal, State, or local lease, permit, license, approval, or other authorization issued after the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary after the effective date of the regulations in subpart P, provided that:

(1) The applicant notifies the Director, in writing, of the application for such authorization (and of any application for an amendment, renewal, or extension of such authorization) within fifteen (15) days of the date of filing of the application or the effective date of Sanctuary designation, or in the case of the Florida Keys National Marine Sanctuary the effective date of the regulations in subpart P, whichever is later;

(2) The applicant complies with the other provisions of this section;

(3) The Director notifies the applicant and authorizing agency that he or she does not object to issuance of the authorization (or amendment, renewal, or extension); and

(4) The applicant complies with any terms and conditions the Director deems reasonably necessary to protect Sanctuary resources and qualities.

(b) Any potential applicant for an authorization described in paragraph (a)

of this section may request the Director to issue a finding as to whether the activity for which an application is intended to be made is prohibited by subparts L through P of this part, or subparts R through T of this part, as appropriate.

(c) Notification of filings of applications should be sent to the Director, Office of National Marine Sanctuaries at the address specified in subparts L through P of this part, or subparts R through T of this part, as appropriate. A copy of the application must accompany the notification.

(d) The Director may request additional information from the applicant as he or she deems reasonably necessary to determine whether to object to issuance of an authorization described in paragraph (a) of this section, or what terms and conditions are reasonably necessary to protect Sanctuary resources and qualities. The information requested must be received by the Director within 45 days of the postmark date of the request. The Director may seek the views of any persons on the application.

(e) The Director shall notify, in writing, the agency to which application has been made of his or her pending review of the application and possible objection to issuance. Upon completion of review of the application and information received with respect thereto, the Director shall notify both the agency and applicant, in writing, whether he or she has an objection to issuance and what terms and conditions he or she deems reasonably necessary to protect Sanctuary resources and qualities, and reasons therefor.

(f) The Director may amend the terms and conditions deemed reasonably necessary to protect Sanctuary resources and qualities whenever additional information becomes available justifying such an amendment.

(g) Any time limit prescribed in or established under this section may be extended by the Director for good cause.

(h) The applicant may appeal any objection by, or terms or conditions imposed by, the Director to the Assistant Administrator or designee in accordance with the provisions of § 922.50.

■ 12. Revise § 922.50 to read as follows:

§ 922.50 Appeals of administrative action.

(a)(1) Except for permit actions taken for enforcement reasons (see subpart D of 15 CFR part 904 for applicable procedures), an applicant for, or a holder of, a National Marine Sanctuary permit; an applicant for, or a holder of, a Special Use permit issued pursuant to section 310 of the Act; a person requesting certification of an existing lease, permit, license or right of subsistence use or access under § 922.47; or, for those Sanctuaries described in subparts L through P and R through T of this part, an applicant for a lease, permit, license or other authorization issued by any Federal, State, or local authority of competent jurisdiction (hereinafter appellant) may appeal to the Assistant Administrator:

(i) The granting, denial, conditioning, amendment, suspension or revocation by the Director of a National Marine Sanctuary or Special Use permit;

(ii) The conditioning, amendment, suspension or revocation of a certification under § 922.47; or

(iii) For those Sanctuaries described in subparts L through P and subpart R through T, the objection to issuance of or the imposition of terms and conditions on a lease, permit, license or other authorization issued by any Federal, State, or local authority of competent jurisdiction.

(2) For those National Marine Sanctuaries described in subparts F through K and S and T of this part, any interested person may also appeal the same actions described in paragraphs (a)(1)(i) and (ii) of this section. For appeals arising from actions taken with respect to these National Marine Sanctuaries, the term ''appellant'' includes any such interested persons.

(b) An appeal under paragraph (a) of this section must be in writing, state the action(s) by the Director appealed and the reason(s) for the appeal, and be received within 30 days of receipt of notice of the action by the Director. Appeals should be addressed to the Assistant Administrator for Ocean Services and Coastal Zone Management, NOAA 1305 East-West Highway, 13th Floor, Silver Spring, MD 20910.

(c)(1) The Assistant Administrator may request the appellant to submit such information as the Assistant Administrator deems necessary in order for him or her to decide the appeal. The information requested must be received by the Assistant Administrator within 45 days of the postmark date of the request. The Assistant Administrator may seek the views of any other persons. For the Monitor National Marine Sanctuary, if the appellant has requested a hearing, the Assistant Administrator shall grant an informal hearing. For all other National Marine Sanctuaries, the Assistant Administrator may determine whether to hold an informal hearing on the appeal. If the Assistant Administrator determines that an informal hearing should be held, the Assistant Administrator may designate an officer before whom the hearing shall be held.

(2) The hearing officer shall give notice in the **Federal Register** of the time, place and subject matter of the hearing. The appellant and the Director may appear personally or by counsel at the hearing and submit such material and present such arguments as deemed appropriate by the hearing officer. Within 60 days after the record for the hearing closes, the hearing officer shall recommend a decision in writing to the Assistant Administrator.

(d) The Assistant Administrator shall decide the appeal using the same regulatory criteria as for the initial decision and shall base the appeal decision on the record before the Director and any information submitted regarding the appeal, and, if a hearing has been held, on the record before the hearing officer and the hearing officer's recommended decision. The Assistant Administrator shall notify the appellant of the final decision and the reason(s) therefore in writing. The Assistant Administrator's decision shall constitute final agency action for the purpose of the Administrative Procedure Act.

(e) Any time limit prescribed in or established under this section other than the 30-day limit for filing an appeal may be extended by the Assistant Administrator or hearing office for good cause.

Subpart S—[Added and Reserved]

■ 13. Add and reserve subpart S.

■ 14. Add subpart T to read as follows:

SUBPART T—WISCONSIN-LAKE MICHIGAN NATIONAL MARINE SANCTUARY

Sec.

922.210 Boundary.
922.211 Definitions.
922.212 Co-management.
922.213 Prohibited or otherwise regulated activities.
922.214 Emergency regulations.
922.215 Permit procedures and review criteria.
922.216 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.
Appendix A to Subpart T of Part 922—Wisconsin-Lake Michigan Marine Sanctuary Boundary Description and Coordinates of the Lateral Boundary Closures and Excluded Areas
Appendix B to Subpart T of Part 922—Wisconsin-Lake Michigan Marine Sanctuary Terms of Designation

§ 922.210 Boundary.

The Wisconsin-Lake Michigan National Marine Sanctuary consists of an area of approximately 812 square nautical miles (nmi2) (1,075 sq. mi) of

Lake Michigan waters within the state of Wisconsin and the submerged lands thereunder, over, around, and under the submerged underwater cultural resources in Lake Michigan. The precise boundary coordinates are listed in appendix A to this subpart. The eastern boundary of the sanctuary begins approximately 9.5 miles east of the Wisconsin shoreline in Lake Michigan at Point 1 roughly on the border between Manitowoc and Kewaunee County. From this point the boundary continues SSW in a straight line to Point 2 and then SW to Point 3 at roughly the border between Ozaukee and Milwaukee County. From this point the boundary continues west towards Point 4 until it intersects the shoreline at the ordinary high water mark near Mequon, WI. From this intersection the boundary continues north following the shoreline cutting across the mouths of creeks and streams until it intersects the line segment formed between Point 5 and Point 6 at the end of the southern breakwater at the mouth of Sauk Creek at Port Washington. From this intersection the boundary continues across the river mouth towards Point 6 until it intersects the shoreline at the ordinary high water mark at the end of the northern breakwater. From this intersection the boundary continues north following the shoreline until it intersects the line segment formed between Point 7 and Point 8 at the end of the southern breakwater at the mouth of the Sheboygan River. From this intersection the boundary continues across the river mouth towards Point 8 until it intersects the shoreline at the ordinary high water mark at the end of the northern breakwater. From this intersection the boundary continues north along the shoreline until it intersects the line segment formed between Point 9 and Point 10 at the end of the southern breakwater at the mouth of Manitowoc Harbor. From this intersection the boundary continues across the harbor mouth towards Point until it intersects the shoreline at the ordinary high water mark10 at the end of the northern breakwater. From this intersection the boundary continues north following the shoreline until it intersects the line segment formed between Point 11 and Point 12 at the end of the western breakwater at the mouth of East Twin River. From this intersection the boundary continues across the river mouth towards Point 12 until it intersects the shoreline at the ordinary high water mark at the end of the eastern breakwater. From this intersection the boundary follows the shoreline NE around Rawley Point and then NNW until it intersects the line segment formed between Point 13 and Point 14 along the shoreline at approximately the border between Manitowoc and Kewaunee County near Twin Creeks, WI. Finally, from this intersection the boundary moves east across Lake Michigan to Point 14.

§ 922.211 Definitions.

(a) The following terms are defined for purposes of this subpart:

(1) *Sanctuary resource* means all prehistoric, historic, archaeological, and cultural sites and artifacts within the sanctuary boundary, including but not limited to, all shipwrecks and related components.

(2) *Shipwreck site* means any sunken watercraft, its components, cargo, contents, and associated debris field.

(b) All other terms appearing in the regulations in this subpart are defined at 15 CFR 922.3, and/or in the Marine Protection, Research, and Sanctuaries Act, as amended, 33 U.S.C. 1401 *et seq.,* and 16 U.S.C. 1431 *et seq.*

§ 922.212 Co-management.

NOAA has primary responsibility for the management of the Sanctuary pursuant to the Act. However, as the Sanctuary is in state waters, NOAA will co-manage the Sanctuary in collaboration with the State of Wisconsin. The Director may enter into a Memorandum of Understanding regarding this collaboration that may address, but not be limited to, such aspects as areas of mutual concern, including Sanctuary resource protection, programs, permitting, activities, development, and threats to Sanctuary resources.

§ 922.213 Prohibited or otherwise regulated activities.

(a) Except as specified in paragraph (b) of this section, the following activities are prohibited and thus are unlawful for any person to conduct or to cause to be conducted:

(1) Moving, removing, recovering, altering, destroying, possessing, or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a sanctuary resource.

(2) Grappling into or anchoring on shipwreck sites.

(3) Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation or any permit issued under the Act.

(b) The prohibitions in paragraphs (a)(1) through (3) of this section do not apply to any activity necessary to respond to an emergency threatening life, property or the environment; or to activities necessary for valid law enforcement purposes.

§ 922.214 Emergency regulations.

(a) Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource, or to minimize the imminent risk of such destruction, loss, or injury, any and all activities are subject to immediate temporary regulation, including prohibition. An emergency regulation shall not take effect without the approval of the Governor of Wisconsin or her/his designee or designated agency.

(b) Emergency regulations remain in effect until a date fixed in the rule or six months after the effective date, whichever is earlier. The rule may be extended once for not more than six months.

§ 922.215 Permit procedures and review criteria.

(a) *Authority to issue general permits.* The Director may allow a person to conduct an activity that would otherwise be prohibited by this subpart, through issuance of a general permit, provided the applicant complies with:

(1) The provisions of subpart E of this part; and

(2) The relevant site specific regulations appearing in this subpart.

(b) *Sanctuary general permit categories.* The Director may issue a sanctuary general permit under this subpart, subject to such terms and conditions as he or she deems appropriate, if the Director finds that the proposed activity falls within one of the following categories:

(1) Research—activities that constitute scientific research on or scientific monitoring of national marine sanctuary resources or qualities;

(2) Education—activities that enhance public awareness, understanding, or appreciation of a national marine sanctuary or national marine sanctuary resources or qualities; or

(3) Management—activities that assist in managing a national marine sanctuary.

(c) *Review criteria.* The Director shall not issue a permit under this subpart, unless he or she also finds that:

(1) The proposed activity will be conducted in a manner compatible with the primary objective of protection of national marine sanctuary resources and qualities, taking into account the following factors:

(i) The extent to which the conduct of the activity may diminish or enhance national marine sanctuary resources and qualities; and

(ii) Any indirect, secondary or cumulative effects of the activity.

(2) It is necessary to conduct the proposed activity within the national marine sanctuary to achieve its stated purpose.

(3) The methods and procedures proposed by the applicant are appropriate to achieve the proposed activity's stated purpose and eliminate, minimize, or mitigate adverse effects on sanctuary resources and qualities as much as possible.

(4) The duration of the proposed activity and its effects are no longer than necessary to achieve the activity's stated purpose.

(5) The expected end value of the activity to the furtherance of national marine sanctuary goals and purposes outweighs any potential adverse impacts on sanctuary resources and qualities from the conduct of the activity.

(6) The applicant is professionally qualified to conduct and complete the proposed activity.

(7) The applicant has adequate financial resources available to conduct and complete the proposed activity and terms and conditions of the permit.

(8) There are no other factors that would make the issuance of a permit for the activity inappropriate.

§ 922.216 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by § 922.213(a)(1) through (3) if such activity is specifically authorized by a valid Federal, state, or local lease, permit, license, approval, or other authorization, or tribal right of subsistence use or access in existence prior to the effective date of sanctuary designation and within the sanctuary designated area and complies with § 922.49 and provided that the holder of the lease, permit, license, approval, or other authorization complies with the requirements of paragraph (e) of this section.

(b) In considering whether to make the certifications called for in this section, the Director may seek and consider the views of any other person or entity, within or outside the Federal government, and may hold a public hearing as deemed appropriate.

(c) The Director may amend, suspend, or revoke any certification made under this section whenever continued operation would otherwise be inconsistent with any terms or conditions of the certification. Any such action shall be forwarded in writing to both the holder of the certified permit, license, or other authorization and the issuing agency and shall set forth reason(s) for the action taken.

(d) Requests for findings or certifications should be addressed to the Director, Office of National Marine Sanctuaries; ATTN: Sanctuary Superintendent, Wisconsin-Lake Michigan National Marine Sanctuary, 1305 East-West Hwy, 11th Floor, Silver Spring, MD 20910. A copy of the lease, permit, license, approval, or other authorization must accompany the request.

(e) For an activity described in paragraph (a) of this section, the holder of the authorization or right may conduct the activity prohibited by § 922.213(a)(1) through (3) provided that:

(1) The holder of such authorization or right notifies the Director, in writing, within 180 days of the effective date of Sanctuary designation, of the existence of such authorization or right and requests certification of such authorization or right;

(2) The holder complies with the other provisions of this section; and

(3) The holder complies with any terms and conditions on the exercise of such authorization or right imposed as a condition of certification, by the Director, to achieve the purposes for which the Sanctuary was designated.

(f) The holder of an authorization or right described in paragraph (a) of this section authorizing an activity prohibited by § 922.213 may conduct the activity without being in violation of applicable provisions of § 922.213, pending final agency action on his or her certification request, provided the holder is otherwise in compliance with this section.

(g) The Director may request additional information from the certification requester as he or she deems reasonably necessary to condition appropriately the exercise of the certified authorization or right to achieve the purposes for which the Sanctuary was designated. The Director must receive the information requested within 45 days of the postmark date of the request. The Director may seek the views of any persons on the certification request.

(h) The Director may amend any certification made under this section whenever additional information becomes available that he/she determines justifies such an amendment.

(i) Upon completion of review of the authorization or right and information received with respect thereto, the Director shall communicate, in writing, any decision on a certification request or any action taken with respect to any certification made under this section, in writing, to both the holder of the certified lease, permit, license, approval, other authorization, or right, and the issuing agency, and shall set forth the reason(s) for the decision or action taken.

(j) The holder may appeal any action conditioning, amending, suspending, or revoking any certification in accordance with the procedures set forth in § 922.50.

(k) Any time limit prescribed in or established under this section may be extended by the Director for good cause.

Appendix A to Subpart T of Part 922—Wisconsin-Lake Michigan Marine Sanctuary Boundary Description and Coordinates of the Lateral Boundary Closures and Excluded Areas

Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983.

TABLE A1—COORDINATES FOR SANCTUARY

Point ID	Latitude	Longitude
1	44.32749	−87.34795
2	43.45716	−87.48817
3	43.19198	−87.62813
4*	43.19203	−87.89245
5*	43.38447	−87.86079
6*	43.38523	−87.85963
7*	43.74858	−87.69479
8*	43.74946	−87.69265
9*	44.09135	−87.64377
10*	44.09262	−87.64373
11*	44.14226	−87.56161
12*	44.14267	−87.56069
13*	44.32751	−87.54400
14	44.32749	−87.34795

Note: The coordinates in the table above marked with an asterisk (*) are not a part of the sanctuary boundary. These coordinates are landward reference points used to draw a line segment that intersects with the shoreline.

Appendix B to Subpart T of Part 922—Wisconsin-Lake Michigan Marine Sanctuary Terms of Designation

Terms of Designation for the Proposed Wisconsin-Lake Michigan National Marine Sanctuary Under the authority of the National Marine Sanctuaries Act, as amended (the ''Act'' or ''NMSA''), 16 U.S.C. 1431 *et seq.,* 1,075 square miles of Lake Michigan off the coast of Wisconsin's coastal counties of Ozaukee, Sheboygan and Manitowoc are hereby designated as a National Marine Sanctuary for the purposes of providing long-term protection and management of the historical resources and recreational, research, educational, and aesthetic qualities of the area.

Article I: Effect of Designation

The NMSA authorizes the issuance of such regulations as are necessary and reasonable to implement the designation, including managing and protecting the historical resources and recreational, research, and educational qualities of the Wisconsin-Lake Michigan National Marine Sanctuary (the ''Sanctuary''). Section 1 of Article IV of this Designation Document lists those activities that may have to be regulated on the effective date of designation, or at some later date, in order to protect Sanctuary resources and qualities. Listing an activity does not necessarily mean that it will be regulated; however, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original Sanctuary designation was made.

Article II: Description of the Area

The Wisconsin-Lake Michigan National Marine Sanctuary consists of an area of approximately 812 square nautical miles (nmi2) (1,075 sq. mi) of Lake Michigan waters within the state of Wisconsin and the submerged lands thereunder, over, around, and under the submerged underwater cultural resources in Lake Michigan. The eastern boundary of the sanctuary begins approximately 9.5 miles east of the Wisconsin shoreline in Lake Michigan roughly on the border between Manitowoc and Kewaunee County. From this point the boundary continues in Lake Michigan roughly to the SSW until it intersects the border between Ozaukee and Milwaukee County at a point approximately 13 miles east of the shoreline. The southern boundary continues west approximating the border between these same two counties until it intersects the shoreline near Mequon, WI. The western boundary continues north following the shoreline for approximately 90 miles cutting across the mouths of rivers and streams; specifically those of Sauk Creek at Port Washington, the Sheboygan River at Sheboygan, Manitowoc Harbor as Manitowoc, and East Twin River at Two Rivers as well as any other smaller streams and creeks. The western boundary ends at roughly the border between Manitowoc and Kewaunee County along the shoreline near Twin Creeks, WI. The northern boundary continues from the shoreline east approximating the border between these same two counties back to its point of origin 9.5 miles offshore.

Article III: Special Characteristics of the Area

The historic shipwrecks in the Wisconsin-Lake Michigan National Marine Sanctuary are representative of vessels that sailed and steamed the Lake Michigan corridor, carrying grain and raw materials east as other vessels came west loaded with coal, manufactured good, and immigrants. Eighteen of the 37 shipwrecks are listed on the National Register of Historic Places. Many of the shipwrecks in the proposed sanctuary retain an unusual degree of architectural integrity, with 14 vessels virtually intact. Well preserved by Lake Michigan's cold, fresh water, the shipwrecks and related underwater cultural sites in and around the Wisconsin-Lake Michigan National Marine Sanctuary possess exceptional historical, archaeological and recreational value.

Article IV: Scope of Regulations

Section 1. Activities Subject to Regulation. The following activities are subject to regulation, including prohibition, to the extent necessary and reasonable to ensure the protection and management of the historical resources and recreational, research and educational qualities of the area:

a. Damaging sanctuary resources.

b. Using grappling hooks and anchors at shipwreck sites.

c. Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation issued under the Act.

d. Reporting shipwreck discoveries and locations to the sanctuary.

Section 2. Emergencies. Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality; or minimize the imminent risk of such destruction, loss, or injury, any activity, including those not listed in Section 1, is subject to immediate temporary regulation. An emergency regulation shall not take effect without the approval of the Governor of Wisconsin or her/his designee or designated agency.

Article V: Relation to Other Regulatory Programs

Section 1. Fishing Regulations, Licenses, and Permits. Fishing in the Sanctuary shall not be regulated as part of the Sanctuary management regime authorized by the Act. However, fishing in the Sanctuary may be regulated by other Federal, State, Tribal and local authorities of competent jurisdiction, and designation of the Sanctuary shall have no effect on any regulation, permit, or license issued thereunder.

Section 2. Other Regulations, Licenses, and Permits. If any valid regulation issued by any Federal, state, Tribal, or local authority of competent jurisdiction, regardless of when issued, conflicts with a Sanctuary regulation, the regulation deemed by the Director of the Office of National Marine Sanctuaries, National Oceanic and Atmospheric Administration, or designee, in consultation with the State of Wisconsin, to be more protective of Sanctuary resources and qualities shall govern. Pursuant to section 304(c)(1) of the Act, 16 U.S.C. 1434(c)(1), no valid lease, permit, license, approval, or other authorization issued by any Federal, State, Tribal, or local authority of competent jurisdiction, or any right of subsistence use or access, may be terminated by the Secretary of Commerce, or designee, as a result of this designation, or as a result of any Sanctuary regulation, if such lease, permit, license, approval, or other authorization, or right of subsistence use or access was issued or in existence as of the effective date of this designation. However, the Secretary of Commerce or designee, in consultation with the State of Wisconsin, may regulate the exercise of such authorization or right consistent with the purposes for which the Sanctuary is designated.

Article VI. Alteration of This Designation

The terms of designation may be modified only by the same procedures by which the original designation is made, including public meetings, consultation according to the NMSA.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–446]

Schedules of Controlled Substances: Temporary Placement of Six Synthetic Cannabinoids (5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA) Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule six synthetic cannabinoids: Methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). This action is based on a finding by the Administrator that the placement of these synthetic cannabinoids into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, exportation of, and research and conduct with, instructional activities of these synthetic cannabinoids.

DATES: January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to February 8, 2017.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of any intention to temporarily place a substance into schedule I of the CSA.[1] The Acting Administrator transmitted notice of his intent to place 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in schedule I on a temporary basis to the Assistant Secretary by letter dated April 22, 2016. The Assistant Secretary responded to this notice by letter dated May 2, 2016, and advised that based on a review by the Food and Drug Administration (FDA), there were no investigational new drug applications or approved new drug applications for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA. The Assistant Secretary also stated that the HHS had no objection to the temporary placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA into schedule I of the CSA. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA or MDMB-FUBINACA are not currently listed in any schedule under the CSA.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA

Available data and information for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA indicate that these synthetic cannabinoids (SCs) have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Synthetic Cannabinoids

SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed that SCs were first introduced on the designer drug market in several European countries as ''herbal incense'' before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. From 2009 to the present, misuse and abuse of SCs has increased in the United States with law enforcement encounters describing SCs applied onto plant material and in designer drug products intended for human consumption. It has been demonstrated that the substances and the associated designer drug products are abused for their psychoactive properties. With many generations of SCs having been encountered since 2009, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are some of the latest, and the abuse of these substances is negatively impacting communities.

As observed by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters,

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Service (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

applying by spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA have no accepted medical use in the United States. Use of these specific SCs has been reported to result in adverse effects in humans including deaths (see 3-Factor document in ''Supporting and Related Material'' section). Use of other SCs has resulted in signs of addiction and withdrawal, and based on the similar pharmacological profile of these six substances, it is believed that there will be similar observed adverse effects.

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are SCs that have pharmacological effects similar to the schedule I hallucinogen delta-Δ-tetrahydrocannabinol (THC) and temporarily and permanently controlled schedule I synthetic cannabinoid substances. In addition, the misuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA have been associated with either overdoses requiring emergency medical intervention or death (see factor 6). With no approved medical use and limited safety or toxicological information, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have emerged on the designer drug market, and the abuse of these substances for their psychoactive properties is concerning. The DEA's analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under docket number DEA–443.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed over the last 30 years as tools for investigating the endocannabinoid system (*e.g.,* determining CB1 and CB2 receptor activity). The first encounter of SCs within the United States occurred in November 2008 by CBP. Since then the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA are SCs that have been recently encountered (see ''Supporting and Related Material,'' Factor 5). Multiple overdoses involving emergency medical intervention or deaths have been associated with 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and/or psychoactive ''high,'' believed to be similar to marijuana. Data gathered from published studies, supplemented by discussions on Internet discussion Web sites, demonstrate that these products are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as ''legal'' alternatives to marijuana. In recent overdoses, 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have been shown to be applied onto plant material, similar to the SCs that have been previously available.

Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs (including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA) are mixed together, as well as large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the substance(s) during the manufacturing process. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, similar to other SCs, have been encountered in form of dried leaves or herbal blends.

The designer drug products laced with SCs, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, are often sold under the guise of ''herbal incense'' or ''potpourri,'' use various product names, and are routinely labeled ''not for human consumption.'' Additionally, these products are marketed as a ''legal high'' or ''legal alternative to marijuana'' and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and that labeling these products as ''not for human consumption'' is a legal defense to criminal prosecution.

A major concern, as reiterated by public health officials and medical professionals, is the targeting and direct marketing of SCs and SC-containing products to adolescents and youth. This is supported by law enforcement encounters and reports from emergency departments; however, all age groups have been reported by media as abusing these substances and related products. Individuals, including minors, are purchasing SCs from Internet Web sites, gas stations, convenience stores, and head shops.

Factor 5. Scope, Duration and Significance of Abuse

SCs, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA, continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Numerous substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report abuse of these substances and their associated products.

As described by the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity.

The threat of serious injury to the individual following the ingestion of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA and other SCs persists. Numerous calls have been received by poison centers regarding the abuse of products potentially laced with SCs that have resulted in visits to emergency departments. Law enforcement continues to encounter novel SCs on the illicit market, including 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA (see factor 5 in ''Supporting and Related Material'').

The following information details information obtained through NFLIS [2] (queried on November 7, 2016),

[2] The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

including dates of first encounter, exhibits/reports, and locations.

5F-ADB: NFLIS—2,311 reports, first encountered in September 2014, locations include: Arizona, Arkansas, California, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Missouri, New Jersey, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, and Wisconsin.

5F-AMB: NFLIS—3,349 reports, first encountered in January 2014, locations include: Arizona, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

5F-APINACA: NFLIS—1,936 reports, first encountered in August 2012, locations include: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, West Virginia, Wisconsin, and Wyoming.

ADB-FUBINACA: NFLIS—942 reports, first encountered in March 2014, locations include: Arkansas, California, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Missouri, New Jersey, New Mexico, New York, North Dakota, Ohio, Pennsylvania, Texas, Utah, Virginia, and Wyoming.

MDMB-CHMICA: NFLIS—227 reports, first encountered in March 2015, locations include: Arkansas, Georgia, Indiana, Kentucky, Louisiana, Nevada, Ohio, Oklahoma, South Carolina, and Texas.

MDMB-FUBINACA: NFLIS—507 reports, first encountered in July 2015, locations include: Arkansas, California, Colorado, Connecticut, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Wisconsin, and West Virginia.

Factor 6. What, if Any, Risk There Is to the Public Health

5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA have all been identified in overdose and/or cases involving death attributed to their abuse. Adverse health effects reported from these incidents involving 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and/or MDMB-FUBINACA have included: nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness and/or cardio toxicity. Large clusters of overdoses requiring medical care have been reported involving 5F-AMB, MDMB-FUBINACA, MDMB-CHMICA and 5F-ADB. Reported deaths involving these SCs have included 5F-ADB (8); 5F-AMB (6); 5F-APINACA (1); ADB-FUBINACA (2); MDMB-CHMICA (4), European Monitoring Centre for Drugs and Drug Addiction has reported an additional 12 deaths involving MDMB-CHMICA; and MDMB-FUBINACA (1) (see factor 6 in ''Supporting and Related Material'').

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA indicate that these SCs have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 22, 2016, notified the Assistant Secretary of the DEA's intention to temporarily place these six substances in schedule I.

Conclusion

This notice of intent initiates a temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA] and methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA] in schedule I of the CSA, and finds that the placement of these substances into schedule I of the CSA on a temporary basis is necessary to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place these SCs into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, research, conduct of instructional activities, and chemical analysis and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures

done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(23) through (28) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(23) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-ADB; 5F-MDMB-PINACA)	(7034)
(24) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-AMB)	(7033)
(25) *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5F-APINACA, 5F-AKB48)	(7049)
(26) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ADB-FUBINACA)	(7010)
(27) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MDMB-CHMICA, MMB-CHMINACA)	(7042)
(28) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MDMB-FUBINACA)	(7020)

* * * * *

Dated: December 13, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–00275 Filed 1–6–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 57, 70, 72, and 75

[Docket No. MSHA–2014–0031]

RIN 1219–AB86

Exposure of Underground Miners to Diesel Exhaust

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for information; reopening of the comment period.

SUMMARY: In response to requests from the public, the Mine Safety and Health Administration (MSHA) is reopening the proposed rulemaking record for public comment on the Agency's request for information on Exposure of Underground Miners to Diesel Exhaust.

DATES: The comment period for the request for information, published on June 8, 2016 (81 FR 36826), and closed

on November 30, 2016, (81 FR 58424) is reopened. Comments must be received on or before midnight Eastern Standard Time on January 9, 2018.

ADDRESSES: Submit comments and informational materials for the rulemaking record, identified by RIN 1219–AB86 or Docket No. MSHA–2014–0031, by one of the following methods:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-Mail: zzMSHA-comments@dol.gov.*
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.
- *Hand Delivery or Courier:* 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th floor East, Suite 4E401.
- *Fax:* 202–693–9441.

Instructions: All submissions must include ''RIN 1219–AB86'' or ''Docket No. MSHA–2014–0031.'' Do not include personal information that you do not want publicly disclosed; MSHA will post all comments without change to *http://www.regulations.gov* and *http://arlweb.msha.gov/currentcomments.asp,* including any personal information provided.

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* or *http://arlweb.msha.gov/currentcomments.asp.* To read background documents, go to *http://www.regulations.gov.* Review the docket in person at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal Holidays. Sign in at the receptionist's desk in Suite 4E401.

E-Mail Notification: To subscribe to receive an email notification when MSHA publishes rules in the **Federal Register**, go to *http://www.msha.gov.*

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email), 202–693–9440 (voice); or 202–693–9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: On June 8, 2016 (81 FR 36826), MSHA published a request for information (RFI) on Exposure of Underground Miners to Diesel Exhaust. The RFI sought input from the public that will help MSHA evaluate the Agency's existing standards and policy guidance on controlling miners' exposures to diesel exhaust to evaluate the effectiveness of the protection now in place to preserve miners' health.

On June 27, 2016, (81 FR 41486), MSHA published a notice in the **Federal Register** announcing four public meetings on the RFI. Public meetings were held on July 19, 21, and 26 and August 4, 2016. The comment period was scheduled to close on September 6, 2016; however, in response to requests from the public, MSHA extended the comment period until November 30, 2016 (81 FR 58424).

During the comment period, MSHA received requests for MSHA and the National Institute for Occupational Safety and Health (NIOSH) to convene a Diesel Exhaust Health Effects Partnership (Partnership) with the mining industry, diesel engine manufacturers, academia and representatives of organized labor to gather information regarding the complex questions contained in the RFI. In response to these requests, MSHA and NIOSH agreed to form a Partnership that includes all relevant stakeholders from the mining community to come together to understand the health effects from underground miners' exposure to diesel exhaust. The Partnership will also provide stakeholders an opportunity to consider best practices and new technologies including engineering controls that enhance control of diesel exhaust exposures to improve protections for miners.

The first meeting of the Diesel Exhaust Health Effects Partnership was held on December 8, 2016, in Washington, Pennsylvania.

During the comment period and at the Partnership meeting, MSHA received requests from stakeholders to reopen the rulemaking record for comment on the RFI and allow the comment period to remain open during the Partnership proceedings. In response to these requests, MSHA is reopening the record for comment and extending the comment period to January 9, 2018. The reopening of the record for comment will allow all interested parties an additional opportunity to re-evaluate all issues related to miners' exposure to diesel exhaust and to determine if improvements can be made.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 2017–00104 Filed 1–6–17; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

[Docket No. MSHA–2014–0019]

RIN 1219–AB78

Proximity Detection Systems for Mobile Machines in Underground Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; reopening the comment period.

SUMMARY: The Mine Safety and Health Administration (MSHA) is reopening the rulemaking record and requesting additional comments on the Agency's proposed rule on Proximity Detection Systems for Mobile Machines in Underground Mines which was published in the **Federal Register** on September 2, 2015. The proposed rule would require underground coal mine operators to equip coal hauling machines and scoops with proximity detection systems. Miners working near these machines face pinning, crushing, and striking hazards that result in accidents involving life-threatening injuries and death.

DATES: The comment period for the proposed rule published September 2, 2015 (80 FR 53070) is reopened. Comments must be received by midnight Daylight Saving Time on February 8, 2017.

ADDRESSES: Submit comments and informational materials, identified by RIN 1219–AB78 or Docket No. MSHA–2014–0019 by one of the following methods:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-Mail: zzMSHA-comments@dol.gov.*
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.
- *Hand Delivery or Courier:* 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th Floor East, Suite 4E401.
- *Fax:* 202–693–9441.

Instructions: All submissions must include RIN 1219–AB78 or Docket No. MSHA–2014–0019. Do not include personal information that you do not want publicly disclosed; MSHA will

post all comments without change, including any personal information provided.

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* or *http://www.msha.gov/currentcomments.asp.* To read background documents, go to *http://www.regulations.gov.* Review the docket in person at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th Floor East, Suite 4E401.

Email notification: To subscribe to receive email notification when the Agency publishes rulemaking documents in the **Federal Register**, go to *http://www.msha.gov/subscriptions.*

FOR FURTHER INFORMATION CONTACT:

Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email), 202–693–9440 (voice), or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 2, 2015, MSHA published a proposed rule, Proximity Detection Systems for Mobile Machines in Underground mines (80 FR 53070). MSHA is reopening the rulemaking record and requesting comments on issues that were raised by commenters during the comment period and on issues that developed after the record closed.

MSHA also observed the operation of proximity detection systems on both continuous mining machines and mobile machines (shuttle cars, ram cars and scoops) on working sections in the United States and South Africa after the record closed. There are 106 mobile machines operating on working sections equipped with proximity detection systems in the United States. MSHA visited six mines that operated 79 of these machines. These mines varied by physical, geological, and environmental conditions. MSHA is also including in the rulemaking record MSHA's field-trip report on the use of proximity detection in South Africa's underground coal mines and materials presented at the National Institute for Occupational Safety and Health (NIOSH) Proximity Detection Partnership Meeting held on June 22, 2016.

II. Request for Comments

1. Requirements for Proximity Detection Systems

Proposed § 75.1733(b)(1) would require that a proximity detection system cause a machine to stop before contacting a miner except for a miner who is in the on-board operator's compartment. MSHA requested comments on the types of machine movement the proximity detection system should stop. Commenters did not support the total de-energization of all functions of the equipment. One commenter noted that a ''stop all machine movement'' requirement cannot be applied universally to all mobile equipment covered by this proposed rule. The commenter noted that mine operators need the flexibility to configure proximity detection systems and machine responses based on the individual applications needed underground. In support of this comment, the commenter stated that machines that interact with other equipment, machines that require a ground-standing operator to be in contact with the machine, and machines that lack specific capabilities for motion control may need allowances outside of prescriptive requirements. As an example, the commenter stated that shuttle cars and ram cars do not require a miner to stand on the ground nearby to perform required tasks; however, scoops require a miner to touch or be near the machine to do certain work.

One commenter also noted that proximity detection systems present significant problems for performing trouble-shooting and maintenance activities. The commenter provided an example of a mechanic trying to identify a leaking hydraulic hose; the mechanic must remove the miner-wearable component for the machine to be started because the mechanic has to be inside a red zone to diagnose the source of the leak.

The National Institute for Occupational Safety and Health (NIOSH) also commented that requiring all machine movement to stop would potentially limit the development and application of advanced technology for selective shutdown features. NIOSH stated that currently available systems are not capable of providing the level of protection required in the industry while maintaining the operator's freedom to efficiently perform the job. NIOSH further stated that to be acceptable to the miners and to avoid false alarms, a proximity detection system must provide the necessary protection while still allowing normal operation of the machine.

MSHA observed mobile machines with proximity detection systems operating during coal production on working sections. These proximity detection systems functioned as designed to prevent pinning, crushing, and striking accidents. Four of the six mines that MSHA visited in the United States, after the record closed, had proximity detection systems on mobile machines and continuous mining machines on the working section except for full-face mining machines. The mobile machines included shuttle cars, ram cars, and scoops. These mine operators provided all miners on these working sections with miner-wearable components.

MSHA solicits additional comments on whether currently available proximity detection systems are capable of preventing coal hauling machines and scoops from pinning, crushing, and striking miners while maintaining the machine operator's freedom to efficiently perform the job.

Under proposed § 75.1733(b)(1), MSHA would consider stopping a coal hauling machine or scoop to consist of causing it to cease tramming or articulating any part of a machine that could cause the machine to contact a miner. Tramming means to move the machine in a forward or reverse direction. Articulating includes an act of moving or pivoting at a joint, such as when a mobile machine may pivot towards a rib such that the movement could result in pinning, striking, or crushing a miner. Under the proposal, the machine would remain stopped while any miner is within a programmed stop zone. Unexpected tramming and articulation in the direction of a miner may be hazardous. However, MSHA is considering whether it is necessary to stop the movement of all parts of the machine, such as auxiliary movements, as long as the tramming and articulating machine motion that can pin, crush, or strike a miner is stopped. In MSHA's experience, striking, pinning, or crushing hazards are not caused by auxiliary functions such as operation of a pump motor or diesel engine, ram extension, winch movement, vertical bucket movement, or battery lift.

MSHA is also aware of proximity detection system features that only allow authorized miners to perform maintenance. For example, an authorized miner may swipe an identification card over a card reader mounted on the machine or have a separate miner-wearable component that is programmed to allow a miner to perform maintenance. The proximity detection system records each time

maintenance is performed. Miners authorized to perform maintenance on machines equipped with proximity detection systems would continue to observe standard safety procedures, such as removing stored energy and blocking the machine to prevent motion, while maintaining and repairing the machine.

MSHA is considering a revision to proposed § 75.1733(b)(1) that would require a proximity detection system to stop a machine from tramming or articulating before contacting a miner except for a miner who (i) is in the on-board operator's compartment, or (ii) performing maintenance with the proximity detection system in maintenance mode.

MSHA observed a miner and a scoop operator perform maintenance by changing the battery on a scoop equipped with a proximity detection system. The miner stayed near the scoop, directed the scoop operator's movement of the machine, and maintained a safe position outside of the proximity detection system's warning zone. MSHA also observed a ram car equipped with a proximity detection system that was installed and programmed to modify its warning and shutdown zone dimensions to allow miners to safely approach the machine to perform maintenance and repairs without causing it to shut down. The warning and shutdown zones extended around the entire machine perimeter during normal operation; however, activating the parking brake reduced these zones to encompass only the pinch point areas around the articulation joint.

MSHA solicits comments on the types of machine movement a proximity detection system should allow for miners to perform necessary maintenance without exposing them to pinning, crushing, or striking hazards. MSHA also solicits comments on miners' and mine operators' experiences with proximity detection systems that allow a miner to conduct maintenance on a machine without activating the stop movement function.

Several commenters also noted that sudden stopping of equipment presents hazards for on-board machine operators. A commenter noted that sudden stops and equipment shut downs, like any other unexpected operations, could put the operator of the machine at risk of injury or death based on the size and speed of the machine, and other related factors. One commenter stated concerns that the requirement to stop the machine before contacting a miner could create a hazard for machine operators, especially diesel-powered machine operators since their ground speed is typically faster than electric-powered machines. However, another commenter stated that MSHA should not require that machines slow down before stopping because some machines, such as battery-powered direct current traction drives, do not have this capability; in some cases, it is more important to stop the machine as fast as possible to prevent contact with miners.

NIOSH commented that field tests of proximity detection systems on continuous mining machines and input from stakeholders found that detection range, environmental effects/limitations, detection accuracy, and system repeatability are considered critical parameters. MSHA observed mobile machines operating in mines in the United States with properly functioning proximity detection systems of various manufacturers with appropriate zone dimensions. These mobile machines worked in a range of seam heights, in dry and wet conditions, on varying grades, with and without wire mesh, with various mine ventilation controls. In MSHA's experience, mine operators work with machine manufacturers and proximity detection system manufacturers to determine the appropriate warning and shutdown zones for the specific mining conditions and practices that the machine encounters. MSHA is aware that proximity detection system manufacturers provide site-specific testing during commissioning of proximity detection systems. MSHA also observed proximity detection system testing used to confirm appropriate zone dimensions for the equipment and the mining conditions at the time of commissioning. MSHA solicits additional comments on appropriate warning and stopping zones for each type of machine movement and various mining conditions including any differences in cost for differing conditions or machines.

Current NIOSH research is identifying critical parameters that impact the performance of proximity detection systems on mobile machines, such as stopping distances and deceleration rates. MSHA is aware that NIOSH research on proximity detection systems for underground mobile equipment is scheduled to conclude in September, 2018. Several commenters expressed concern that the Agency will require proximity detection systems to be installed on coal haulage machines and scoops before the findings from NIOSH research on proximity detection systems on underground mobile machines are released. MSHA is also aware that some mine operators have installed and are operating proximity detection systems on mobile machines. MSHA observed variations in the installation, maintenance and performance of these systems. MSHA anticipates that a final rule would provide minimum standards for installation, performance, maintenance, and recordkeeping to assure that miners are adequately protected. MSHA observed several dynamic tests of mobile machines equipped with proximity detection systems in which the machine decelerated to a full stop without injury to the on-board operator. MSHA also observed warning and shutdown zone incursions on mobile machines equipped with proximity detection systems that are being used on working sections during normal mine production operations. These proximity detection systems appropriately slowed and/or stopped these mobile machines without injuring the on-board machine operator. MSHA is not aware of any on-board operator injuries resulting from a proximity detection system decelerating and/or stopping a mobile machine.

MSHA will continue to work with original equipment manufacturers, proximity detection system manufacturers, NIOSH, States, and mine operators to consider the benefits and timing of requiring proximity detection systems on mobile machines in underground coal mines.

MSHA solicited and received several comments on how the use of proximity detection systems and the overlap of proximity detection system protection zones on multiple types of machines operating on the same working section might affect miners' work positions. One commenter stated that testing, which was conducted in a controlled environment, demonstrated that it was impossible to provide full coverage on the rear section of the coal hauler without creating a shutdown zone in the locations where the continuous mining machine operator was required to stand. A modification to the system allowed the shutdown zone to shrink as the coal hauler backed into the loading position. Due to the shape of the zone, however, the modification removed protective coverage of the rear corners of the coal hauler.

MSHA observed continuous mining machines and mobile machines equipped with proximity detection systems successfully interact during production on working sections where all of the miners had miner-wearable components. MSHA solicits additional information regarding how coal hauling machines using proximity detection systems work with continuous mining machines equipped with proximity

detection systems while allowing continuous mining machine operators to remain in a safe location. MSHA is interested in additional information describing the installation and programming of proximity detection systems and examples of related work practices established to assure that the continuous mining machine operator remains outside of the coal hauling machine warning and shutdown zones.

Another commenter observed, during tests of proximity detection systems on continuous mining machines and battery haulers, instances in which miners (primarily continuous mining machine operators) could not properly perform necessary tasks without getting closer to the continuous mining machine than the proximity detection system allowed. The commenter noted that without the capability to temporarily bypass proximity detection, these personnel would either be forced to operate equipment without a clear line of sight or they would need to stand in conditions that pose different hazards, such as roof or rib hazards, or in locations that are not permitted under other regulations. The commenter recommended that the proximity detection system regulation for mobile equipment allow for personnel to temporarily bypass proximity detection when such conditions are encountered.

MSHA may consider such a feature and seeks comment on the availability, use, and appropriateness of a temporary bypass feature. MSHA solicits information regarding how this feature could work with existing proximity detection systems and specific benefits or hazards that could result.

One commenter noted that coal haulers and scoops would encounter sensors (miner-wearable components) much more frequently during operation than would continuous mining machines. Thus, there is an increased potential for nuisance tripping caused by inadvertent exposure into the detection zones of coal haulers, scoops, and other equipment. The commenter further noted the operation of equipment during the mining process requires multiple machines to operate, often in close proximity and can result in cross zone interference and nuisance tripping. As an example, the commenter noted a mine had to install additional equipment to help alleviate the cross zone interference issue. MSHA is aware that proximity detection system manufacturers must consider the interaction of machines with on-board operators to prevent unnecessary shut downs. MSHA observed a loading machine on which proximity detection equipment was installed to provide a silent zone for the on-board loading machine operator. This silent zone allowed the shuttle car to approach the loading machine without the loading machine operator causing the shuttle car to stop. MSHA is also aware that proximity detection system manufacturers have addressed this situation through programming miner-wearable components with specific permissions.

In addition, MSHA received a comment from a machine manufacturer stating that its field testing experience with coal customers within the United States demonstrates measurable section production tonnage drops, within five to ten percent of normal production levels, when proximity detection is active on haulage equipment.

MSHA is aware of mine operators that installed proximity detection systems on all mobile machines on the working section and experienced production decreases. Two of these mine operators reported that production later returned to pre-installation levels. MSHA observed that miners with experience working with mobile machines equipped with proximity detection systems are aware of the warning and shutdown zone locations and position themselves to minimize machine shutdowns. MSHA did observe a proximity detection system provide both a warning and then shut down the machine while the miner-wearable component was physically located outside the established warning and shutdown zones. This mine operator reported working with the proximity detection system manufacturer to resolve this type of occurrence. MSHA is aware of proximity detection system manufacturers that have mitigated nuisance alarms and other issues through engineering solutions. MSHA is also aware that proximity detection system manufacturers continue to improve their technology and develop solutions to minimize unwarranted warnings and shutdowns.

MSHA solicits definitive data, including cost and time estimates, on delays in production caused by proximity detection system alarms due to cross zone interference and nuisance tripping as well as data on the length of time to return to pre-installation production levels. MSHA also seeks information on how to reduce or eliminate production delays when working with mobile machines equipped with proximity detection systems.

MSHA solicits comments on how miners can place themselves in a safe work position to avoid causing nuisance alarms when one or more machines with proximity detection systems are on the working section. MSHA also solicits comments on miners' and mine operators' experiences when more than one miner may be in close proximity to one or more machines with proximity detection systems.

MSHA solicited and received several comments on proposed training for miners who operate or work near machines equipped with proximity detection systems. NIOSH commented that gaining an in-depth view of miners' perspectives and how their job tasks and environment could be or are affected and then incorporating that information into training may help to prevent accidents and injuries that have been labeled as human error in the workplace. NIOSH further commented that studies of continuous mining machine operators have found that unintended consequences, such as a disruption in situational awareness, risks, hazards, and decision-making capabilities, can be avoided if human factors considerations are integrated into each stage of the technology design and implementation process. In addition, NIOSH stated that each piece of equipment needs to have a uniquely prescribed proximity system and the methods and amounts of training for each system should be designed specifically for each system and common platforms established where possible.

One commenter stated that it has been evaluating and testing proximity detection system technologies since 2011. The commenter further stated that inadequate situational awareness is one of the primary factors in incidents attributed to human error and that the primary purpose of any proximity detection system/collision avoidance technology is to enhance situational awareness.

Another commenter stated that proximity detection system technology has the potential to dangerously change how miners interact with mobile equipment in underground mines. The commenter further stated that it has witnessed multiple instances where miners have taken higher risks because of a false sense of security and that implementation of proximity detection systems on all mobile machines will lead miners to unsafely rely on the devices and act contrary to their intuition and training. In addition, the commenter stated that the first priority [of the final rule] should be a safe working position for a miner or machine operator, and second a noncontact rule.

MSHA has observed miners relocate themselves to safer locations because of proximity detection system visible and

audible warnings. These warnings increased the miner's situational awareness regarding their location with respect to hazardous areas around the mobile machines.

MSHA is interested in receiving additional information on miners' and mine operators' experiences with the effect that proximity detection systems have on miners' and machine operators' situational awareness and any examples where reliance on proximity detection technology may cause the miner to develop work practices that introduce additional hazards.

MSHA observed representatives of mine operators and proximity detection system manufacturers provide instruction and task training to miners on the working section where proximity detection systems have been installed on mobile machines. Miners have demonstrated their knowledge of the installation, maintenance, and use of proximity detection systems to MSHA personnel. For example, MSHA observed one mine operator instruct miners to move into a crosscut adjacent to a coal haulage travelway. This increased their distance from the coal haulage travelway, averted unwanted proximity zone incursions, and ultimately placed the workers in a safer location. MSHA also observed a South African mine operator utilize data reports from the proximity detection systems to reinforce safe work practices specified in company policy. These data reports logged the instances when miner-wearable components entered the established warning and shutdown zones.

MSHA is also interested in miners', mine operators' and proximity detection system manufacturers' experiences with training that could be done to increase miners' and machine operators' situational awareness around machines with proximity detection systems.

2. Electromagnetic Interference

Electrical systems used in the mine, including proximity detection systems, can adversely affect the function of other electrical systems through the generation of electromagnetic interference. Several commenters noted that electromagnetic interference generated from a variety of external sources can adversely affect the performance of proximity detection systems. Several commenters stated that electromagnetic interference prevents proximity detection systems from functioning as designed. Another commenter stated that, because of electromagnetic interference, the proximity detection system failed to locate the miner-wearable component with any level of accuracy or consistency. The commenter further stated that, as a result, it was nearly impossible for the coal hauler to work in close proximity to the continuous miner or operator.

In addition, on April 6, 2016, MSHA was made aware of concerns from mine operators regarding electromagnetic interferences with proximity detection systems from respirable coal mine dust sampling devices. On April 15 and May 2, 2016, MSHA notified underground coal mine operators who have a proximity detection system installed on any equipment that they should identify sources of any electromagnetic interference that adversely affect the performance of the proximity detection system. The above-referenced notices are included in the rulemaking record.

Proposed § 75.1733(b)(5) would require a mine operator to install a proximity detection system to prevent interference that adversely affects performance of any electrical system. MSHA clarifies that proposed § 75.1733(b)(5) would require mine operators to prevent electromagnetic interference from affecting the operation of the proximity detection system or any other electrical system. MSHA intends that the system would be installed, maintained and operated in such a way that no electrical systems would be adversely affected due to interference. This would require periodic post-installation evaluation of all new potential sources of electromagnetic interference.

To clarify this intent, MSHA is considering a revision to proposed § 75.1733(b)(5) that would require proximity detection systems to be both installed and operated in a manner that prevents interferences that adversely affect the performance of any electrical system, including the proximity detection system. The operation of other electrical systems and equipment must not interfere with the performance of the proximity detection system, and the proximity detection system must not interfere with the performance of other electrical systems.

MSHA has found that one type of common interference can be identified when electrical devices are placed within several inches of the miner-wearable component of the proximity detection system. Electromagnetic interference between these two systems can be mitigated by maintaining a minimum distance between a miner-wearable component and electrical devices. MSHA's technical staff estimated that each mine would require an average of 20 hours for a mining engineer to identify sources of electromagnetic interference and the minimum distance needed to mitigate the interference. Mining engineers will test the compatibility between electrical devices and proximity detection system components. Tests will be based on equipment use and mining conditions. MSHA anticipates that mining engineers will conduct physical tests for compatibility, review equipment user manuals, and consult with the original equipment manufacturers and the proximity detection system manufacturer.

Based on MSHA's mine visits, the Agency estimated that mine operators are likely, on average, to introduce new electrical equipment twice per year. This would require a mining engineer two hours to identify and mitigate adverse interference from the new electrical equipment.

Holding all other variables of the preliminary regulatory economic analysis constant, MSHA estimated that, on average, it would cost each mine operator $3,500 over ten years to comply with proposed § 75.1733(b)(5). MSHA seeks comments on the cost drivers for compatibility testing and the Agency's cost estimate for proposed § 75.1733(b)(5).

MSHA is aware of best practices that mine operators and proximity detection system manufacturers have established to minimize the effects of electromagnetic interference. MSHA is aware that proximity detection system manufacturers have stated that minimum separation distances need to be maintained between miner-wearable components and other electrical equipment. During mine visits, miners have demonstrated the ability to maintain sufficient separation between miner-wearable components and other equipment to ensure proper proximity detection system function. MSHA is also aware of mine operators that have added inline filters on variable frequency drive shuttle cars to reduce electromagnetic emission interference. MSHA is aware of an electrical equipment manufacturer that added material designed to provide electromagnetic shielding to its gas detection equipment which reportedly reduced interference with proximity detection systems.

MSHA solicits comments on the methods and practices mine operators have used or could use to identify sources of electromagnetic interference. MSHA is also interested in receiving information on the actions an operator has taken or could take to prevent such interference and how electromagnetic interference can be mitigated in instances where a miner needs to wear

multiple miner-wearable components because different proximity detection system models are operating on a working section. Please also describe procedures that were successful and those that were not successful in identifying interferences, as well as solutions to prevent adverse interference.

MSHA has observed that wire mesh and metallic equipment can affect the proximity detection systems' warning and stopping zones. MSHA has also received reports of some pyrite deposits within coal seams affecting the use of the proximity detection system, but has not observed this effect first-hand. MSHA solicits information and data from mine operators and proximity detection system manufacturers on best practices to minimize the effects of these non-electrical interferences.

Since the record closed, MSHA became aware of a proximity detection system design feature on a miner-wearable component that determines if the magnetic field sensing coils have been affected by electromagnetic interference and can no longer detect the magnetic field generated by the machine-mounted components. This feature provides a distinct audible and visible alarm on the miner-wearable component to alert miners when it is not functioning properly due to electromagnetic interference. MSHA is considering requiring this design feature for all miner-wearable components.

MSHA solicits comments on the cost and availability of, and experience with, any proximity detection system feature or other technology that automatically alerts the miner or machine operator when the miner-wearable component or proximity detection system is not functioning properly due to electromagnetic interference.

3. Proximity Detection System Checks

Proposed § 75.1733(c)(1) would require that a mine operator designate a person to perform a check of machine-mounted components of the proximity detection system to verify that components are intact and the system is functioning properly, and to take action to correct defects. MSHA clarifies that under proposed paragraph (c)(1), the check would include verification that the warning and shutdown zones are set for the established proximity detection field distances and to meet the performance requirements under proposed § 75.1733(b)(1) and (b)(2). Under proposed § 75.1733(c)(1), the person designated to perform the check would verify that the machine-mounted components are intact and correctly mounted and the system is operating properly to identify a miner-wearable component and stop the machine. The check assures that the warning and shutdown zones around the perimeter of the machine are set according to a mine operator's specifications. In MSHA's experience, proximity detection system manufacturers have determined the type of checks that should be conducted to assure that their system is functioning properly. Mine operators are expected to follow the check procedures suggested by the manufacturers. MSHA has observed that a check of the warning and shutdown zones can be made by a miner walking around the machine with a miner-wearable component to confirm proper zone range. MSHA has also observed checking the machine shutdown function of the proximity detection system. This check involves placing a miner wearable component inside the shutdown zone and then attempting to initiate machine movements such as tramming. If the proximity detection system prevents machine movement, the system is functioning properly.

The check would also include an examination of the machine-mounted components to assure that the field generators, antennas, cabling, and other components are undamaged and correctly mounted. The check would also assure that appropriate audible and visual warning signals are working as required. MSHA solicits comments on how the warning and shutdown zones can be checked, or tested, without putting machine operators at risk.

With the clarification in this notice, MSHA estimates that the average time required for a check, which includes a verification that the warning and shutdown zones are set to meet the performance requirements under proposed § 75.1733(b)(1) and (b)(2), would increase from 20 seconds to 6 minutes. MSHA's revised estimate of 6 minutes reflects the time needed to: (1) Verify that the machine-mounted components are intact and correctly mounted and the system is operating properly to identify a miner-wearable component and stop the machine, and (2) test and validate that the warning and stopping zones meet performance requirements. MSHA substituted the 6 minutes into the calculations of the proposed rule, held all other variables constant, and calculated that the average 10-year cost per mine increase would be $182,000. Many other assumptions and data values will be updated in a final regulatory analysis. MSHA seeks comments on the Agency's revisions to its proposed time estimate to comply with § 75.1733(c)(1).

4. South Africa Field-Trip Report and NIOSH Partnership Meeting

The rulemaking record includes MSHA's Field-Trip Report on Proximity Detection Use in South Africa. On April 2 through April 13, 2016, MSHA and NIOSH representatives visited South Africa to investigate the progress of proximity detection system technology in South Africa. The group visited two proximity detection system manufacturing facilities and observed proximity detection system performance in three underground coal mines. In addition, the group met with a proximity detection system technology developer with experience in proximity detection system development in South Africa and other countries. Among other topics, they discussed the developer's experiences with proximity detection system interference in South Africa.

MSHA and NIOSH also met with representatives of South Africa's Department of Mineral Resources on the implementation of proximity detection systems on electric-powered, trackless mobile machinery in South Africa's surface and underground mines. MSHA's report and presentation materials from the South Africa trip are included in the rulemaking record and available for comment.

MSHA has also included in the rulemaking record materials from the NIOSH Proximity Detection Partnership Meeting. On June 22, 2016, NIOSH held a partnership meeting that included representatives from MSHA, industry, labor, and proximity detection system manufacturers. Materials presented during the partnership meeting are included in the rulemaking record and available for comment.

III. Compliance Cost Revision

MSHA initially estimated that the proposed rule would cost mine operators, over ten years, approximately $536,000 per mine. MSHA has revised estimates for two provisions to reflect the Agency's clarification on the proposed requirements. Table 1 summarizes the changes to estimated cost for these two provisions.

TABLE 1—AVERAGE 10-YEAR TOTAL COST PER MINE

	Average 10-year per mine cost
Total 10-Year Cost as Proposed on 09/02/2015	$536,000
Changes:	
Proximity Detection System Checks	182,000
Electromagnetic Interference Evaluation	3,500
Total Change	185,500
Total Revised Cost	$721,500
Percent increase in average cost per mine	35%

The rulemaking record and comment period for the proposed rule is reopened until February 8, 2017. MSHA solicits comments on all aspects of the proposed rule. The Agency requests that comments be specific as possible and include any technological and economic feasibility data.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0940]

RIN 1625–AA08

Special Local Regulation; Manatee River; Bradenton, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation for certain waters of the Manatee River during the Bradenton Area River Regatta. This action is necessary to protect the safety of race participants, participant vessels, spectators, and the general public on these navigable waters of the United States during the event. The special local regulation would restrict vessel traffic in the waters of the Manatee River in the vicinity of Bradenton, Florida. It would establish the following three areas: Two spectator areas, where all vessels must be anchored or operate at No Wake Speed; and an enforcement area where designated representatives may control vessel traffic as determined by the prevailing conditions.

DATES: Comments and related material must be received by the Coast Guard on or before February 8, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0940 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Boatswain's Mate First Class Tyrone J. Stafford, Sector St. Petersburg Prevention Department, Coast Guard; telephone 813–228–2191, email *Tyrone.J.Stafford@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Coast Guard proposes to establish a special local regulation on the waters of the Manatee River, Bradenton, Florida during the Bradenton Area River Regatta. This event is a high speed boat race with approximately 12 Formula 2 Class boats, traveling at speeds in excess of 100 miles per hour. There will also be approximately 14, 1000 cc Hydrocross jet skis participating in scheduled races during this event. Additionally, there will be a jet ski and water ski exhibition located within the regulated area. It is anticipated that 250 spectator vessels will be present along the race course. The race is scheduled to take place annually from approximately 9 a.m. to 9 p.m. during the first Saturday of February.

This proposed rulemaking is necessary to provide for the safety of race participants, participant vessels, spectators, and the general public on these navigable waters of the United States during the Bradenton Area River Regatta. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233.

III. Discussion of Proposed Rule

This proposed rulemaking would encompass certain waters of the Manatee River in Bradenton, Florida. The special local regulation would be enforced from 9 a.m. to 9 p.m. normally occurring during the first Saturday of February. The special local regulation would establish the following three areas: (1) Two spectator areas, where all vessels must be anchored or operate at No Wake Speed; and (2) an enforcement area that encompasses all race courses and demonstrations, where designated representatives may control vessel traffic as determined by the prevailing conditions.

Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port St. Petersburg by telephone at 727–824–7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and/or on-scene designated representatives.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking.

Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

The economic impact of this rule is not significant for the following reasons: (1) The special local regulation will be enforced for only twelve hours; (2) although persons and vessels are prohibited to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port St. Petersburg or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the regulated area or anchor in the sponsor's designated spectator area, during the enforcement period if authorized by the Captain of the Port St. Petersburg or a designated representative; and (4) the Coast Guard will provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners and/or Broadcast Notice to Mariners.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of the Manatee River, Bradenton, Florida, encompassed within the special local regulation from 9 a.m. until 9 p.m. annually on the first Saturday of February. For the reasons stated in section IV.A above, this rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation issued in conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph (34)(h) of Figure 2–1 of Commandant Instruction M16475.lD. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comments can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment

applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.723 to read as follows:

§ 100.723 Special Local Regulation; Bradenton Area River Regatta, Manatee River; Bradenton, FL.

(a) *Regulated Areas.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Spectator Area #1.* An area marked by the event sponsor encompassed within the following points: 27°30.43′ N., 82°34.55′ W., thence to position 27°30.43′ N., 82°34.43′ W., thence to position 27°30.23′ N., 82°34.43′ W., thence to position 27°30.13′ N., 82°34.30′ W., thence to position 27°30.09′ N., 82°34.30′ W., thence to position 27°30.09′ N., 82°34.55′ W., thence back to the original position 27°30.43′ N., 82°34.55′ W.

(2) *Spectator Area #2.* An area marked by the event sponsor east of the CSX Railroad train trestle eastbound of a line connected by the following points: 27°30.73′ N., 82°34.13′ W., thence to position 27°29.99′ N., 82°34.07′ W.

(3) *Enforcement Area.* The designated race and demonstration areas that are composed of all waters of the Manatee River encompassed within the following points: 27°30.58′ N., 82°34.62′ W., thence to position 27°30.58′ N., 82°34.13′ W., thence to position 27°29.99′ N., 82°34.06′ W., thence to position 27°29.99′ N., 82°34.62′ W., thence back to the original position 27°30.58′ N., 82°34.62′ W.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port St. Petersburg in the enforcement of the regulated areas.

(c) *Regulations.*

(1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the enforcement area unless authorized by the Captain of the Port St. Petersburg or a designated representative.

(2) Designated representatives may control vessel traffic throughout the enforcement area as determined by the prevailing conditions.

(3) All vessels are to be anchored and/or operate at a No Wake Speed in the spectator area. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated areas by contacting the Captain of the Port St. Petersburg by telephone at 727–824–7506, or a designated representative via VHF radio on channel 16.

(d) *Enforcement period:* This section will be enforced from 9:00 a.m. to 9:00 p.m. annually on the first Saturday during the month of February.

Dated: December 27, 2016.

H.L. Najarian,

Captain, U.S. Coast Guard, Captain of the Port Saint Petersburg.

[FR Doc. 2017–00109 Filed 1–6–17; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Electronic Induction (eInduction®) Option

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes to revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to add an option to streamline the processing of drop shipments and expedited plant load mailings.

DATES: Submit comments on or before February 8, 2017.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *ProductClassification@usps.gov,* with a subject line of ''eInduction Option.'' Faxed comments are not accepted.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor North, Washington, DC 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Direct questions or comments to Heather Dyer by email at *heather.l.dyer@usps.gov* or phone (207) 482–7217, or Jacqueline Erwin by email at *jacqueline.r.erwin@usps.gov* or phone (202) 268–2158.

SUPPLEMENTARY INFORMATION: The Electronic Induction (eInduction) option is a process that streamlines the preparation and induction (how and where the mail physically enters the Postal Service mailstream) of drop shipments and expedited plant load mailings. eInduction links scans of Intelligent Mail container barcodes (IMcb) to the electronic documentation (eDoc) information, allowing the Postal Service to verify that postage was paid prior to accepting a mailer shipped container. eInduction eliminates the need for paper PS Forms 8125, 8125–CD, and 8017, and manual reconciliation at the entry facility. Correct postage payment is verified both at the entry facility and during post-induction processing in *PostalOne!.*

Mailers who would like to use the eInduction option must meet eligibility requirements and request authorization by contacting the Facility Access Shipping Tracking, (FAST)® Helpdesk. Business Mailer Support will provide final authorization. Additional information, including information regarding verification and associated assessments, is provided in Publication 6850, *Publication for Streamlined Mail Acceptance for Letters and Flats,*

available at *https://postalpro.usps.com/node/581.*

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comments on the following proposed revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. *See* 39 CFR 111.1.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

[*Add new section 20.0, to read as follows:*]

20.0 eInduction Option

20.1 Description

Electronic Induction (eInduction) is an electronic alternative to using the following paper PS Forms 8125, 8125C, 8125CD, and 8017 for all containers entered at the dock of a processing facility or claiming a Destination Delivery Unit (DDU) discount. eInduction uses Intelligent Mail container barcode (IMcb) scans to determine container payment and delivery status, and verifies payment and entry location by matching IMcb scan data to electronic documentation (eDoc) information. Containers are eligible for eInduction at certain designated facilities. Additional information, including information regarding verification and associated assessments, is provided in Publication 6850, *Publication for Streamlined Mail Acceptance for Letters and Flats,* at *https://postalpro.usps.com/node/581.*

20.2 Approval

Mailers must be authorized by the USPS to participate in the eInduction program.

20.3 General Eligibility Standards

First-Class Mail, Periodicals, Standard Mail letters and flats, and Bound Printed Matter presorted or carrier route barcoded flats and packages are eligible for eInduction. All containers entered under eInduction must:

a. Be labeled with a USPS placard and a unique Intelligent Mail container barcode. All required pallets and similar containers (such as all-purpose containers, hampers, and gaylords) and all containers prepared under 8.0 must display container placards that include accurately encoded Intelligent Mail container barcodes (IMcb) as described in 708.6.6. Mailing documentation must indicate each container participating in eInduction. b. Be part of a mailing using an approved electronic method to transmit a postage statement and mailing documentation to the *PostalOne!* system.

c. Not include containers included on paper PS Forms 8125/8017.

d. Be included on a scheduled FAST appointment when entered at a USPS processing facility.

20.4 Additional Standards

20.4.1 Special Support for Continuous Mailers

Mailers who cannot generate a finalized postage statement two hours before container entry may request approval for an eInduction Continuous Mailer ID, (MID). Once approved, mailers using an authorized MID in the IMcb may enter any container with the approved MID in the IMcb prior to the receipt of electronic documentation. Mailers are required to submit an eDoc and generate a finalized postage statement for all eInduction MID containers within one calendar day of the unload scan. Mailers may request authorization for an MID through the Business Customer Gateway. The USPS must approve the mailer request before the mailer may participate in the MID process.

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes, if our proposal is adopted.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–32056 Filed 1–6–17; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 7 and 9

[EPA–HQ–OA–2013–0031; FRL–9958–03–OA]

RIN 2090–AA39

Nondiscrimination in Programs or Activities Receiving Federal Assistance From the Environmental Protection Agency

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; withdrawal.

SUMMARY: The Environmental Protection Agency (EPA) is withdrawing a proposed rule for which the EPA no longer intends to issue a final rule. This document identifies the proposed rule and explains the EPA's decision to withdraw the proposal. The withdrawal of this proposed rule does not preclude the EPA from initiating the same or similar rulemaking at a future date. It does, however, close out the entry for this proposed rule in the EPA Semi-Annual Regulatory Agenda, published as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). Should the EPA decide at some future date to initiate the same or similar rulemaking, it will add an appropriate new entry to the EPA Semi-Annual Regulatory Agenda to reflect the initiation of the action.

DATES: The EPA is withdrawing the proposed rule as of January 9, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OA–2013–0031. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kurt Temple, Environmental Protection Agency, Office of Civil Rights, (Mail

Code 1201A), 1200 Pennsylvania Ave. NW., Washington, DC 20460, telephone number: (202) 564–7272 or (202) 564–7299; email address: *temple.kurt@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general, and may be of particular interest to those persons who follow proposed rules related to the EPA's regulations about Nondiscrimination in Programs or Activities Receiving Federal Assistance from the EPA. Since others may also be interested, the EPA has not attempted to describe all the specific entities potentially interested.

II. Why is the EPA issuing this withdrawal document?

This document announces to the public that the EPA is withdrawing a certain proposed rule for which the EPA no longer intends to issue a final rule.

For the reasons described in this document, the EPA has decided not to finalize this rulemaking at this time. By withdrawing the proposed rule, the EPA is eliminating the pending nature of the regulatory action. Should the EPA determine to pursue anything in these areas in the future, it will issue a new proposed rule and invite public comment through notice in the **Federal Register**.

III. Background

1. What was proposed? On December 14, 2015, the EPA published a proposed rule in the **Federal Register** (80 FR 77284), to amend its nondiscrimination regulation regarding compliance information requirements for recipients of EPA financial assistance and Agency Compliance Procedures, as well as a technical correction to the reference to the Paperwork Reduction Act.

2. *Why is it being withdrawn?* The agency proposed amending its regulation to bring it into conformance with more than 20 other federal agencies. In other words, this proposed regulatory amendment concerned the EPA's internal processes, including the investigation of complaints and compliance reviews, and not obligations imposed on external stakeholders.

Nonetheless, the EPA received several adverse comments about this proposed amendment; especially regarding the proposal to remove numeric deadlines from the administrative complaint processing regulations. The EPA has considered all comments received. Although the EPA continues to believe that the proposed amendments, including the elimination of the numeric deadlines, are needed in order to better position the EPA to strategically manage and individually tailor resolution approaches to its administrative investigation of complaints and compliance reviews, the EPA has decided to withdraw the proposed amendments.

Instead of continuing to pursue this rulemaking, the EPA will implement and evaluate the ability of its internal procedural guidance documents and accountability measures that were finalized in December 2016 (including the Case Resolution Manual and the EPA's OCR External Compliance Program Strategic Plan) to achieve prompt effective, and efficient docket management. Based on its evaluation, the EPA may decide at some future date to initiate a new rulemaking to amend its non-discrimination regulation. The EPA is withdrawing the proposed amendments, as opposed to leaving them inactive, to promote transparency and certainty with regard to the status of its non-discrimination regulation.

3. Where can I get more information about this action? The EPA has established a docket for this action under Docket ID No. EPA–HQ–OA–2013–0031. See the **ADDRESSES** section above for more detail information about this docket.

List of Subjects

40 CFR Part 7

Environmental protection, Administrative practice and procedure, Age discrimination, Civil rights, Equal employment opportunity, Individuals with disabilities, Reporting and recordkeeping requirements, Sex discrimination.

40 CFR Part 9

Environmental protection, Control number, Office of Management and Budget, and Paperwork Reduction Act.

Dated: December 29, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2017–00050 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2014–0430; FRL–9957–91–Region 4]

Air Quality Plans; Tennessee; Infrastructure Requirements for the 2012 $PM_{2.5}$ National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the State Implementation Plan (SIP) submission, submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), on December 16, 2015, for inclusion into the Tennessee SIP. This proposal pertains to the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2012 Annual Fine Particulate Matter ($PM_{2.5}$) national ambient air quality standard (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure SIP submission.'' TDEC certified that the Tennessee SIP contains provisions that ensure the 2012 Annual $PM_{2.5}$ NAAQS is implemented, enforced, and maintained in Tennessee. EPA is proposing to determine that portions of Tennessee's infrastructure SIP submission, provided to EPA on December 16, 2015, satisfy certain required infrastructure elements for the 2012 Annual $PM_{2.5}$ NAAQS.

DATES: Written comments must be received on or before February 8, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2014–0430 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment

contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta 30303–8960. Ms. Bell can be reached via electronic mail at *bell.tiereny@epa.gov* or via telephone at (404) 562–9088.

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On December 14, 2012 (78 FR 3086, January 15, 2013), EPA promulgated a revised primary annual $PM_{2.5}$ NAAQS. The standard was strengthened from 15.0 micrograms per cubic meter (μg/m^3) to 12.0 μg/m^3. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2012 Annual $PM_{2.5}$ NAAQS to EPA no later than December 14, 2015.[1]

This rulemaking is proposing to approve portions of Tennessee's December 16, 2015 $PM_{2.5}$ infrastructure SIP submission for the applicable requirements of the 2012 Annual $PM_{2.5}$ NAAQS, with the exception of the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), for which EPA is not proposing any action in this rulemaking regarding these requirements. For the aspects of Tennessee's submittal proposed for approval in this rulemaking, EPA notes that the Agency is not approving any specific rule, but rather proposing that Tennessee's already approved SIP meets certain CAA requirements.

II. What elements are required under sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for ''infrastructure'' SIP requirements related to a newly established or revised NAAQS. As mentioned above, these requirements include basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. The requirements are summarized below and in EPA's September 13, 2013, memorandum entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2).''[2]

- 110(a)(2)(A): Emission Limits and Other Control Measures
- 110(a)(2)(B): Ambient Air Quality Monitoring/Data System
- 110(a)(2)(C): Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources
- 110(a)(2)(D)(i)(I) and (II): Interstate Pollution Transport
- 110(a)(2)(D)(ii): Interstate Pollution Abatement and International Air Pollution
- 110(a)(2)(E): Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies
- 110(a)(2)(F): Stationary Source Monitoring and Reporting
- 110(a)(2)(G): Emergency Powers
- 110(a)(2)(H): SIP Revisions
- 110(a)(2)(I): Plan Revisions for Nonattainment Areas[3]
- 110(a)(2)(J): Consultation with Government Officials, Public Notification, and Prevention of Significant Deterioration (PSD) and Visibility Protection
- 110(a)(2)(K): Air Quality Modeling and Submission of Modeling Data
- 110(a)(2)(L): Permitting fees
- 110(a)(2)(M): Consultation and Participation by Affected Local Entities

III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Tennessee that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2012 Annual $PM_{2.5}$ NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions.

[1] In these infrastructure SIP submissions States generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federally-approved SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Throughout this rulemaking, the cited regulation has either been approved, or submitted for approval into Tennessee's federally-approved SIP.

[2] Two elements identified in section 110(a)(2) are not governed by the three-year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D, title I of the CAA; and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, title I of the CAA. This proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

[3] As mentioned above, this element is not relevant to this proposed rulemaking.

Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA, ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review (NNSR) permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[4] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that ''each'' SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.[5] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.[6] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit ''a plan'' to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[7] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[8]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[9]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the ''applicable requirements'' of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD

[4] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

[5] See, *e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[6] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.,* that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

[7] See, *e.g.,* ''Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,'' 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and ''Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS,'' (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[8] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007, submittal.

[9] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[10] EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).[11] EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[12] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's implementation plan appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.,* whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and new source review (NSR) pollutants, including greenhouse gases (GHG). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 $PM_{2.5}$ NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia,* the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor NSR program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.,* already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions (''SSM''); (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (''NSR Reform''). Thus, EPA believes it may

[10] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[11] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act sections 110(a)(1) and 110(a)(2),'' Memorandum from Stephen D. Page, September 13, 2013.

[12] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City,* 696 F.3d7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations. On March 17, 2016, EPA released a memorandum titled, ''Information on the Interstate Transport 'Good Neighbor' Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I)'' to provide guidance to states for interstate transport requirements specific to the $PM_{2.5}$ NAAQS.

approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[13] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[14] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[15] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[16]

IV. What is EPA's analysis of how Tennessee addressed the elements of the sections 110(a)(1) and (2) ''infrastructure'' provisions?

The Tennessee infrastructure submission addresses the provisions of sections 110(a)(1) and (2) as described below.

1. 110(a)(2)(A) *Emission Limits and Other Control Measures:* Section 110(a)(2)(A) requires that each implementation plan include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements. Several regulations within Tennessee's SIP are relevant to air quality control regulations. The regulations described below include enforceable emission limitations and other control measures. SIP-approved Tennessee Air Pollution Control Regulations (TAPCR) 1200–03–03, *Ambient Air Quality Standards,* 1200–03–04, *Open Burning,* 1200–03–06, *Non-process Emission Standards,* 1200–03–07, *Process Emission Standards,* 1200–03–09, *Construction and Operating Permits,* 1200–03–14, *Control of Sulfur Dioxide Emission,* 1200–03–19, *Emission Standards and Monitoring Requirements for Additional Control Areas,* 1200–03–21, *General Alternate Emission Standards,* 1200–03–24, *Good Engineering Practice Stack Height Regulations,* and 1200–03–27, *NO_X emissions from designated source categories* collectively establish enforceable emissions limitations and other control measures, means or techniques, for activities that contribute to $PM_{2.5}$ concentrations in the ambient air, and provide authority for TDEC to establish such limits and measures as well as schedules for compliance to meet the applicable requirements of the CAA. Additionally, State statutes established in the Tennessee Air Quality Act and adopted in the Tennessee Code Annotated (TCA) section 68–201–105(a), *Powers and duties of board—Notification of vacancy—Termination due to vacancy,* provide the Tennessee Air Pollution Control Board and TDEC's Division of Air Pollution Control the authority to take actions in support of this infrastructure element such as issue permits, promulgate regulations, and issue orders to implement the Tennessee Air Quality Act and the CAA, as relevant. EPA has made the preliminary determination that the provisions contained in these State

[13] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

[14] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,'' 74 FR 21639 (April 18, 2011).

[15] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[16] See, *e.g.,* EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

regulations and State statute satisfy Section 110(a)(2)(A) for the 2012 Annual $PM_{2.5}$ NAAQS in the State.

In this action, EPA is not proposing to approve or disapprove any existing state provisions with regard to excess emissions during start up, shut down, and malfunction (SSM) operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown'' (September 20, 1999), and the Agency is addressing such state regulations in a separate action.[17]

Additionally, in this action, EPA is not proposing to approve or disapprove any existing state rules with regard to director's discretion or variance provisions. EPA believes that a number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109 (November 24, 1987)), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B) *Ambient Air Quality Monitoring/Data System:* Section 110(a)(2)(B) requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to (i) monitor, compile, and analyze data on ambient air quality, and (ii) upon request, make such data available to the Administrator. TCA 68–201–105(b)(4) gives TDEC the authority to provide technical, scientific and other services as may be required to implement the provisions of the Tennessee Air Quality Act. Annually, states develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, includes the annual ambient monitoring network design plan, and includes a certified evaluation of the agency's ambient monitors and auxiliary support equipment.[18] On June 30, 2015, Tennessee submitted its most recent plan to EPA, which was approved by EPA on October 26, 2015. Tennessee's monitoring network plan can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2014–0430. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for the ambient air quality monitoring and data system related to the 2012 Annual $PM_{2.5}$ NAAQS.

3. 110(a)(2)(C) *Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources:* This element consists of three sub-elements: Enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources, and preconstruction permitting of major sources and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (*i.e.,* the major source PSD program). TDEC's 2012 Annual $PM_{2.5}$ NAAQS infrastructure SIP submission cites a number of SIP provisions to address these requirements. EPA's rationale for its proposed action regarding each sub-element is described below.

Enforcement: The following SIP-approved regulation provides TDEC with authority for enforcement of $PM_{2.5}$ emission limits and control measures. TAPCR 1200–03–13–.01, *Violation Statement,* states that, ''Failure to comply with any of the provisions of these regulations shall constitute a violation thereof and shall subject the person or persons responsible therefore to any and all the penalties provided by law.'' Also note, under TCA 68–201–116, *Orders and assessments of damages and civil penalty—Appeal,* the State's Technical Secretary is authorized to issue orders requiring correction of violations of any part of the Tennessee Air Quality Act, or of any regulation promulgated under this State statute. Violators are subject to civil penalties of up to 25,000 dollars per day for each day of violation and for any damages to the State resulting from the violations.

Preconstruction PSD Permitting for Major Sources: EPA interprets the PSD sub-element to require that a state's infrastructure SIP submission for a particular NAAQS demonstrate that the state has a complete PSD permitting program in place covering the structural PSD requirements for all regulated NSR pollutants. A state's PSD permitting program is complete for this sub-element (and prong 3 of D(i) and J related to PSD) if EPA has already approved or is simultaneously approving the state's implementation plan with respect to all structural PSD requirements that are due under the EPA regulations or the CAA on or before the date of the EPA's proposed action on the infrastructure SIP submission. For the, 2012 Annual $PM_{2.5}$ NAAQS, Tennessee's authority to regulate construction of new and modified stationary sources to assist in the protection of air quality in attainment or unclassifiable areas is established in TAPCR 1200–03–09–.01(4), *Prevention of Significant Deterioration of Air Quality.* Tennessee's infrastructure SIP submission demonstrates that new major sources and major modifications in areas of the State designated attainment or unclassifiable for the specified NAAQS are subject to a federally-approved PSD permitting program meeting all the current structural requirements of part C of title I of the CAA to satisfy the infrastructure SIP PSD elements.[19]

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the SIP to include provisions that govern the minor source program that regulates emissions of the 2012 Annual $PM_{2.5}$ NAAQS. TAPCR 1200–03–09–.01, *Construction Permits,* and TAPCR 1200–03–09–.03, *General Provisions,* collectively govern the preconstruction permitting of modifications and construction of minor stationary sources, and minor modifications of major stationary sources.

EPA has made the preliminary determination that Tennessee's SIP is adequate for program enforcement of control measures, regulation of minor sources and modifications, and preconstruction permitting of major sources and major modifications related to the 2012 Annual $PM_{2.5}$ NAAQS.

4. 110(a)(2)(D)(i)(I) and (II) *Interstate Pollution Transport:* Section 110(a)(2)(D)(i) has two components: 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components has two subparts resulting in four distinct components, commonly referred to as ''prongs,'' that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of

[17] On June 12, 2015, EPA published a final action entitled, ''State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction.'' *See* 80 FR 33840.

[18] The annual network plans are approved by EPA in accordance with 40 CFR part 58, and, on occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

[19] More information concerning how the Tennessee infrastructure SIP submission currently meets applicable requirements for the PSD elements (110(a)(2)(C); (D)(i)(I), prong 3; and (J)) can be found in the technical support document in the docket for today's rulemaking.

emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (''prong 1''), and interfering with maintenance of the NAAQS in another state (''prong 2''). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state (''prong 3''), or to protect visibility in another state (''prong 4'').

110(a)(2)(D)(i)(I)—prongs 1 and 2: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states of section 110(a)(2)(D)(i)(I) (prongs 1 and 2). EPA will consider these requirements in relation to Tennessee's 2012 Annual $PM_{2.5}$ NAAQS infrastructure submission in a separate rulemaking.

110(a)(2)(D)(i)(II)—prong 3: With regard to section 110(a)(2)(D)(i)(II), the PSD element, referred to as prong 3, may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a PSD program meeting all the current structural requirements of part C of title I of the CAA, or (if the state contains a nonattainment area that has the potential to impact PSD in another state), a NNSR program. As discussed in more detail above under section 110(a)(2)(C), Tennessee's SIP contains provisions for the State's PSD program that reflects the required structural PSD requirements to satisfy prong 3 of section 110(a)(2)(D)(i)(II). Tennessee addresses prong 3 through TAPCR 1200–03–09–.01(4), *Prevention of Significant Deterioration of Air Quality,* and TAPCR 1200–03–09–.01(5), *Growth Policy,* for the PSD and NNSR programs, respectively. EPA has made the preliminary determination that Tennessee's SIP is adequate for PSD permitting of major sources and major modifications for interstate transport related to the 2012 Annual $PM_{2.5}$ NAAQS for section 110(a)(2)(D)(i)(II) (prong 3).

110(a)(2)(D)(i)(II)—prong 4: EPA is not proposing any action in this rulemaking related to the interstate transport provisions pertaining to visibility in other states of section 110(a)(2)(D)(i)(II) (prong 4) and will consider these requirements in relation to Tennessee's 2012 Annual $PM_{2.5}$ NAAQS infrastructure submission in a separate rulemaking.

5. 110(a)(2)(D)(ii): *Interstate Pollution Abatement and International Air Pollution:* Section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement. Regulation 1200–03–09 03, *General Provisions,* requires the permitting authority to notify air agencies whose areas may be affected by emissions from a source. Additionally, Tennessee does not have any pending obligation under sections 115 and 126 of the CAA relating to international or interstate pollution abatement. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for ensuring compliance with the applicable requirements relating to interstate and international pollution abatement for the 2012 Annual $PM_{2.5}$ NAAQS.

6. 110(a)(2)(E) *Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies:* Section 110(a)(2)(E) requires that each implementation plan provide: (i) Necessary assurances that the state will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the state comply with the requirements respecting state boards pursuant to section 128 of the Act, and (iii) necessary assurances that, where the state has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the state has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Tennessee's infrastructure SIP submission as meeting the requirements of sub-elements 110(a)(2)(E)(i), (ii), and (iii). EPA's rationale for today's proposal respecting each section of 110(a)(2)(E) is described in turn below.

In support of EPA's proposal to approve sub-elements 110(a)(2)(E)(i) and (iii), TCA 68–201–105, *Powers and duties of board—Notification of vacancy—Termination due to vacancy,* gives the Tennessee Air Pollution Control Board the power and duty to promulgate rules and regulations to implement the Tennessee Air Quality Act. The Board may define ambient air quality standards, set emission standards, set forth general policies or plans, establish a system of permits, and identify a schedule of fees for review of plans and specifications, issuance or renewal of permits or inspection of air contaminant sources.

TAPCR 1200–03–26, *Administrative Fees Schedule,* establishes construction fees, annual emission fees, and permit review fees sufficient to supplement existing State and Federal funding and to cover reasonable costs associated with the administration of Tennessee's air pollution control program. These costs include costs associated with the review of permit applications and reports, issuance of permits, source inspections and emission unit observations, review and evaluation of stack and/or ambient monitoring results, modeling, and costs associated with enforcement actions.

TCA 68–201–115, *Local pollution control programs—Exemption from state supervision—Applicability of part to air contaminant sources burning wood waste—Open burning of wood waste,* states that ''Any municipality or county in this state may enact, by ordinance or resolution respectively, air pollution control regulations not less stringent than the standards adopted for the state pursuant to this part, or any such municipality or county may also adopt or repeal an ordinance or resolution which incorporates by reference any or all of the regulations of the board, or any federal regulations including any changes in such regulations, when such regulations are properly identified as to date and source.'' Before such ordinances or resolutions become effective, the municipality or county must receive a certificate of exemption from the Board to enact local regulations in the State. In granting any certificate of exemption, the State of Tennessee reserves the right to enforce any applicable resolution, ordinance, or regulation of the local program.

TCA 68–201–115 also directs TDEC to ''frequently determine whether or not any exempted municipality or county meets the terms of the exemption granted and continues to comply with this section.'' If TDEC determines that the local program does not meet the terms of the exemption or does not otherwise comply with the law, the Board may suspend the exemption in whole or in part until the local program complies with the State standards.

As evidence of the adequacy of TDEC's resources with respect to sub-elements (i) and (iii), EPA submitted a letter to Tennessee on June 30, 2015, outlining section 105 grant commitments and the current status of these commitments for fiscal year 2015. The letter EPA submitted to Tennessee can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2014–0430. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Tennessee

satisfactorily met all commitments agreed to in the Air Planning Agreement for fiscal year 2015, therefore Tennessee's grants were finalized and closed out. EPA has made the preliminary determination that Tennessee has adequate resources and authority for implementation of the 2012 Annual $PM_{2.5}$ NAAQS.

Section 110(a)(2)(E)(ii) requires that the state comply with section 128 of the CAA. Section 128 requires that the SIP provide: (a)(1) the majority of members of the state board or body which approves permits or enforcement orders represent the public interest and do not derive any significant portion of their income from persons subject to permitting or enforcement orders under the CAA; and (a)(2) any potential conflicts of interest by such board or body, or the head of an executive agency with similar powers be adequately disclosed. Section 110(a)(2)(E)(ii) obligations for the 2012 Annual $PM_{2.5}$ NAAQS and the requirements of CAA section 128 are met in Regulation 0400–30–17, *Conflict of Interest.* Under this regulation, the Tennessee board with authority over air permits and enforcement orders is required to determine annually and after receiving a new member that at least a majority of its members represent to public interest and do not derive any significant portion of income from persons subject to such permits and enforcement orders. Further, the board cannot act to hear contested cases until it has determined it can do so consistent with CAA section 128. The regulation also requires TDEC's Technical Secretary and board members to declare any conflict-of-interest in writing prior to the issuance of any permit, variance or enforcement order that requires action on their part.

EPA has made the preliminary determination that the State has adequately addressed the requirements of section 128, and accordingly has met the requirements of section 110(a)(2)(E)(ii) with respect to infrastructure SIP requirements. Therefore, EPA is proposing to approve Tennessee's infrastructure SIP submission as meeting the requirements of sub-elements 110(a)(2)(E)(i), (ii) and (iii).

7. 110(a)(2)(F) *Stationary Source Monitoring and Reporting:* Section 110(a)(2)(F) requires SIPs to meet applicable requirements addressing: (i) The installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources, (ii) periodic reports on the nature and amounts of emissions and emissions related data from such sources, and (iii) correlation of such reports by the state agency with any emission limitations or standards established pursuant to this section, which reports shall be available at reasonable times for public inspection. TDEC's infrastructure SIP submission identifies requirements for compliance testing by emissions sampling and analysis, and for emissions and operation monitoring to ensure the quality of data in the State, and also the collection of source emission data throughout the State and the assurance of the quality of such data. These data are used to compare against current emission limits and to meet requirements of EPA's Air Emissions Reporting Rule (AERR). Specifically, TAPCR 1200–03–10, *Required Sampling, Recording, and Reporting,* gives the State's Technical Secretary the authority to monitor emissions at stationary sources, and to require these sources to conduct emissions monitoring and to submit periodic emissions reports. This rule requires owners or operators of stationary sources to compute emissions, submit periodic reports of such emissions and maintain records as specified by various regulations and permits, and to evaluate reports and records for consistency with the applicable emission limitation or standard on a continuing basis over time. The monitoring data collected and records of operations serve as the basis for a source to certify compliance, and can be used by Tennessee as direct evidence of an enforceable violation of the underlying emission limitation or standard.

Additionally, Tennessee is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the AERR on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and the precursors that form them—nitrogen oxides, sulfur dioxides, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Tennessee made its latest update to the 2011 NEI on April 9, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html.* EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for the stationary source monitoring systems related to the 2012 Annual $PM_{2.5}$ NAAQS.

Regarding credible evidence, TAPCR 1200–3–10–04, *Sampling, Recording, and Reporting Required for Major Stationary Sources,* states that: ''the Technical Secretary is authorized to require by permit condition any periodic or enhanced monitoring, recording and reporting that he deems necessary for the verification of the source's compliance with the applicable requirements as defined in paragraph 1200–03–09–02(11).'' EPA is unaware of any provision preventing the use of credible evidence in the Tennessee SIP. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for the stationary source monitoring systems related to the Annual $PM_{2.5}$ NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(F).

8. 110(a)(2)(G): *Emergency Powers:* Section 110(a)(2)(G) of the Act requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority. Tennessee's emergency powers are outlined in TAPCR 1200–03–15, *Emergency Episode Plan,* which establishes the criteria for declaring an air pollution episode (air pollution alert, air pollution warning, or air pollution emergency), specific emissions reductions for each episode level, and emergency episode plan requirements for major sources located in or significantly impacting a nonattainment area. Additional emergency powers are codified in TCA 68–201–109, *Emergency Stop Orders for Air Contaminant Sources.* Under TCA 68–201–109, if the Commissioner of TDEC finds that emissions from the operation of one or more sources are causing imminent danger to human health and safety, the Commissioner may, with the approval of the Governor, order the source(s) responsible to reduce or discontinue immediately its (their) air emissions. Additionally, this State law requires a hearing to be held before

the Commissioner within 24 hours of any such order.

Regarding the public welfare and environment, TCA 68–201–106, *Matters to be considered in exercising powers,* states that ''In exercising powers to prevent, abate and control air pollution, the board or department shall give due consideration to all pertinent facts, including, but not necessarily limited to: (1) The character and degree of injury to, or interference with, the protection of the health, general welfare and physical property of the people. . .'' Also, TCA 68–201–116, *Orders and assessments of damages and civil penalty Appeal,* provides in subsection (a) that if the Tennessee technical secretary discovers that any State air quality regulation has been violated, the Tennessee technical secretary may issue an order to correct the violation, and this order shall be complied with within the time limit specified in the order. EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for emergency powers related to the 2012 Annual $PM_{2.5}$ NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(G).

9. 110(a)(2)(H) *SIP Revisions:* Section 110(a)(2)(H), in summary, requires each SIP to provide for revisions of such plan (i) as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and (ii) whenever the Administrator finds that the plan is substantially inadequate to attain the NAAQS or to otherwise comply with any additional applicable requirements. As previously discussed, TDEC is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS in Tennessee.

Section 68–201–105(a) of the Tennessee Air Quality Act authorizes the Tennessee Air Pollution Control Board to promulgate rules and regulations to implement this State statute, including setting and implementing ambient air quality standards, emission standards, general policies or plans, a permits system, and a schedule of fees for review of plans and specifications, issuance or renewal of permits, and inspection of sources. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate a commitment to provide future SIP revisions related to the 2012 Annual $PM_{2.5}$ NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(H).

10. 110(a)(2)(J) *Consultation with Government Officials, Public Notification, and PSD and Visibility Protection:* EPA is proposing to approve Tennessee's infrastructure SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that complies with the applicable consultation requirements of section 121, the public notification requirements of section 127, PSD and visibility protection. EPA's rationale for each sub-element is described below.

Consultation with government officials (121 consultation): Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and Federal Land Managers (FLMs) carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. The following State rule, as well as the State's Regional Haze Implementation Plan (which allows for consultation between appropriate state, local, and tribal air pollution control agencies as well as the corresponding FLMs), provide for consultation with government officials whose jurisdictions might be affected by SIP development activities: TAPCR 1200–03–34, *Conformity,* provides for interagency consultation on transportation and general conformity issues. Tennessee adopted state-wide consultation procedures for the implementation of transportation conformity which includes the development of mobile inventories for SIP development. These consultation procedures were developed in coordination with the transportation partners in the State and are consistent with the approaches used for development of mobile inventories for SIPs. Required partners covered by Tennessee's consultation procedures include Federal, state and local transportation and air quality agency officials. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate consultation with government officials related to the 2012 Annual $PM_{2.5}$ NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(J) consultation with government officials.

Public notification: These requirements are met through the State's existing Air Quality Index and Air Quality Forecasting programs, which provide a method to alert the public if any NAAQS is exceeded in an area. Additionally, the State's annual monitoring plan update is sent out each year for public review and comment. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate the State's ability to provide public notification related to the 2012 Annual $PM_{2.5}$ NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(J) public notification.

PSD: With regard to the PSD element of section 110(a)(2)(J), this requirement is met by a state's confirmation in an infrastructure SIP submission that it has a PSD program meeting all the current structural requirements of part C of title I of the CAA. As discussed in more detail above under section 110(a)(2)(C), Tennessee's SIP contains a PSD program that includes the required structural PSD requirements to satisfy the requirement of the PSD element of section 110(a)(2)(J). EPA has made the preliminary determination that Tennessee's SIP and practices are adequate for PSD permitting of major sources and major modifications related to the 2012 Annual $PM_{2.5}$ NAAQS for the PSD element of section 110(a)(2)(J). Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to the PSD element of section 110(a)(2)(J).

Visibility protection: EPA's 2013 Guidance notes that it does not treat the visibility protection aspects of section 110(a)(2)(J) as applicable for purposes of the infrastructure SIP approval process. EPA recognizes that states are subject to visibility protection and regional haze program requirements under part C of the Act (which includes sections 169A and 169B). However, there are no newly applicable visibility protection obligations after the promulgation of a new or revised NAAQS. Thus, EPA has determined that states do not need to address the visibility component of 110(a)(2)(J) in infrastructure SIP submittals. As such, EPA has made the preliminary determination that it does not need to address the visibility protection element of section 110(a)(2)(J) in Tennessee's infrastructure SIP submission related to the 2012 Annual $PM_{2.5}$ NAAQS.

11. 110(a)(2)(K) *Air Quality Modeling and Submission of Modeling Data:* Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and

submission of such data to the EPA can be made. TAPCR 1200–03–09–.01(4), *Prevention of Significant Air Quality Deterioration,* specifies when modeling and when monitoring (pre- or post-construction) must be performed and that the resulting data be made available for review to EPA. Tennessee also states that it has personnel with training and experience to conduct dispersion modeling consistent with models approved by EPA protocols. Also note that TCA 68–201–105(b)(7) grants TDEC the power and duty to collect and disseminate information relative to air pollution. Additionally, Tennessee participates in a regional effort to coordinate the development of emissions inventories and conduct regional modeling for several NAAQS, including the 2012 Annual $PM_{2.5}$ NAAQS, for the Southeastern states. Taken as a whole, Tennessee's air quality regulations and practices demonstrate that TDEC has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the Annual $PM_{2.5}$ NAAQS. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate the State's ability to provide for air quality modeling, along with analysis of the associated data, related to the 2012 Annual $PM_{2.5}$ NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(K).

12. 110(a)(2)(L) *Permitting fees:* Section 110(a)(2)(L) requires the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover: (i) The reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

In Tennessee, funding for review of PSD and NNSR permits comes from permit-specific fees that are charged to new applicants and from annual emission fees charged to existing title V emission sources that are applying for major modifications under PSD or NNSR. The cost of reviewing, approving, implementing, and enforcing PSD and major NNSR permits are covered under the following State regulations: (1) TAPCR 1200–03–26–.02(5) requires each new major stationary source to pay a construction permit application filing/processing fee and (2) TAPCR 1200–03–26–.02(9), *Annual Emission Fees for Major Sources,*[20] mandates that existing major stationary sources pay annual title V emission fees, which are used to cover the permitting costs for any new construction or modifications at these facilities as well as implementation and enforcement of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Tennessee adequately provides for permitting fees related to the 2012 Annual $PM_{2.5}$ NAAQS when necessary. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(L).

13. 110(a)(2)(M) *Consultation/participation by affected local entities:* Section 110(a)(2)(M) of the Act requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. TCA 68–201–105, *Powers and duties of board Notification of vacancy Termination due to vacancy,* authorizes and requires the Tennessee Air Pollution Control Board to promulgate rules and regulations related to consultation under the provisions of the State's Uniform Administrative Procedures Act. TCA 4–5–202, *When hearings required,* requires agencies to precede all rulemaking with a notice and public hearing, except for exemptions. TCA 4–5–203, *Notice of hearing,* states that whenever an agency is required by law to hold a public hearing as part of its rulemaking process, the agency shall: ''(1) Transmit written notice of the hearings to the secretary of state for publication in the notice section of the administrative register Web site . . . and (2) Take such other steps as it deems necessary to convey effective notice to persons who are likely to have an interest in the proposed rulemaking.'' TCA 68–201–105(b)(7) authorizes and requires TDEC to ''encourage voluntary cooperation of affected persons or groups in preserving and restoring a reasonable degree of air purity; advise, consult and cooperate with other agencies, persons or groups in matters pertaining to air pollution; and encourage authorized air pollution agencies of political subdivisions to handle air pollution problems within their respective jurisdictions to the greatest extent possible and to provide technical assistance to political subdivisions. . .''. TAPCR 1200–03–34, *Conformity,* requires interagency consultation on transportation and general conformity issues. Additionally, TDEC has, in practice, consulted with local entities for the development of its transportation conformity SIP and has worked with the FLMs as a requirement of EPA's regional haze rule. EPA has made the preliminary determination that Tennessee's SIP and practices adequately demonstrate consultation with affected local entities related to the 2012 Annual $PM_{2.5}$ NAAQS. Accordingly, EPA is proposing to approve Tennessee's infrastructure SIP submission with respect to section 110(a)(2)(M).

[20] Title V program regulations are federally-approved but not incorporated into the federally-approved SIP.

V. Proposed Action

With the exception of interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states and visibility protection requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), EPA is proposing to approve Tennessee's infrastructure submission submitted on December 16, 2015, for the 2012 Annual $PM_{2.5}$ NAAQS for the above described infrastructure SIP requirements. EPA is proposing to approve Tennessee's infrastructure SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS because the submission is consistent with section 110 of the CAA.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 20, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2017–00162 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR- 2016–0702; FRL–9957–95-Region 9]

Approval of Arizona Air Plan Revisions, Arizona Department of Environmental Quality and Pinal County Air Quality Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Arizona State Implementation Plan (SIP). These revisions include a state statute and certain state rules that govern air pollution sources under the Arizona Department of Environmental Quality (ADEQ) and the Pinal County Air Quality Control District (PCAQCD). These revisions concern emissions of particulate matter (PM) from construction sites, agricultural activity and other fugitive dust sources. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by February 8, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0702 at *http://www.regulations.gov,* or via email to *Steckel.Andrew@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, (415) 947–4125, *vineyard.christine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What statute and rules did the State submit?

Table 1 lists the statute and rules addressed by this proposal with the dates that they were adopted by the state or local air agency and submitted by the ADEQ.

TABLE 1—SUBMITTED STATUTE AND RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
PCAQCD	Chapter 4—Article 1	Fugitive Dust	10/28/15	12/21/15
PCAQCD	Chapter 4—Article 3	Construction Sites—Fugitive Dust	10/28/15	12/21/15
Arizona Revised Statutes (ARS)	**Statute No.**	**Statute title**	**Effective date**	**Submitted**
ARS	§ 49–424	Duties of Department	4/18/14	12/21/15
Arizona Administrative Code (AAC) Rule No.	**AAC No.**	**AAC title**	**Amended/ effective date**	**Submitted**
AAC	R18–2–210	Attainment, Nonattainment, and Unclassifiable Area Designations.	07/01/14	12/21/15
AAC	R18–2–610	Definitions for R18–2–610.01, R18–2–610.02, and R18–2–610.03.	07/02/15	12/21/15
AAC	R18–2–610.03	Agricultural PM General Permit for Crop Operations; Pinal County PM Nonattainment Area.	07/02/15	12/21/15
AAC	R18–2–612	Definitions for R18–2–612.01	07/02/15	12/21/15
AAC	R18–2–612.01	Agricultural PM General Permit for Irrigation Districts; PM Nonattainment Areas Designated After June 1, 2009.	07/02/15	12/21/15
AAC	Appendix 2	Test Methods and Protocols	07/02/15	12/21/15

On March 21, 2016, the EPA determined that the submitted revisions from ADEQ and PCAQCD listed in Table 1 met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of the statute and rules?

There are no previous versions of PCAQCD Chapter 4, Articles 1 and 3 in the SIP. Table 2 lists versions of the statute and rules EPA has previously approved into the SIP.

TABLE 2—SIP-APPROVED RULES

ARS	Title	Existing SIP-approved rule superseded by this action	Previous approval
§ 49–424	Duties of Department	49–424 (2011) Duties of Department	77 FR 66398 11/05/12
AAC	**Title**	**Existing SIP superseded by this action**	**Previous Approval**
R18–2–210	Attainment, Nonattainment, and Unclassifiable Area Designations.	Attainment, Nonattainment, and Unclassifiable Area Designations.	79 FR 56656 09/23/14
Appendix 2	Test Methods and Protocols	Test Methods and Protocols	79 FR 56655 09/23/15

In addition, we note that SIP-approved rule R18–2–610, ''Definitions for R18–2–611,'' has the same AAC number as new rule R18–2–610, ''Definitions for R18–2–610.01 R18–2–610.02, and R18–2–610.03,'' but is not superseded by the new rule. *See* 66 FR 51869 (October 11, 2001). Both versions of R18–2–610 will be in the SIP, but can be differentiated by their different titles and dates.

C. What is the purpose of the submitted rule and statute revisions?

Particulate matter, including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10}), contributes to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires states to submit regulations that control PM emissions.

PCAQCD Chapter 4, Article 1—Fugitive Dust

- New rule applies to open areas/vacant lots, unpaved roads, unpaved lots and paved public roadways.
- Establishes a 20 percent opacity limit.
- Requires no trespassing signs, physical barriers or other effective control measures upon evidence of trespass.
- Limits silt content on unpaved lots and roads to eight percent and six percent respectively.

PCAQCD Chapter 4, Article 3—Construction Sites—Fugitive Dust

- New rule designed to regulate PM_{10} emissions attributed to construction activities under both stagnation and windy conditions.
- Limits opacity to 20 percent.

ARS § 49–424—Duties of Department

- Revised rule extends the requirement to develop and disseminate air quality dust forecasts to the Maricopa County PM_{10} maintenance area and any other PM_{10} nonattainment or maintenance areas designated on or after December 31, 2011.

AAC R18–2–210—Attainment, Nonattainment, and Unclassifiable Area Designations

• Revised rule reflects updated 40 CFR 81.303 as amended July 1, 2014.

AAC R18–2–610—Definitions for R18–2–610.01, R18–2–610.02, and R18–2–610.03

• New rule provides definitions for commercial farms general permit rule and applies to general permit rules in other specified nonattainment areas.

AAC R18–2–610.03—Agricultural PM General Permit for Crop Operations; Pinal County PM Attainment Area

• New menu-based rule requires a general permit for commercial farms in the Pinal County PM Nonattainment Area.

• Requires implementation of at least one (best management practice) BMP in the following five categories: Tillage, ground operations and harvest, noncropland, commercial farm roads, and cropland. Beginning in calendar year 2017, and no more than once every subsequent three years, requires facility response to an ADEQ survey on BMP implementation.

AAC R18–2–612—Definitions for R18–2–612.01

• New rule provides definitions for R18–2–612.01.

AAC R18–2–612.01—Agricultural PM General Permit for Irrigation Districts; PM Nonattainment Areas Designated After June 1, 2009

• New menu-based rule requires a general permit for irrigation districts in nonattainment areas designated after June 1, 2009.

• Requires implementation of at least one BMP in the following three categories: unpaved operation and maintenance roads, canals, and unpaved utility access roads.

• Beginning in calendar year 2017, and no more than once every subsequent three years, requires irrigation district response to an ADEQ survey on BMP implementation.

AAC Appendix 2—Test Methods and Protocol

• Revised rule adds section L: 40 CFR 51.128 Appendix A (1)(B) and section M: Silt Content Test Method.

The EPA's technical support documents (TSDs) have more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the statute and rules?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and are limited in how they can modify certain SIP control requirements in nonattainment areas (see CAA section 193).

In addition, generally, SIP rules must implement Reasonably Available Control Measures (RACM), including Reasonably Available Control Technology (RACT), in moderate $PM_{2.5}$/PM_{10} nonattainment areas (see CAA sections 172(c)(1) and 189(a)(1)(C)). The PCAQCD regulates a PM_{10} nonattainment area classified as moderate for the 1987 24-hour PM_{10} National Ambient Air Quality Standard (NAAQS) (40 CFR 81. 303).[1] A RACM evaluation is generally performed in context of a broader plan, so we are not proposing to determine whether ADEQ has demonstrated RACM for the Pinal area as part of this notice.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''PM–10 Guideline Document,'' EPA 452/R–93–008, April 1993.
5. ''Fugitive Dust Background Document and Technical Information Document for Best Available Control Measures,'' EPA 450/2–92–004, September 1992.

B. Do the rules and statute meet the evaluation criteria?

We believe these rules and statute are consistent with CAA requirements and relevant guidance and fulfill the evaluation criteria. The statute and rules are clear and contain adequate testing, recordkeeping and reporting requirements to be sufficiently enforceable. The statute and rules strengthen effective requirements (*e.g.,* by strengthening/adding general permit rules and BMPs for agricultural operations) and are consistent with CAA section 193. The statute and rules generally impose RACT-level requirements (*e.g.,* the revisions limit silt content on unpaved lots and roads to eight percent and six percent respectively) for the affected categories.

The TSDs have more information on our evaluation.

C. EPA recommendations To Further Improve the Rules

The TSDs describe additional rule revisions that we recommend for the next time the state and local agency modifies the rules.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules and statute because we believe they fulfill all relevant requirements. We will accept comments from the public on this proposal until February 8, 2017. Unless we receive convincing new information during the comment period, we intend to publish a final approval action that will incorporate these rules and statute into the federally-enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the PCAQCD/ADEQ rules/statute as described in Table 1 of this notice. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does

[1] The 1997 PM_{10} 24-hour National Ambient Air Quality Standard (primary and secondary) is 150 micrograms per cubic meter. See *https://www.epa.gov/criteria-air-pollutants/naaqs-table.*

not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 20, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2017–00054 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2016–0287; FRL–9957–63-Region 9]

Approval of Arizona Air Plan Revisions; Ajo and Morenci, Arizona; Second 10-Year Sulfur Dioxide Maintenance Plans and Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the second ten-year maintenance plans for the Ajo and Morenci areas in Arizona for the 1971 National Ambient Air Quality Standards (NAAQS) for sulfur dioxide (SO_2), and to correct an error in the description of the Ajo, Arizona SO_2 maintenance area in the *Code of Federal Regulations.*

DATES: Any comments on this proposal must arrive by February 8, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0287 at *http://www.regulations.gov,* or via email to Wienke Tax, at *tax.wienke@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Wienke Tax, EPA Region IX, (415) 947–4192, *tax.wienke@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA. This proposal addresses the second ten-year maintenance plans submitted by the Arizona Department of Environmental Quality to address the 1971 SO_2 NAAQS in the Ajo and Morenci maintenance areas, AZ. In the Rules and Regulations section of this **Federal Register**, we are approving these second ten-year maintenance plans in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. If we receive adverse comment on a distinct provision of this rulemaking, *i.e.,* our action regarding only one maintenance plan, we will publish a timely withdrawal in the **Federal Register** indicating which provisions we are withdrawing. The provisions that are not withdrawn, *i.e.,* our approval of the other maintenance plan that is not the subject of an adverse comment, will become effective on the date set out above, notwithstanding adverse comment on the other maintenance plan.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: December 15, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2016–31636 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 82, No. 5

Monday, January 9, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Rural Broadband Access Loans and Loan Guarantees Program

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Solicitation of Applications (NOSA).

SUMMARY: The Rural Utilities Service (RUS), an agency of the United States Department of Agriculture (USDA), announces that it is accepting applications for fiscal year (FY) 2017 for the Rural Broadband Access Loan and Loan Guarantee program (the Broadband Program). There will be two application windows for FY 2017.

In addition to announcing the application windows, RUS announces the minimum and maximum amounts for broadband loans for FY 2017.

DATES: Unless otherwise extended by a notice of funds availability, applications for the first application window under this NOSA must be submitted from March 1, 2017, through March 31, 2017, and for the second application window from September 1, 2017, through September 30, 2017. Applications can only be submitted through the Agency's online application system during the periods specified above; however, applicants may begin working on their applications in the online system as outlined below.

FOR FURTHER INFORMATION CONTACT: For further information contact Shawn Arner, Deputy Assistant Administrator, Loan Originations and Approval Division, Rural Utilities Service, Room 2844, STOP 1597, 1400 Independence Avenue SW., Washington, DC 20250–1597, Telephone: (202) 720–0800, or email: *Shawn.Arner@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

General Information

The Rural Broadband Access Loan and Loan Guarantee Program (the ''Broadband Program'') is authorized by the Rural Electrification Act (7 U.S.C. 901 *et seq.*), as amended by the Agricultural Act of 2014 (Pub. L. 113–79) also referred to as the 2014 Farm Bill.

During FY 2017, loans will be made available for the construction, improvement, and acquisition of facilities and equipment to provide service at the broadband lending speed for eligible rural areas. Applications are subject to the requirements of 7 CFR 1738.

Application Assistance

Since the implementation of the requirements of the 2014 Farm Bill, RUS has held two application windows. After reviewing the applications for eligibility, RUS has determined that there is considerable misunderstanding of the revised requirements for the Broadband Program. Under the two previous windows, once an application was submitted, RUS could not contact an applicant for additional information and the application had to be evaluated on the information that was submitted. If incorrect or inadequate information was submitted or a regulatory requirement was not met, an applicant did not have the ability to adjust its application and RUS was forced to reject it as incomplete or inadequate. In order to break with the pattern of wide scale applications that do not meet the regulation's requirements, RUS will place additional emphasis on providing assistance to applicants with submitting complete applications. As a result, RUS will open pre-application periods, in which National Office staff as well as the General Field Representative assigned to the project will be able to review the draft application, provide detailed comments, and identify when an application is not meeting eligibility requirements for funding. The online application system will allow RUS staff to assist an applicant with completing every part of an application as it is being developed.

The first pre-application window will open on January 9, 2017, and application assistance will be available until the application is formally submitted for consideration by the applicant, but no later than midnight, Eastern Time, on March 24, 2017. Once the application is formally submitted, RUS will be unable to provide additional assistance with completing the application and will begin reviewing the application for conformance with the broadband regulation with respect to eligibility and technical and financial feasibility. In addition, once an application is formally submitted through the online system, the applicant can no longer submit supporting information. For assistance with an application, please contact Shawn Arner, Deputy Assistant Administrator, Loan Originations and Approval Division, Rural Utilities Service, Room 2844, STOP 1597, 1400 Independence Avenue SW., Washington, DC 20250–1597, Telephone: (202) 720–0800, or email: *Shawn.Arner@wdc.usda.gov.* If an application is ultimately found to be incomplete or inadequate for funding after it is formally submitted, a detailed explanation will be provided to the applicant at least thirty days prior to the opening of the second window of FY 2017 for formally submitting applications.

The second pre-application window will open on July 1, 2017, and application assistance will be available until the application is formally submitted for consideration by the applicant, but not later than midnight, Eastern Time, on September 22, 2017. As with the first pre-application window, once an application is formally submitted, RUS will be unable to provide additional assistance with completing the application and will begin reviewing the application for conformance with the broadband regulation with respect to eligibility and technical and financial feasibility. In addition, once an application is formally submitted through the online system, the applicant can no longer submit supporting information. Please contact Shawn Arner at the above contact information if you would like assistance with your application. If an application is ultimately found to be incomplete or inadequate, a detailed explanation will be provided to the applicant.

To further assist in the preparation of applications, an application guide is available online at: *http://www.rd.usda.gov/programs-services/farm-bill-broadband-loans-loan-guarantees.* Application guides may also be requested from the RUS contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Application requirements: All requirements for submission of an application under the Broadband Program are subject to 7 CFR 1738.

Application Materials/Submission: Applications must be submitted through the Agency's online application system located at *http://www.rd.usda.gov/programs-services/rd-apply.* All materials required for completing an application are included in the online system.

Items of Special Emphasis: The following items have been overlooked or inadequately addressed in a number of applications received in the last two application cycles. They are highlighted below to help ensure that future applications do not have the same deficiencies.

• *Calculation of Additional Cash Requirement 7 CFR 1738.208:* Certain applications may need to satisfy an additional cash requirement even though they have addressed the equity requirement covered in 7 CFR 1738.207 (an element of a complete application in accordance with 7 CFR 1738.202(c)). If an applicant is either a start-up operation or has not demonstrated positive cash flow from operations for the two years prior to the submission date of the application, then the applicant must submit adjusted financial projections in which projected revenues are decreased by 50 percent for each year of the five-year forecast period, unless revenues are based on documented binding commitments which would preclude such a drop. If the adjusted financial projections show an inadequate cash balance at the end of any year during the five-year forecast period, the amount of cash necessary to eliminate that cash insufficiency is the Additional Cash Requirement for the application.

• *Equity requirement 7 CFR 1738.207:* If an applicant has equity at the time of application equal to less than 10 percent of the requested loan amount, then the applicant must submit either an investor commitment or a commitment to issue a general obligation bond, along with a legal opinion demonstrating that the applicant has the authority to issue such a bond in an amount sufficient to meet the equity requirement (this second option is available to State, Tribal and local government applicants only). If an applicant submits more than one application, then the equity requirement will be calculated based on the sum of the requested loan amounts, as if all applications will be successful.

• *Market survey (7 CFR 1738.209):* If a market survey is required, the survey must have been completed within 6 months of the application submission date.

• *Methodology and Assumptions included with Financial Information (7 CFR 1738.211):* The narrative explaining the methodology and assumptions used to develop the financial projections for the five-year forecast period (7 CFR 1738.211(b)(2)) and the adjusted financial projections, if applicable (7 CFR 1738.208(a)(2)), must adequately address every category in the pro-forma financial statements. This narrative should include a discussion of any historical trends or anomalies and their impact on the forecast(s). The applicant should not only include any calculations or percentage changes in the assumptions but also discuss the reasons for choosing any multipliers or percentage increases/decreases for the forecast.

• *Audited Financial Statements vs. Unaudited Financial Statements plus Tax Returns (7 CFR 1738.211(a)(1)–(3)):* Audited financial statements submitted in compliance with 7 CFR 1738.211(a)(1)–(3) must be audited and certified by an independent certified public accountant (CPA) and include an opinion, balance sheet, income statement, statement of changes in financial position, and notes to the financial statements. Compilations or reviews are considered unaudited financial statements, even if a CPA was involved in their preparation or presentation. If an applicant submits unaudited statements, tax returns for the relevant years are also required. Start-up entities must provide, at a minimum, an opening balance sheet dated within 30 days of the final submission of all application material.

Minimum and Maximum Loan Amounts

Loans under this authority will not be made for less than $100,000. The maximum loan amount that will be considered for FY 2017 is $10,000,000.

Required Definitions for Broadband Program Regulation

The regulation for the Broadband Program requires that certain definitions affecting eligibility be revised and published from time to time by the agency in the **Federal Register**. For the purposes of this NOSA, the agency is revising the definition of Broadband Service, such that for applications submitted under these two windows, existing Broadband Service shall mean the minimum rate-of-data transmission of ten megabits downstream and one megabit upstream for both mobile and fixed service. With respect to the Broadband Lending Speed, the rate at which applicants must propose to offer new broadband service is a minimum bandwidth of ten megabits downstream and one megabit upstream for mobile service and twenty-five megabits downstream and three megabits upstream for fixed service to the customer.

Priority for Approving Loan Applications

Applications for FY 2017 will be accepted from March 1, 2017, through March 30, 2017, for the first application window and from September 1, 2017, through September 30, 2017, for the second application window. Although review of applications will start when they are submitted for each window, all applications submitted for the first application period will be evaluated and ranked together based on the percentage of unserved households in the proposed funded service area. Likewise, all applications submitted for the second window will be evaluated and ranked together based on the percentage of unserved households in the proposed funded service area. Subject to available funding, eligible applications that propose to serve the highest percentage of unserved households will receive funding offers before other eligible applications that have been submitted. The amount available for each window will be published on the Agency Web page once the annual appropriation process has been completed.

Applications will not be accepted after September 30, 2017, until a new funding window has been opened with the publication of an additional NOSA in the **Federal Register**.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements associated with Broadband loans, as covered in this NOSA, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0572–0130.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political

beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Dated: November 21, 2016.

Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2017–00137 Filed 1–6–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–1–2017]

Foreign-Trade Zone (FTZ) 221—Mesa, Arizona; Notification of Proposed Production Activity; Apple Inc. (Data Server Cabinets); Mesa, Arizona

The City of Mesa Office of Economic Development, grantee of FTZ 221, submitted a notification of proposed production activity to the FTZ Board on behalf of Apple Inc. (Apple), located in Mesa, Arizona. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on December 27, 2016.

Apple already has authority to produce certain components for consumer electronics within Subzone 221A. The current request would add finished products and foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Apple from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, Apple would be able to choose the duty rate during customs entry procedures that applies to finished server assembly cabinets (duty-free) for the foreign-status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include: Tape; plastic boxes; polyethylene bags; plastic bags; plastic packing; plastic washers; rubber washers; rubber spacers; steel screw hooks; steel screws; steel nuts; steel standoff; steel spring washers; steel washers, not spring/lock type; steel rivets; steel cotter pins; steel springs; steel springs, of wire; steel baffles; copper washers; copper boss; copper nuts; nickel fasteners; aluminum screws; aluminum hooks; metal hinges; metal brackets; fans; fan blades, fan unit housings; servers; input/output units; storage units; smart cables; card readers; server housing/enclosures; printed circuit board assemblies; electric motors; transformers; static converters; inductors; magnets; lithium batteries; lithium polymer batteries; routers and network switches; microphones; CDs, software; solid state drives; semiconductor media; monitors; capacitors; fuses; circuit breakers; power strips; relays; switches; electrical connectors; optical fiber cable connectors; terminals; power strips with rack mounts; diodes; transistors; thyristors; LEDs; electronic integrated circuits; infrared LED strips; data server cables; copper and power cables; cables; optical fiber cables; metal furniture; and, server rack rails (duty rate ranges from duty-free to 8.6%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is February 21, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: January 3, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00144 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–62–2016]

Foreign-Trade Zone (FTZ) 20—Newport News, Virginia; Authorization of Production Activity; Canon Virginia, Inc.; Subzone 20D (Toner Cartridges); Newport News, Virginia

On September 2, 2016, Canon Virgina, Inc., submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within Subzone 20D, in Newport News, Virginia.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (81 FR 64870, September 21, 2016). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: January 3, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00147 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–02–2017]

Foreign-Trade Zone (FTZ) 44—Morris County, New Jersey; Notification of Proposed Production Activity; AGFA Corporation (Aluminum Digital Printing Plates); Branchburg, New Jersey

AGFA Corporation (AGFA) submitted a notification of proposed production

activity to the FTZ Board for its facility in Branchburg, New Jersey, within FTZ 44. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on December 19, 2016.

A separate application for subzone designation at the AGFA facility has been submitted and is being processed under Section 400.31 of the FTZ Board's regulations (S–152–2016). The facility is used for the production of aluminum digital printing plates used in the commercial printing industry. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status component and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt AGFA from customs duty payments on the foreign-status components used in export production. On its domestic sales, AGFA would be able to choose the duty rate during customs entry procedures that applies to aluminum digital printing plates (duty free) for foreign-status aluminum coils (duty rate 3%). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is February 21, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: January 3, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00148 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Order Temporarily Denying Export Privileges

Mahan Airway, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran;

Pejman Mahmood Kosarayanifard, a/k/a Kosarian Fard, P.O. Box 52404, Dubai, United Arab Emirates;

Mahmoud Amini, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates and P.O. Box 52404, Dubai, United Arab Emirates and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates;

Kerman Aviation, a/k/a GIE Kerman Aviation, 42 Avenue Montaigne 75008, Paris, France;

Sirjanco Trading LLC, P.O. Box 8709, Dubai, United Arab Emirates;

Ali Eslamian, 33 Cavendish Square, 4th Floor, London, W1G0PW, United Kingdom and 2 Bentinck Close, Prince Albert Road St. Johns Wood, London NW87RY, United Kingdom;

Mahan Air General Trading LLC, 19th Floor Al Moosa Tower One, Sheik Zayed Road; Dubai 40594, United Arab Emirates;

Skyco (UK Ltd., 33 Cavendish Square, 4th Floor, London, W1G 0PV, United Kingdom;

Equipco (UK Ltd., 2 Bentinck Close, Prince Albert Road, London, NW8 7RY, United Kingdom;

Mehdi Bahrami, Mahan Airways—Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey;

Al Naser Airlines, a/k/a al-Naser Airlines, a/k/a Alnaser Airlines and Air Freight Ltd., Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq and Al Amirat Street, Section 309, St. 3/H.20, Al Mansour Baghdad, Iraq and P.O. Box 28360, Dubai, United Arab Emirates and P.O. Box 911399, Amman 11191, Jordan;

Ali Abdullah Alhay, a/k/a Ali Alhay, a/k/a Ali Abdullah Ahmed Alhay, Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq and Anak Street, Qatif, Saudi Arabia 61177;

Bahar Safwa General Trading, P.O. Box 113212, Citadel Tower, Floor-5, Office #504, Business Bay, Dubai, United Arab Emirates and P.O. Box 8709, Citadel Tower, Business Bay, Dubai, United Arab Emirates;

Sky Blue Bird Group, a/k/a Sky Blue Bird Aviation,a/k/a Sky Blue Bird Ltd, a/k/a Sky Blue Bird FZC, P.O. Box 16111, Ras Al Khaimah Trade Zone, United Arab Emirates;

Issam Shammout, a/k/a Muhammad Isam Muhammad Anwar Nur Shammout, a/k/a Issam Anwar, Philips Building, 4th Floor, Al Fardous Street, Damascus, Syria and Al Kolaa, Beirut, Lebanon 151515 and 17–18 Margaret Street, 4th Floor, London, W1W 8RP, United Kingdom and Cumhuriyet Mah. Kavakli San St. Fulya, Cad. Hazar Sok. No.14/A Silivri, Istanbul, Turkey;

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2016) (''EAR'' or the ''Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the July 7, 2016 Temporary Denial Order (the ''TDO''). The July 7, 2016 Order denied the export privileges of Mahan Airways, Pejman Mahmood Kosarayanifard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., Equipco (UK) Ltd., Mehdi Bahrami, Al Naser Airlines, Ali Abdullah Alhay, Bahar Safwa General Trading, Sky Blue Bird Group, and Issam Shammout.[2] I find that renewal of the TDO is necessary in the public interest to prevent an imminent violation of the EAR.

I. Procedural History

On March 17, 2008, Darryl W. Jackson, the then-Assistant Secretary of Commerce for Export Enforcement (''Assistant Secretary''), signed a TDO denying Mahan Airways' export privileges for a period of 180 days on the grounds that its issuance was necessary in the public interest to prevent an imminent violation of the Regulations. The TDO also named as denied persons Blue Airways, of Yerevan, Armenia (''Blue Airways of Armenia''), as well as the ''Balli Group Respondents,'' namely, Balli Group PLC, Balli Aviation, Balli Holdings, Vahid Alaghband, Hassan Alaghband, Blue Sky One Ltd., Blue Sky Two Ltd., Blue Sky Three Ltd., Blue Sky Four Ltd., Blue Sky Five Ltd., and Blue Sky Six Ltd., all of the United Kingdom. The TDO was issued *ex parte* pursuant to Section 766.24(a), and went into effect on March 21, 2008, the date it was published in the **Federal Register**.

The TDO subsequently has been renewed in accordance with Section 766.24(d), including most recently on July 7, 2016.[3] As of March 9, 2010, the

[1] The Regulations, currently codified at 15 CFR parts 730–774 (2016), originally issued pursuant to the Export Administration Act of 1979. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 4, 2016 (81 FR 52,58748,223 (Aug. 8, 2016)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

[2] See note 3, *infra.*

[3] The July 7, 2016 Order was published in the **Federal Register** on July 13, 2016 (81 Fed Reg. 45276). The TDO previously had been renewed on September 17, 2008, March 16, 2009, September 11, 2009, March 9, 2010, September 3, 2010, February 25, 2011, August 24, 2011, February 15, 2012, August 9, 2012, February 4, 2013, July 31, 2013, January 24, 2014, July 22, 2014, January 16, 2015, July 13, 2015, and January 7, 2016. The August 24, 2011 renewal followed the modification of the TDO on July 1, 2011, which added Zarand Aviation as a respondent. The July 13, 2015 renewal followed the modification of the TDO on May 21, 2015, which added Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading as

Balli Group Respondents and Blue Airways were no longer subject to the TDO. As part of the February 25, 2011 TDO renewal, Gatewick LLC (a/k/a Gatewick Freight and Cargo Services, a/k/a Gatewick Aviation Services), Mahmoud Amini, and Pejman Mahmood Kosarayanifard (''Kosarian Fard'') were added as related persons in accordance with Section 766.23 of the Regulations.[4] On July 1, 2011, the TDO was modified by adding Zarand Aviation as a respondent in order to prevent an imminent violation.[5] As part of the August 24, 2011 renewal, Kerman Aviation, Sirjanco Trading LLC, and Ali Eslamian were added to the TDO as related persons. Mahan Air General Trading LLC, Skyco (UK) Ltd., and Equipco (UK) Ltd. were added as related persons on April 9, 2012. Mehdi Bahrami was added to the TDO as a related person as part of the February 4, 2013 renewal order.

On May 21, 2015, the TDO was modified to add Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading as respondents. Sky Blue Bird Group and its chief executive officer Issam Shammout were added to the TDO as related persons as part of the July 13, 2015 renewal order.[6]

On December 13, 2016, BIS, through its Office of Export Enforcement (''OEE''), submitted a written request for renewal of the TDO. The written request was made more than 20 days before the scheduled expiration of the current TDO, which issued on July 7, 2016. Notice of the renewal request also was provided to Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received. Furthermore, no appeal of the related person determinations made as part of the September 3, 2010, February 25, 2011, August 24, 2011, April 9, 2012, February 4, 2013, and July 13, 2015 renewal or modification orders has been made by Kosarian Fard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., Equipco (UK) Ltd., Mehdi Bahrami, Sky Blue Bird Group, or Issam Shammout.[7]

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue or renew an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent [.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the TDO renewals in this matter and the evidence developed over the course of this investigation indicating a blatant disregard of U.S. export controls and the TDO. The initial TDO was issued as a result of evidence that showed that Mahan Airways and other parties engaged in conduct prohibited by the EAR by knowingly re-exporting to Iran three U.S.-origin aircraft, specifically Boeing 747s (''Aircraft 1–3''), items subject to the EAR and classified under Export Control Classification Number (''ECCN'') 9A991.b, without the required U.S. Government authorization. Further evidence submitted by BIS indicated that Mahan Airways was involved in the attempted re-export of three additional U.S.-origin Boeing 747s (''Aircraft 4–6'') to Iran.

As discussed in the September 17, 2008 renewal order, evidence presented by BIS indicated that Aircraft 1–3 continued to be flown on Mahan Airways' routes after issuance of the TDO, in violation of the Regulations and the TDO itself.[8] It also showed that Aircraft 1–3 had been flown in further violation of the Regulations and the TDO on the routes of Iran Air, an Iranian Government airline. Moreover, as discussed in the March 16, 2009, September 11, 2009 and March 9, 2010 Renewal Orders, Mahan Airways registered Aircraft 1–3 in Iran, obtained Iranian tail numbers for them (EP–MNA, EP–MNB, and EP–MNE, respectively), and continued to operate at least two of them in violation of the Regulations and the TDO,[9] while also committing an additional knowing and willful violation when it negotiated for and acquired an additional U.S.-origin aircraft. The additional acquired aircraft was an MD–82 aircraft, which subsequently was painted in Mahan Airways' livery and flown on multiple Mahan Airways' routes under tail number TC–TUA.

The March 9, 2010 Renewal Order also noted that a court in the United Kingdom (''U.K.'') had found Mahan Airways in contempt of court on February 1, 2010, for failing to comply with that court's December 21, 2009 and January 12, 2010 orders compelling Mahan Airways to remove the Boeing 747s from Iran and ground them in the Netherlands. Mahan Airways and the Balli Group Respondents had been litigating before the U.K. court concerning ownership and control of Aircraft 1–3. In a letter to the U.K. court dated January 12, 2010, Mahan Airways' Chairman indicated, *inter alia,* that Mahan Airways opposes U.S. Government actions against Iran, that it continued to operate the aircraft on its routes in and out of Tehran (and had 158,000 ''forward bookings'' for these aircraft), and that it wished to continue to do so and would pay damages if required by that court, rather than ground the aircraft.

The September 3, 2010 renewal order discussed the fact that Mahan Airways' violations of the TDO extended beyond operating U.S.-origin aircraft and

respondents. Each renewal or modification order was published in the **Federal Register**.

[4] On August 13, 2014, BIS and Gatewick LLC resolved administrative charges against Gatewick, including a charge for acting contrary to the terms of a BIS denial order (15 CFR 764.2(k)). In addition to the payment of a civil penalty, the settlement includes a seven-year denial order. The first two years of the denial period are active, with the remaining five years suspended on condition that Gatewick LLC pays the civil penalty in full and timely fashion and commits no further violation of the Regulations during the seven-year denial period. The Gatewick LLC Final Order was published in the **Federal Register** on August 20, 2014. *See* 79 FR 49283 (Aug. 20, 2014).

[5] As of July 22, 2014, Zarand Aviation was no longer subject to the TDO.

[6] The U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') designated Sky Blue Bird and Issam Shammout as Specially Designated Global Terrorists (''SDGTs'') on May 21, 2015, pursuant to Executive Order 13324, for ''providing support to Iran's Mahan Air.'' See 80 FR 30762 (May 29, 2015).

[7] A party named or added as a related person may not oppose the issuance or renewal of the underlying temporary denial order, but may file an appeal of the related person determination in accordance with Section 766.23(c).

[8] Engaging in conduct prohibited by a denial order violates the Regulations. 15 CFR 764.2(a) and (k).

[9] The third Boeing 747 appeared to have undergone significant service maintenance and may not have been operational at the time of the March 9, 2010 renewal order.

attempting to acquire additional U.S.-origin aircraft. In February 2009, while subject to the TDO, Mahan Airways participated in the export of computer motherboards, items subject to the Regulations and designated as EAR99, from the United States to Iran, via the United Arab Emirates (''UAE''), in violation of both the TDO and the Regulations, by transporting and/or forwarding the computer motherboards from the UAE to Iran. Mahan Airways' violations were facilitated by Gatewick LLC, which not only participated in the transaction, but also has stated to BIS that it acted as Mahan Airways' sole booking agent for cargo and freight forwarding services in the UAE.

Moreover, in a January 24, 2011 filing in the U.K. court, Mahan Airways asserted that Aircraft 1–3 were not being used, but stated in pertinent part that the aircraft were being maintained in Iran especially ''in an airworthy condition'' and that, depending on the outcome of its U.K. court appeal, the aircraft ''could immediately go back into service . . . on international routes into and out of Iran.'' Mahan Airways' January 24, 2011 submission to U.K. Court of Appeal, at p. 25, ¶¶ 108, 110. This clearly stated intent, both on its own and in conjunction with Mahan Airways' prior misconduct and statements, demonstrated the need to renew the TDO in order to prevent imminent future violations. Two of these three 747s subsequently were removed from Iran and are no longer in Mahan Airways' possession. The third of these 747s, with Manufacturer's Serial Number (''MSN'') 23480 and Iranian tail number EP–MNE, remained in Iran under Mahan's control. Pursuant to Executive Order 13324, it was designated a Specially Designated Global Terrorist (''SDGT'') by the U.S. Department of the Treasury's Office of Foreign Assets Control (''OFAC'') on September 19, 2012.[10] Furthermore, as discussed in the February 4, 2013 Order, open source information indicated that this 747, painted in the livery and logo of Mahan Airways, had been flown between Iran and Syria, and was suspected of ferrying weapons and/or other equipment to the Syrian Government from Iran's Islamic Revolutionary Guard Corps. Open source information showed that this aircraft had flown from Iran to Syria as recently as June 30, 2013, and continues to show that it remains in active operation in Mahan Airways' fleet.

In addition, as first detailed in the July 1, 2011 and August 24, 2011 orders, and discussed in subsequent renewal orders in this matter, Mahan Airways also continued to evade U.S. export control laws by operating two Airbus A310 aircraft, bearing Mahan Airways' livery and logo, on flights into and out of Iran.[11] At the time of the July 1, 2011 and August 24, 2011 Orders, these Airbus A310s were registered in France, with tail numbers F–OJHH and F–OJHI, respectively.[12]

The August 2012 renewal order also found that Mahan Airways had acquired another Airbus A310 aircraft subject to the Regulations, with MSN 499 and Iranian tail number EP–VIP, in violation of the TDO and the Regulations.[13] On September 19, 2012, all three Airbus A310 aircraft (tail numbers F–OJHH, F–OJHI, and EP–VIP) were designated as SDGTs.[14]

The February 4, 2013 Order laid out further evidence of continued and additional efforts by Mahan Airways and other persons acting in concert with Mahan, including Kral Aviation and another Turkish company, to procure U.S.-origin engines—two GE CF6–50C2 engines, with MSNs 517621 and 517738, respectively—and other aircraft parts in violation of the TDO and the Regulations.[15] The February 4, 2013 renewal order also added Mehdi Bahrami as a related person in accordance with Section 766.23 of the Regulations. Bahrami, a Mahan Vice-President and the head of Mahan's Istanbul Office, also was involved in Mahan's acquisition of the original three Boeing 747s (Aircraft 1–3) that resulted in the original TDO, and has had a business relationship with Mahan dating back to 1997.

The July 31, 2013 Order detailed additional evidence obtained by OEE showing efforts by Mahan Airways to obtain another GE CF6–50C2 aircraft engine (MSN 528350) from the United States via Turkey. Multiple Mahan employees, including Mehdi Bahrami, were involved in or aware of matters related to the engine's arrival in Turkey from the United States, plans to visually inspect the engine, and prepare it for shipment from Turkey.

Mahan sought to obtain this U.S.-origin engine through Pioneer Logistics Havacilik Turizm Yonetim Danismanlik (''Pioneer Logistics''), an aircraft parts supplier located in Turkey, and its director/operator, Gulnihal Yegane, a Turkish national who previously had conducted Mahan related business with Mehdi Bahrami and Ali Eslamian. Moreover, as referenced in the July 31, 2013 Order, a sworn affidavit by Kosol Surinanda, also known as Kosol Surinandha, Managing Director of Mahan's General Sales Agent in Thailand, stated that the shares of Pioneer Logistics for which he was the listed owner were ''actually the property of and owned by Mahan.'' He further stated that he held ''legal title to the shares until otherwise required by Mahan'' but would ''exercise the rights granted to [him] exactly and only as instructed by Mahan and [his] vote and/or decisions [would] only and exclusively reflect the wills and demands of Mahan[.]'' [16]

The January 24, 2014 Order outlined OEE's continued investigation of Mahan Airways' activities and detailed an attempt by Mahan, which OEE

[10] *See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/pages/20120919.aspx.*

[11] The Airbus A310s are powered with U.S.-origin engines. The engines are subject to the EAR and classified under Export Control Classification (''ECCN'') 9A991.d. The Airbus A310s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR. They are classified under ECCN 9A991.b. The export or reexport of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[12] OEE subsequently presented evidence that after the August 24, 2011 renewal, Mahan Airways worked along with Kerman Aviation and others to de-register the two Airbus A310 aircraft in France and to register both aircraft in Iran (with, respectively, Iranian tail numbers EP–MHH and EP–MHI). It was determined subsequent to the February 15, 2012 renewal order that the registration switch for these A310s was cancelled and that Mahan Airways then continued to fly the aircraft under the original French tail numbers (F–OJHH and F–OJHI, respectively). Both aircraft apparently remain in Mahan Airways' possession.

[13] See note 12, *supra.*

[14] *See http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/pages/20120919.aspx.* Mahan Airways was previously designated by OFAC as a SDGT on October 18, 2011. 77 FR 64,427 (October 18, 2011).

[15] Kral Aviation was referenced in the February 4, 2013 Order as ''Turkish Company No. 1.'' Kral Aviation purchased a GE CF6–50C2 aircraft engine (MSN 517621) from the United States in July 2012, on behalf of Mahan Airways. OEE was able to prevent this engine from reaching Mahan by issuing a redelivery order to the freight forwarder in accordance with Section 758.8 of the Regulations. OEE also issued Kral Aviation a redelivery order for the second CF6–50C2 engine (MSN 517738) on July 30, 2012. The owner of the second engine subsequently cancelled the item's sale to Kral Aviation. In September 2012, OEE was alerted by a U.S. exporter that another Turkish company (''Turkish Company No. 2'') was attempting to purchase aircraft spare parts intended for re-export by Turkish Company No. 2 to Mahan Airways. *See* February 4, 2013 Order.

On December 31, 2013, Kral Aviation was added to BIS's Entity List, Supplement No. 4 to Part 744 of the Regulations. *See* 78 FR75458 (Dec. 12, 2013). Companies and individuals are added to the Entity List for engaging in activities contrary to the national security or foreign policy interests of the United States. *See* 15 CFR 744.11.

[16] Pioneer Logistics, Gulnihal Yegane, and Kosol Surinanda also were added to the Entity List on December 12, 2013. *See* 78 FR 75458 (Dec. 12, 2013).

thwarted, to obtain, via an Indonesian aircraft parts supplier, two U.S.-origin Honeywell ALF–502R–5 aircraft engines (MSNs LF5660 and LF5325), items subject to the Regulations, from a U.S. company located in Texas. An invoice of the Indonesian aircraft parts supplier dated March 27, 2013, listed Mahan Airways as the purchaser of the engines and included a Mahan ship-to address. OEE also obtained a Mahan air waybill dated March 12, 2013, listing numerous U.S.-origin aircraft parts subject to the Regulations—including, among other items, a vertical navigation gyroscope, a transmitter, and a power control unit—being transported by Mahan from Turkey to Iran in violation of the TDO.

The July 22, 2014 Order discussed open source evidence from the March-June 2014 time period regarding two BAE regional jets, items subject to the Regulations, that were painted in the livery and logo of Mahan Airways and operating under Iranian tail numbers EP–MOK and EP–MOI, respectively.[17] In addition, aviation industry resources indicated that these aircraft were obtained by Mahan Airways in late November 2013 and June 2014, from Ukrainian Mediterranean Airline, a Ukrainian airline that was added to BIS's Entity List (Supplement No. 4 to Part 744 of the Regulations) on August 15, 2011, for acting contrary to the national security and foreign policy interests of the United States.[18] OEE's on-going investigation indicates that both BAE regional jets remain active in Mahan's fleet, with open source information showing EP–MOI being used on flights into and out of Iran as recently as January 12, 2015. The continued operation of these aircraft by Mahan Airways violates the TDO.

The January 16, 2015 Order detailed evidence of additional attempts by Mahan Airways to acquire items subject the Regulations in further violation of the TDO. Specifically, in March 2014, OEE became aware of an inertial reference unit bearing serial number 1231 (''the IRU'') that had been sent to the United States for repair. The IRU is subject to the Regulations, classified under ECCN 7A103, and controlled for missile technology reasons. Upon closer inspection, it was determined that IRU came from or had been installed on an Airbus A340 aircraft bearing MSN 056. Further investigation revealed that as of approximately February 2014, this aircraft was registered under Iranian tail number EP–MMB and had been painted in the livery and logo of Mahan Airways.

The January 16, 2015 Order also described related efforts by the Departments of Justice and Treasury to further thwart Mahan's illicit procurement efforts. Specifically, on August 14, 2014, the United States Attorney's Office for the District of Maryland filed a civil forfeiture complaint for the IRU pursuant to 22 U.S.C. 401(b) that resulted in the court issuing an Order of Forfeiture on December 2, 2014. EP–MMB remains listed as active in Mahan Airways' fleet.

Additionally, on August 29, 2014, OFAC blocked the property and interests in property of Asian Aviation Logistics of Thailand, a Mahan Airways affiliate or front company, pursuant to Executive Order 13224. In doing so, OFAC described Mahan Airways' use of Asian Aviation Logistics to evade sanctions by making payments on behalf of Mahan for the purchase of engines and other equipment.[19]

The May 21, 2015 modification order detailed the acquisition of two aircraft, specifically an Airbus A340 bearing MSN 164 and an Airbus A321 bearing MSN 550, that were purchased by Al Naser Airlines in late 2014/early 2015 and are currently located in Iran under the possession, control, and/or ownership of Mahan Airways.[20] The sales agreements for these two aircraft were signed by Ali Abdullah Alhay for Al Naser Airlines.[21] Payment information reveals that multiple electronic funds transfers (''EFT'') were made by Ali Abdullah Alhay and Bahar Safwa General Trading in order to acquire MSNs 164 and 550.

The May 21, 2015 modification order also laid out evidence showing the respondents' attempts to obtain other controlled aircraft, including aircraft physically located in the United States in similarly-patterned transactions during the same recent time period. Transactional documents involving two Airbus A320s bearing MSNs 82 and 99, respectively, again showed Ali Abdullah Alhay signing sales agreements for Al Naser Airlines.[22] A review of the payment information for these aircraft similarly revealed EFTs from Ali Abdullah Alhay and Bahar Safwa General Trading that follow the pattern described for MSNs 164 and 550, *supra.* MSNs 82 and 99 were detained by OEE Special Agents prior to their planned export from the United States.

The July 13, 2015 Order outlined evidence showing that Al Naser Airlines' attempts to acquire aircraft on behalf of Mahan Airways extended beyond MSNs 164 and 550 to include a total of nine aircraft.[23] Four of the aircraft, all of which are subject to the Regulations and were obtained by

[17] The BAE regional jets are powered with U.S.-origin engines. The engines are subject to the EAR and classified under ECCN 9A991.d. These aircraft contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR. They are classified under ECCN 9A991.b. The export or reexport of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[18] *See* 76 FR 50407 (Aug. 15, 2011). The July 22, 2014 TDO renewal order also referenced two Airbus A320 aircraft painted in the livery and logo of Mahan Airways and operating under Iranian tail numbers EP–MMK and EP–MML, respectively. OEE's investigation also showed that Mahan obtained these aircraft in November 2013, from Khors Air Company, another Ukrainian airline that, like Ukrainian Mediterranean Airlines, was added to BIS's Entity List on August 15, 2011. Open source evidence indicates the two Airbus A320 aircraft may be been transferred by Mahan Airways to another Iranian airline in October 2014, and issued Iranian tail numbers EP–APE and EP–APF, respectively.

[19] See *http://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Pages/20140829.aspx. See* 79 FR 55073 (Sep. 15, 2014). OFAC also blocked the property and property interests of Pioneer Logistics of Turkey on August 29, 2014. *Id.* Mahan Airways' use of Pioneer Logistics in an effort to evade the TDO and the Regulations was discussed in a prior renewal order, as summarized, *supra,* at 13–14. BIS added both Asian Aviation Logistics and Pioneer Logistics to the Entity List on December 12, 2013. *See* 78 FR 75458 (Dec. 12, 2013).

[20] Both of these aircraft are powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. Both aircraft contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[21] Ali Abdullah Alhay is a 25% owner of Al Naser Airlines.

[22] Both aircraft were physically located in the United States and therefore are subject to the Regulations pursuant to Section 734.3(a)(1). Moreover, these Airbus A320s are powered by U.S.-origin engines that are subject to the Regulations and classified under Export Control Classification Number ECCN 9A991.d. The Airbus A320s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[23] This evidence included a press release dated May 9, 2015, that appeared on Mahan Airways' Web site and stated that Mahan ''added 9 modern aircraft to its air fleet [,]'' and that the newly acquired aircraft included eight Airbus A340s and one Airbus A321. See *http://www.mahan.aero/en/mahan-air/press-room/44.* The press release was subsequently removed from Mahan Airways' Web site. Publicly available aviation databases similarly showed that Mahan had obtained nine additional aircraft from Al Naser Airlines in May 2015, including MSNs 164 and 550. As also discussed in the July 13, 2015 renewal order, Sky Blue Bird Group, via Issam Shammout, was actively involved in Al Naser Airlines' acquisition of MSNs 164 and 550, and the attempted acquisition of MSNs 82 and 99 (which were detained by OEE).

Mahan from Al Naser Airlines, had been issued the following Iranian tail numbers: EP–MMD (MSN 164), EP–MMG (MSN 383), EP–MMH (MSN 391) and EP–MMR (MSN 416), respectively.[24] Publicly available flight tracking information provided evidence that at the time of the July 13, 2015 renewal, both EP–MMH and EP–MMR were being actively flown on routes into and out of Iran in violation of the TDO and Regulations.[25]

The January 7, 2016 Order discussed evidence that Mahan Airways had begun actively flying EP–MMD, another of the aircraft Mahan had obtained from Al Naser Airlines (as discussed in the July 13, 2015 renewal order), on international routes into and out of Iran, including from/to Bangkok, Thailand. Additionally, the January 7, 2016 Order described publicly available aviation database and flight tracking information indicating that Mahan Airways was continuing its efforts to acquire Iranian tail numbers and press into active service under Mahan's livery and logo at least two more of the Airbus A340 aircraft it had obtained from or through Al Naser Airlines: EP–MME (MSN 371) and EP–MMF (MSN 376), respectively. Since January 2016, EP–MME has logged flights to and from Tehran, Iran involving various destinations, including Guangzhou, China and Dubai, United Arab Emirates in further violation of the TDO and the Regulations.

The July 7, 2016 Order described Mahan Airways' acquisition of a BAE Avro RJ–85 aircraft (MSN E2392) in violation of the TDO and its subsequent registration under Iranian tail number EP–MOR.[26] This information was corroborated by publicly available information on the Web site of Iran's civil aviation authority. The July 7, 2016 Order also outlined Mahan's continued operation of EP–MMF in violation of the TDO on routes from Tehran Iran to Beijing, China and Shanghai, China, respectively.

The December 13, 2016 renewal request discusses OEE's on-going concerns that Mahan Airways has continued to utilize aircraft, engines, and other aircraft parts that it previously acquired in violation of the TDO. This conduct includes, but is not limited to, operating aircraft originally obtained from or through Al Naser Airlines on international flights into and out of Iran. Publicly available flight tracking information shows that since December 20, 2016, EP–MMD (MSN 164), EP–MMF (MSN 376), and EP–MMH (MSN 391) has each been flown on routes into or out of Tehran, Iran, including from/to Beijing, China, Kuala Lumpur, Malaysia, and Istanbul, Turkey.[27] These flights into or out of Iran by Mahan Airways constitute additional violations of the TDO and the Regulations.[28]

Mahan's acquisition of these aircraft from or through Al Naser Airlines and their subsequent registration in Iran were detailed in the July 13, 2015 and January 7, 2016 renewal orders, respectively. Both Mahan Airways and Al Naser Airways remain subject to an on-going investigation by OEE.

C. Findings

Under the applicable standard set forth in Section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that the denied persons have acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of future violations. Therefore, renewal of the TDO is necessary to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should continue to cease dealing with Mahan Airways, Al Naser Airlines, and the other denied persons under the TDO in connection with export and reexport transactions involving items subject to the Regulations.

IV. Order

IT IS THEREFORE ORDERED:

FIRST, that MAHAN AIRWAYS, Mahan Tower, No. 21, Azadegan St., M.A. Jenah Exp. Way, Tehran, Iran; PEJMAN MAHMOOD KOSARAYANIFARD A/K/A KOSARIAN FARD, P.O. Box 52404, Dubai, United Arab Emirates; MAHMOUD AMINI, G#22 Dubai Airport Free Zone, P.O. Box 393754, Dubai, United Arab Emirates, and P.O. Box 52404, Dubai, United Arab Emirates, and Mohamed Abdulla Alqaz Building, Al Maktoum Street, Al Rigga, Dubai, United Arab Emirates; KERMAN AVIATION A/K/A GIE KERMAN AVIATION, 42 Avenue Montaigne 75008, Paris, France; SIRJANCO TRADING LLC, P.O. Box 8709, Dubai, United Arab Emirates; ALI ESLAMIAN, 33 Cavendish Square, 4th Floor, London W1G0PW, United Kingdom, and 2 Bentinck Close, Prince Albert Road St. Johns Wood, London NW87RY, United Kingdom; MAHAN AIR GENERAL TRADING LLC, 19th Floor Al Moosa Tower One, Sheik Zayed Road, Dubai 40594, United Arab Emirates; SKYCO (UK) LTD., 33 Cavendish Square, 4th Floor, London, W1G 0PV, United Kingdom; EQUIPCO (UK) LTD., 2 Bentinck Close, Prince Albert Road, London, NW8 7RY, United Kingdom; and MEHDI BAHRAMI, Mahan Airways- Istanbul Office, Cumhuriye Cad. Sibil Apt No: 101 D:6, 34374 Emadad, Sisli Istanbul, Turkey; AL NASER AIRLINES A/K/A AL–NASER AIRLINES A/K/A ALNASER AIRLINES AND AIR FREIGHT LTD., Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside Al Jadirya Private Hospital, Baghdad, Iraq, and Al Amirat Street, Section 309, St. 3/H.20, Al Mansour, Baghdad, Iraq, and P.O. Box 28360, Dubai, United Arab Emirates, and P.O. Box 911399, Amman 11191, Jordan; ALI ABDULLAH ALHAY A/K/A ALI ALHAY A/K/A ALI ABDULLAH AHMED ALHAY, Home 46, Al-Karrada, Babil Region, District 929, St 21, Beside

[24] The Airbus A340s are powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. The Airbus A340s contain controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result are subject to the EAR regardless of their location. The aircraft are classified under ECCN 9A991.b. The export or re-export of these aircraft to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[25] There is some publicly available information indicating that the aircraft Mahan Airways is flying under Iranian tail number EP–MMR is now MSN 615, rather than MSN 416. Both aircraft are Airbus A340 aircraft that Mahan acquired from Al Naser Airlines in violation of the TDO and the Regulations. Moreover, both aircraft were designated as SDGTs by OFAC on May 21, 2015, pursuant to Executive Order 13324. See 80 FR 30762 (May 29, 2015).

[26] The BAE Avro RJ–85 is powered by U.S.-origin engines that are subject to the Regulations and classified under ECCN 9A991.d. The BAE Avro RJ–85 contains controlled U.S.-origin items valued at more than 10 percent of the total value of the aircraft and as a result is subject to the EAR regardless of its location. The aircraft is classified under ECCN 9A991.b, and its export or re-export to Iran requires U.S. Government authorization pursuant to Sections 742.8 and 746.7 of the Regulations.

[27] Publicly available flight tracking information shows that on December 22, 2016, EP–MMD (MSN 164) flew from Dubai, UAE to Tehran, Iran. Additionally, between December 20, 2016, and December 22, 2016, EP–MMF (MSN 376) flew on routes from Tehran, Iran to Beijing, China and Istanbul, Turkey, respectively. Similar flight tracking information shows that between December 26, 2016 and December 28, 2016, EP–MMH (MSN 391) flew on routes from Tehran, Iran to Kuala Lumpur, Malaysia.

[28] OEE's December 13, 2016 request also raised its concerns about an Airbus A340 previously registered in the United States. The aircraft was recently exported from the United States to Indonesia contrary to filings made with the U.S. Federal Aviation Administration indicating, first that the aircraft was being flown to Almaty, Kazakhstan, and then indicating that the aircraft should be de-registered in the U.S. because it was being exported to and going to be registered in Ukraine, neither of which has occurred.

Al Jadirya Private Hospital, Baghdad, Iraq, and Anak Street, Qatif, Saudi Arabia 61177; BAHAR SAFWA GENERAL TRADING, P.O. Box 113212, Citadel Tower, Floor-5, Office #504, Business Bay, Dubai, United Arab Emirates, and P.O. Box 8709, Citadel Tower, Business Bay, Dubai, United Arab Emirates; SKY BLUE BIRD GROUP A/K/A SKY BLUE BIRD AVIATION A/K/A SKY BLUE BIRD LTD A/K/A SKY BLUE BIRD FZC, P.O. Box 16111, Ras Al Khaimah Trade Zone, United Arab Emirates; and ISSAM SHAMMOUT A/K/A MUHAMMAD ISAM MUHAMMAD ANWAR NUR SHAMMOUT A/K/A ISSAM ANWAR, Philips Building, 4th Floor, Al Fardous Street, Damascus, Syria, and Al Kolaa, Beirut, Lebanon 151515, and 17–18 Margaret Street, 4th Floor, London, W1W 8RP, United Kingdom, and Cumhuriyet Mah. Kavakli San St. Fulya, Cad. Hazar Sok. No.14/A Silivri, Istanbul, Turkey, and when acting for or on their behalf, any successors or assigns, agents, or employees (each a ''Denied Person'' and collectively the ''Denied Persons'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Export Administration Regulations (''EAR''), or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR.

SECOND, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

THIRD, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to a Denied Person by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be made subject to the provisions of this Order.

FOURTH, that this Order does not prohibit any export, reexport, or other transaction subject to the EAR where the only items involved that are subject to the EAR are the foreign-produced direct product of U.S.-origin technology.

In accordance with the provisions of Sections 766.24(e) of the EAR, Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and/or Bahar Safwa General Trading may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022. In accordance with the provisions of Sections 766.23(c)(2) and 766.24(e)(3) of the EAR, Pejman Mahmood Kosarayanifard, Mahmoud Amini, Kerman Aviation, Sirjanco Trading LLC, Ali Eslamian, Mahan Air General Trading LLC, Skyco (UK) Ltd., Equipco (UK) Ltd., Mehdi Bahrami, Sky Blue Bird Group, and/or Issam Shammout may, at any time, appeal their inclusion as a related person by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and/or Bahar Safwa General Trading as provided in Section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Mahan Airways, Al Naser Airlines, Ali Abdullah Alhay, and Bahar Safwa General Trading and each related person, and shall be published in the **Federal Register**. This Order is effective immediately and shall remain in effect for 180 days.

Dated: December 30, 2016.

Richard R. Majauskas,

Acting Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2017–00092 Filed 1–6–17; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–913]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Preliminary Results of the Countervailing Duty Administrative Review and Preliminary Intent To Rescind, in Part; 2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (PRC). The period of review (POR) is January 1, 2014, through December 31, 2014. Interested parties are invited to comment on these preliminary results.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Gene Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of

Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, the Department issued a countervailing duty (CVD) order on solar cells from the PRC.[1] Several interested parties requested that the Department conduct an administrative review of the countervailing duty order, and February 9, 2016, the Department published in the **Federal Register** a notice of initiation of an administrative review of the *CVD Order* for 45 producers/exporters for the POR.[2]

Scope of the Order

The merchandise subject to the *CVD Order* is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels, and building integrated materials. A full description of the scope of the order is contained in the Department memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China; 2014,'' dated concurrently with this notice (Preliminary Decision Memorandum) and hereby adopted by this notice.

Methodology

The Department is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily find that there is a subsidy, (*i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient) and that the subsidy is specific.[3] In making this preliminary determination, the Department relied, in part, on facts otherwise available, with the application of adverse inferences.[4] For further information, see ''Use of Facts Otherwise Available and Application of Adverse Inferences'' in the accompanying Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is provided at Appendix I to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Intent To Partially Rescind the Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Jinko Solar Co., Ltd., JinkoSolar (U.S.) Inc., Jinko Solar Import and Export Co., Ltd., JinkoSolar International Limited, Zhejiang Jinko Solar Co., Ltd. (collectively, the Jinko Solar Companies); Yingli Green Energy Holding Company Limited (Yingli); ERA Solar Co. Limited (ERA Solar); Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company (Zhejiang Sunflower); and JA Solar Technology Yangzhou Co., Ltd., Shanghai JA Solar Technology Co., Ltd., and JingAo Solar Co., Ltd. (collectively, the JA Solar Companies) timely withdrew their requests for review.[5] No other party requested a review of any of these companies. Therefore, in accordance with 19 CFR 351.213(d)(1), the Department intends to rescind this review of the countervailing duty order on solar cells from the PRC with respect to these companies. A final decision regarding whether to rescind the review of these companies will be issued with the final results of review.

Preliminary Results of Review

As a result of this review, we preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate (percent)
Canadian Solar Manufacturing (Changshu) and its Cross-Owned Affiliates[6] ...	20.98
Changzhou Trina Solar Energy Co., Ltd. and its Cross-Owned Affiliates[7] ...	12.48
Non-Selected Companies Under Review	16.69

Preliminary Rate for the Non-Selected Companies Under Review

For the companies for which a review was requested that were not selected as mandatory company respondents, and for which we did not receive a timely request for withdrawal of review, and which we are not finding to be cross-owned with the mandatory company respondents, we are preliminarily basing the subsidy rate on the weighted-average of the subsidy rates calculated for Canadian Solar and Trina Solar. These rates were above *de minimis* and not based entirely on facts available. For a list of these non-selected companies, please see the Appendix to the Preliminary Decision Memorandum.

Disclosure and Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012) (*CVD Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 6832 (February 9, 2016) (*Initiation Notice*).

[3] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[4] *See* section 776(a) of the Act.

[5] *See* Letter to the Secretary from the Jinko Solar Companies, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Jinko's Withdrawal of Request for Administrative Review,'' (March 14, 2016); Letter to the Secretary from Yingli, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Yingli's Withdrawal of Request for Administrative Review,'' (March 18, 2016); Letter to the Secretary from ERA Solar, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules From The People's Republic of China; ERA Solar Co., Limited's Withdrawal of Request for Review,'' (May 9, 2016); Letter to the Secretary from Zhejiang Sunflower, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From The People's Republic of China; Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company's Withdrawal of Request for Review,'' (May 9, 2016); and Letter to the Secretary from the JA Solar Companies, ''Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Withdrawal of Request for Review,'' (May 9, 2016).

[6] Cross-owned affiliates are: Canadian Solar Manufacturing (Luoyang) Inc.; CSI Cells Co., Ltd.; CSI Solar Power (China) Inc.; CSI Solartronics (Changshu) Co., Ltd.; CSI Solar Technologies Inc.; and CSI Solar Manufacture Inc. *See* Preliminary Decision Memorandum.

[7] Cross-owned affiliates are: Trina Solar (Changzhou) Science & Technology Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Hubei Trina Solar Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; and Changzhou Trina PV Ribbon Materials Co., Ltd. *See* Preliminary Decision Memorandum.

the date of publication of these preliminary results.[8] Interested parties may submit written comments (case briefs) at a date to be determined by the Department and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[9] Rebuttal briefs must be limited to issues raised in the case briefs.[10] Parties who submit case or rebuttal briefs are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[11]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, using Enforcement and Compliance's ACCESS system.[12] Hearing requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing, which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.[13] Parties should confirm by telephone the date, time, and location of the hearing. Issues addressed at the hearing will be limited to those raised in the briefs.[14] All briefs and hearing requests must be filed electronically and received successfully in their entirety through ACCESS by 5:00 p.m. Eastern Time by their respective deadlines.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, the Department intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after publication of these preliminary results.

Assessment Rates and Cash Deposit Requirement

In accordance with 19 CFR 351.221(b)(4)(i), we assigned a subsidy rate for each producer/exporter subject to this administrative review. Upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of review.

Pursuant to section 751(a)(2)(C) of the Act, the Department also intends to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above for each of the respective companies shown above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

These preliminary results of review are issued and published in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213 and 351.221(b)(4).

Dated: December 29, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Intent To Partially Rescind Review
IV. Non-Selected Companies Under Review
V. Scope of the Order
VI. Application of the Countervailing Duty Law to Imports From the PRC
VII. Diversification of the PRC's Economy
VIII. Subsidies Valuation
IX. Interest Rate Benchmarks, Discount Rates, Input, Electricity, and Land Benchmarks
X. Use of Facts Otherwise Available and Application of Adverse Inferences
XI. Analysis of Programs
XII. Verification
XIII. Disclosure and Public Comment
XIV. Conclusion

Appendix I

Non-Selected Companies Under Review

1. BYD (Shangluo) Industrial Co., Ltd.
2. Chint Solar (Zhejiang) Co., Ltd.
3. ET Solar Energy Limited
4. ET Solar Industry Limited
5. Hangzhou Sunny Energy Science and Technology Co., Ltd.
6. Jiawei Solarchina Co., Ltd.
7. Jiawei Solarchina (Shenzhen) Co., Ltd.
8. Lightway Green New Energy Co., Ltd.
9. Luoyang Suntech Power Co., Ltd.
10. Ningbo Qixin Solar Electrical Appliance Co., Ltd.
11. Shanghai BYD Co., Ltd.
12. Shenzhen Topray Solar Co. Ltd.
13. Systemes Versilis, Inc.
14. Taizhou BD Trade Co., Ltd.
15. tenKsolar (Shanghai) Co., Ltd.
16. Toenergy Technology
17. Wuxi Suntech Power Co., Ltd.

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[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(c)(l)(ii) and 351.309(d)(l). Interested parties will be notified through ACCESS regarding the deadline for submitting case briefs.

[10] *See* 19 CFR 351.309(d)(2).

[11] *See* 19 CFR 351.309(c)(2) and (d)(2).

[12] *See* 19 CFR 351.310(c).

[13] *See* 19 CFR 351.310.

[14] *See* 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–971]

Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Review, in Part, and Intent To Rescind the Review in Part; 2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of multilayered wood flooring (wood flooring) from the People's Republic of China (PRC). The period of review (POR) is January 1, 2014, through December 31, 2014.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Dennis McClure or Sergio Balbontin, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–5973 or 202–482–6478, respectively.

Scope of the Order

The product covered by the Order is wood flooring from the PRC. For a complete description of the scope of this administrative review, *see* the Preliminary Decision Memorandum.[1]

[1] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Decision Memorandum for the Preliminary Determination in the Countervailing Duty Administrative Review of Multilayered Wood Flooring from the People's Republic of China: 2014,'' (Preliminary Decision Memorandum) dated concurrently with, and hereby adopted by, this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. This review was initiated on February 9, 2016. One PRC producer/exporter of wood flooring, Jiangsu Keri Wood Co., Ltd. (Jiangsu Keri), withdrew its request for review on February 22, 2016, which was within the 90-day deadline. Therefore, in accordance with 19 CFR 351.213(d)(1), and consistent with our practice, we are rescinding this review with respect to Jiangsu Keri.

Intent To Rescind Administrative Review, in Part

We received timely filed no-shipment certifications from six companies.[2] Because there is no evidence on the record to indicate that Changbai Mountain, Shenyang Senwang, and Jiangsu Yuhui had entries of subject merchandise during the POR, pursuant to 19 CFR 351.213(d)(3), we intend to rescind the review with respect to these companies. A final decision regarding whether to rescind the review of these companies will be made in the final results of this review.

With respect to Dalian Xinjinghua, Henan Xingwangjia, and Xuzhou Antop, we preliminarily determine that there is sufficient evidence on the record of this review to conclude that these companies had reviewable transactions during the POR.[3] Therefore, we are continuing to include Dalian Xinjinghua, Henan Xingwangjia, and Xuzhou Antop in this administrative review for purposes of the preliminary results.

Methodology

The Department is conducting this countervailing duty (CVD) review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[4] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

In making these preliminary results, the Department relied, in part, on facts otherwise available.[5] For further information, *see* ''Provision of Electricity for Less Than Adequate Remuneration (LTAR)'' in the Preliminary Decision Memorandum.

Rate for Non-Selected Companies Under Review

There are 104 companies for which a review was requested and not rescinded, but were not selected as mandatory respondents. For these companies, we calculated the non-selected rate by averaging the rates of mandatory respondents Dalian Penghong Floor Products Co., Ltd. and Fine Furniture (Shanghai) Limited, based on their publicly ranged sales data for the POR, instead of weight-averaging based on their proprietary sales data for the POR, which would risk disclosure of proprietary information. For further information on the calculation of the non-selected rate, refer to the section in the Preliminary Decision Memorandum entitled, ''Preliminary Ad Valorem Rate for Non-Selected Companies Under Review.''

Preliminary Results of the Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated a countervailable subsidy rate for each of the mandatory respondents, Dalian Penghong Floor Products Co., Ltd. (Penghong) and Fine Furniture (Shanghai) Limited (Fine Furniture), and their cross-owned affiliates where applicable.

We preliminarily find the countervailable subsidy rates for the mandatory respondents under review to be as follows:

Producer/exporter	Subsidy rate (percent)
Dalian Penghong Floor Products Co., Ltd	1.45
Dalian Shumaike Floor Manufacturing Co. Ltd.	
Fine Furniture (Shanghai) Limited	1.91

Review-Specific Average Rate Applicable to the Following Non-Selected Companies:

Producer/exporter	Subsidy rate (percent)
A&W (Shanghai) Woods Co., Ltd	1.68
Anhui Boya Bamboo&Wood Products Co., Ltd	1.68
Anhui Longhua Bamboo Product Co., Ltd	1.68
Baishan Huafeng Wood Product Co., Ltd	1.68
Baroque Timber Industries (Zhongshan) Co., Ltd	1.68
Baiying Furniture Manufacturer Co., Ltd	1.68
Benxi Wood Compan	1.68
Changzhou Hawd Flooring Co., Ltd	1.68
Cheng Hang Wood Co., Ltd	1.68
Chinafloors Timber (China) Co., Ltd	1.68
Dalian Dajen Wood Co., Ltd	1.68
Dalian Huade Wood Product Co., Ltd	1.68
Dalian Huilong Wooden Products Co., Ltd	1.68
Dalian Jiahong Wood Industry Co., Lt	1.68
Dalian Jiuyuan Wood Industry Co., Ltd	1.68
Dalian Kemian Wood Industry Co., Ltd	1.68
Dalian T-Boom Wood Products Co., Ltd	1.68
Dalian Xinjinghua Wood Co., Ltd	1.68
Dongtai Fuan Universal Dynamics, LLC	1.68
Dongtai Zhangshi Wood Industry Co. Ltd	1.68
Dun Hua City Jisen Wood Industry Co., Ltd	1.68
Dun Hua Sen Tai Wood Co., Ltd	1.68
Dunhua City Dexin Wood Industry Co., Ltd	1.68
Dunhua City Hongyuan Wood Industry Co., Ltd	1.68
Dunhua City Wanrong Wood Industry Co., Ltd	1.68
Fu Lik Timber (HK) Co., Ltd	1.68

[2] *See* Letter from Changbai Mountain Development and Protection Zone Hongtu Wood Industrial Co., Ltd. (Changbai Mountain), Shenyang Senwang Wooden Industry Co., Ltd. (Shenyang Senwang), Henan Xingwangjia Technology Co., Ltd. (Henan Xingwangjia), Dalian Xinjinghua Wood Co., Ltd. (Dalian Xinjinghua), Xuzhou Antop International Trade Co., Ltd. (Xuzhou Antop), and Jiangsu Yuhui International Trade Co., Ltd., (Jiangsu Yuhui) ''Multilayered Wood Flooring from the People's Republic of China: Submission of No Shipment Certifications,'' dated February 18, 2016.

[3] *See* Preliminary Decision Memorandum.

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] *See* section 776(a) of the Act.

Producer/exporter	Subsidy rate (percent)
Fusong Jinlong Wooden Group Co., Ltd	1.68
Fusong Qianqiu Wooden Product Co., Ltd	1.68
GTP International Ltd	1.68
Guangdong Yihua Timber Industry Co., Ltd	1.68
Guangzhou Homebon Timber Manufacturing Co., Ltd	1.68
Guangzhou Panyu Kangda Board Co., Ltd	1.68
Guangzhou Panyu Southern Star Co., Ltd	1.68
HaiLin LinJing Wooden Products, Ltd	1.68
HaiLin XinCheng Wooden Products, Ltd	1.68
Hangzhou Dazhuang Floor Co., Ltd. (dba Dasso Industrial Group Co., Ltd.	1.68
Hangzhou Hanje Tec Co., Ltd	1.68
Hangzhou Huahi Wood Industry Co., Ltd	1.68
Henan Xingwangjia Technology Co., Ltd	1.68
Huber Engineering Wood Corp	1.68
Hunchun Forest Wolf Wooden Industry Co., Ltd	1.68
Hunchun Xingjia Wooden Flooring Inc	1.68
Huzhou City Nanxun Guangda Wood Co., Ltd	1.68
Huzhou Chenghang Wood Co., Ltd	1.68
Huzhou Fulinmen Imp. & Exp. Co., Ltd	1.68
Huzhou Fuma Wood Co., Ltd	1.68
Huzhou Jesonwood Co., Ltd	1.68
Huzhou Muyun Wood Co., Ltd	1.68
Huzhou Sunergy World Trade Co., Ltd	1.68
Jiafeng Wood (Suzhou) Co., Ltd	1.68
Jiangsu Guyu International Trading Co., Ltd	1.68
Jiangsu Keri Wood Co., Ltd	1.68
Jiangsu Mingle Flooring Co	1.68
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd	1.68
Jiangsu Simba Flooring Co., Ltd	1.68
Jiashan Huijiale Decoration Material Co., Ltd	1.68
Jiashan On-Line Lumber Co., Ltd	1.68
Jiaxing Hengtong Wood Co., Ltd	1.68
Jilin Forest Industry Jinqiao Flooring Group Co., Ltd	1.68
Jilin Xinyuan Wooden Industry Co., Ltd	1.68
Karly Wood Product Limited	1.68
Kemian Wood Industry (Kunshan) Co., Ltd	1.68
Kingman Floors Co., Ltd	1.68
Linyi Anying Wood Co., Ltd	1.68
Linyi Bonn Flooring Manufacturing Co., Ltd	1.68
Linyi Youyou Wood Co., Ltd	1.68
Mudanjiang Bosen Wood Industry Co., Ltd	1.68
Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd	1.68
Pinge Timber Manufacturing (Zhejiang) Co., Ltd	1.68
Puli Trading Limite	1.68
Qingdao Barry Flooring Co., Ltd	1.68
Riverside Plywood Corporation	1.68
Samling Elegant Living Trading (Labuan) Limited	1.68
Samling Riverside Co., Ltd	1.68
Shandong Kaiyuan Wood Industry Co., Ltd	1.68
Shanghai Anxin (Weiguang) Timber Co., Ltd	1.68
Shanghai Eswell Timber Co., Ltd	1.68
Shanghai Lairunde Wood Co., Ltd	1.68
Shanghai Lizhong Wood Products Co., Ltd. (also known as The Lizhong Wood Industry Limited Company of Shanghai)	1.68
Shanghai New Sihe Wood Co., Ltd	1.68
Shanghai Shenlin Corporation	1.68
Shenyang Haobainian Wooden Co., Ltd	1.68
Shenzhenshi Huanwei Woods Co., Ltd	1.68
Sino-Maple (Jiangsu) Co., Ltd	1.68
Suzhou Dongda Wood Co., Ltd. (8M)	1.68
Tongxiang Jisheng Import and Export Co., Ltd	1.68
Vicwood Industry (Suzhou) Co. Ltd	1.68
Xiamen Yung De Ornament Co., Ltd	1.68
Xuzhou Antop International Trade Co., Ltd	1.68
Xuzhou Shenghe Wood Co., Ltd	1.68
Yekalon Industry, Inc	1.68
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd	1.68
Yixing Lion-King Timber Industry	1.68
Zhejiang AnJi Xinfeng Bamboo and Wood Industry Co., Ltd	1.68
Zhejiang Biyork Wood Co., Ltd	1.68
Zhejiang Dadongwu Green Home Wood Co., Ltd	1.68
Zhejiang Desheng Wood Industry Co., Ltd	1.68
Zhejiang Fudeli Timber Industry Co., Ltd	1.68
Zhejiang Fuerjia Wooden Co., Ltd	1.68
Zhejiang Fuma Warm Technology Co., Ltd.	1.68
Zhejiang Haoyun Wooden Co., Ltd.	1.68
Zhejiang Longsen Lumbering Co., Ltd.	1.68
Zhejiang Shiyou Timber Co., Ltd.	1.68
Zhejiang Shuimojiangnan New Material Technology Co., Ltd.	1.68

Disclosure and Public Comment

We will disclose to parties in this proceeding the calculations performed in reaching the preliminary results within five days of publication of these preliminary results.[6] Interested parties may submit written comments (case briefs) on the preliminary results no later than 30 days from the date of publication of this **Federal Register** notice, and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[7] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a date and time to be determined.[8] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, we intend to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after publication of these preliminary results.

Assessment Rates

Consistent with section 751(a)(1) of the Act, upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, the Department intends to instruct CBP to collect cash deposits of

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[8] *See* 19 CFR 351.310.

estimated countervailing duties in the amounts shown for each of the respective companies listed above. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: December 30, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
  A. Case History
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  C. Period of Review
  D. Rescission of Review, in Part
  E. Intent To Rescind, in Part, the Administrative Review
III. Scope of the Order
IV. Subsidies Valuation
  A. Allocation Period
  B. Attribution of Subsidies
  C. Denominators
  D. Loan Benchmarks and Discount Rates
V. Analysis of Programs
  A. Programs Preliminarily Determined To Be Countervailable
  B. Programs Which Provided No Measurable Benefit During the POR
  C. Programs Preliminarily Determined To Be Not Used
VI. Preliminary *Ad Valorem* Rate for Non-Selected Companies Under Review
VII. Recommendation

[FR Doc. 2017–00139 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–808, A–791–805, A–583–830, C–791–806]

Stainless Steel Plate in Coils From Belgium, South Africa, and Taiwan: Continuation of Antidumping Duty Orders and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Department) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) orders on stainless steel plate in coils (SSPC) from Belgium, South Africa, and Taiwan, and the countervailing duty (CVD) order on SSPC from South Africa, would likely lead to a continuation or recurrence of dumping and countervailable subsidies and material injury to an industry in the United States, the Department is publishing a notice of continuation of the AD orders and the CVD order.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Victoria Cho or Yasmin Bordas, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2312 or (202) 482–3813, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2016, the Department published the notice of initiation of the third sunset reviews of the AD orders on SSPC from Belgium, South Africa, and Taiwan, and the CVD order on SSPC from South Africa, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] As a result of the reviews, the Department determined that revocation of the AD orders would likely lead to a continuation or recurrence of dumping, and that revocation of the CVD order would likely lead to continuation or recurrence of countervailable subsidies.[2] The Department, therefore, notified the ITC of the magnitude of the dumping margins and net countervailable subsidy rates likely to prevail should the AD orders and the CVD order be revoked. On January 3, 2016, the ITC published notice of its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the AD orders on SSPC from Belgium, South Africa, and Taiwan, and the CVD order on SSPC from South Africa, would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[3]

Scope of the Orders

The product covered by these orders is certain stainless steel plate in coils. Stainless steel is alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject plate products are flat-rolled products, 254 mm or over in width and 4.75 mm or more in thickness, in coils, and annealed or otherwise heat treated and pickled or otherwise descaled. The subject plate may also be further processed (*e.g.,* cold-rolled, polished, *etc.*) provided that it maintains the specified dimensions of plate following such processing. Excluded from the scope of these orders are the following: (1) Plate not in coils, (2) plate that is not annealed or otherwise heat treated and pickled or otherwise descaled, (3) sheet and strip, and (4) flat bars. The merchandise subject to these orders is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 7219.11.00.30, 7219.11.00.60, 7219.12.00.02, 7219.12.00.05, 7219.12.00.06, 7219.12.00.20, 7219.12.00.21, 7219.12.00.25, 7219.12.00.26, 7219.12.00.50, 7219.12.00.51, 7219.12.00.55, 7219.12.00.56, 7219.12.00.65, 7219.12.00.66, 7219.12.00.70, 7219.12.00.71, 7219.12.00.80, 7219.12.00.81, 7219.31.00.10, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.11.00.00, 7220.20.10.10, 7220.20.1 0.15, 7220.20.1 0.60, 7220.20.1 0.80, 7220.20.60.05, 7220.20.60.1 0, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.90.00.1 0, 7220.90.00.15, and 7220.90.00.60.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to these orders is dispositive.

Continuation of the Orders

As a result of the determinations by the Department and the ITC that revocation of the AD orders and the CVD order would likely lead to a continuation or recurrence of dumping and countervailable subsidies and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), the Department hereby orders the continuation of the AD orders on SSPC from Belgium, South Africa, and Taiwan, and the CVD order on SSPC from South Africa.

[1] *See Initiation of Five-Year ("Sunset") Reviews,* 81 FR 43185 (July 1, 2016).

[2] *See Stainless Steel Plate in Coils from Belgium, South Africa, and Taiwan: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders,* 81 FR 78774 (November 9, 2016) (*AD Final Results*); *see also Stainless Steel Plate in Coils from South Africa: Final Results of Expedited Sunset Review of the Countervailing Duty Order,* 81 FR 78115 (November 7, 2016) (*CVD Final Results*).

[3] *See Stainless Steel Plate in Coils from Belgium, South Africa, and Taiwan: Investigation Nos. 701–TA–379 and 701–TA–782, 792, and 793 (Third Review),* USITC Publication 4658 (December 2016); *see also Stainless Steel Plate in Coils from Belgium, South Africa, and Taiwan; Determination,* 81 FR 140 (January 3, 2017).

U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year sunset reviews of the orders not later than 30 days prior to the fifth anniversary of the effective date of continuation.

These five-year sunset reviews and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: January 3, 2017

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–00140 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF136

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Highly Migratory Species Advisory Subpanel (HMSAS) will hold a webinar, which is open to the public.

DATES: The HMSAS webinar will be on Tuesday, January 31, 2017, from 1:30 to 3:30 p.m. Pacific Time, or when business for the day is complete.

ADDRESSES: To attend the HMSAS webinar visit this link: *http://www.gotomeeting.com/online/webinar/join-webinar.* Enter the Webinar ID: 957–023–963. Please enter your name and email address (required). After logging into the webinar, dial this TOLL number +1 (562) 247–8422 (not a toll-free number), enter the attendee phone audio access code 370–921–429, then enter your audio phone PIN (shown after joining the webinar). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback. If you do not select ''Use Telephone'' after joining the webinar you will be connected to audio using your computer's microphone and speakers (VolP). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2280, extension 425 for technical assistance. A listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kit Dahl, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The HMSAS will be briefed on proposed changes to the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species (HMS FMP). Changes are proposed in Chapters 1, 4, 6, and 8. These changes are not intended to change the management framework described in the FMP or any related policies; rather, edits to update descriptive information and improve the readability of the document.

Although nonemergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during the meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Technical Information and System Requirements

PC-based attendees: Windows® 7, Vista, or XP operating system required. Mac®-based attendees: Mac OS® X 10.5 or newer required. Mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet required (use GoToMeeting Webinar Apps).

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 at least 10 days prior to the meeting date.

Dated: January 4, 2017.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2017–00114 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Foreign Fishing Vessel Permits, Vessel, and Gear Identification, and Reporting Requirements

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before March 10, 2017.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Christopher Rogers, Office for International Affairs and Seafood Inspection (F/IS5), 1315 East-West Highway, Silver Spring, Maryland 20910, 301–427–8350 or *christopher.rogers@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. The National Marine Fisheries Service (NMFS) issues permits, under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.;* MSA), to foreign fishing vessels fishing or operating in United States' (U.S.) waters. MSA and associated regulations at 50 CFR part 600 require that vessels apply for fishing permits, that vessels and certain gear be marked for identification purposes, that observers be embarked on selected vessels, and that permit holders report their fishing effort and catch or, when processing fish under joint ventures, the amount and locations of fish received from U.S. vessels. These requirements apply to all foreign vessels fishing, transshipping, or processing fish in U.S. waters.

Information is collected from persons who operate a foreign fishing vessel in U.S. waters to participate in a directed fishery or joint venture operation, transship fish harvested by a U.S. vessel to a location outside the U.S., or process fish in internal waters. Each person operating a foreign fishing vessel under MSA authority may be required to submit information for a permit, mark their vessels and gear, or submit information about their fishing activities. To facilitate observer coverage, foreign fishing vessel operators must provide a quarterly schedule of fishing effort and upon request must also provide observers with copies of any required records. For foreign fishing vessels that process fish in internal waters, the information collected varies somewhat from other foreign fishing vessels that participate in a directed fishery or a joint venture operation. In particular, these vessels may not be required to provide a permit application or mark their vessels. The information submitted in applications is used to determine whether permits should be used to authorize directed foreign fishing, participation in joint ventures with U.S. vessels, or transshipments of fish or fish products within U.S. waters. The display of identifying numbers on vessels and gear aid in fishery law enforcement and allows other fishermen to report suspicious activity. Reporting of fishing activities allows monitoring of fish received by foreign vessels.

II. Method of Collection

Foreign fishing activity reports are made by radio when fishing begins or ceases, to report on transfers of fish, and to file weekly reports on the catch or receipt of fish. Weekly reports may be submitted by fax or email. Recordkeeping requirements for foreign vessels include a communications log, a transfer log, a daily fishing log, a consolidated fishing or joint venture log, and a daily joint venture log. These records must be maintained for three years. Paper forms are used for foreign fishing vessel permit applications. No information is submitted to NMFS for the vessel and gear marking requirements.

III. Data

OMB Control Number: 0648–0075.

Form Number: None.

Type of Review: Regular (extension of a currently approved collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 8.

Estimated Time per Response: For permit applications: One and one half hours for an application for a directed fishery; two hours for a joint venture application, and 45 minutes for a transshipment permit; for fishing activity reporting: 6 minutes for a joint venture report; 30 minutes per day for joint venture record-keeping; and 7.5 minutes per day for record-keeping by transport vessels; for weekly reports, 30 minutes per response; for foreign vessel and gear identification marking: 15 minutes per marking.

Estimated Total Annual Burden Hours: 82.

Estimated Total Annual Cost to Public: $3,337 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 4, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–00150 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Management and Oversight of the National Estuarine Research Reserve System

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before March 10, 2017.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Erica Seiden, 240–533–0781, *Erica.Seiden@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

The Coastal Zone Management Act of 1972 (CZMA; 16 U.S.C. 1461 *et seq.*) provides for the designation of estuarine research reserves representative of various regions and estuarine types in the United States to provide opportunities for long-term research, education and interpretation. During the site selection and designation process, information is collected from states in order to prepare a management plan and environmental impact statement. Designated reserves apply annually for operations funds by submitting a work plan; subsequently progress reports are required every six months for the duration of the award. Each reserve compiles an ecological characterization or site profile to describe the biological and physical environment of the reserve, research to date and research gaps. Reserves revise their management plans every five years. This information is required to ensure that reserves are adhering to regulations and that the reserves are in keeping with the purpose for which they were designated.

II. Method of Collection

Respondents have a choice of either electronic or paper submissions. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0121.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Non-profit institutions; state, local, or tribal government.

Estimated Number of Respondents: 75.

Estimated Time per Response: Management plan, 1,800 hours; site profile, 1,800 hours; award application, 8 hours; award reports, 5 hours; designations, 2,000 hours; NEPA documentation, 40 hours.

Estimated Total Annual Burden Hours: 8,216.

Estimated Total Annual Cost to Public: $1,000 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 4, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–00145 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF089

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Data Scoping Webinar for South Atlantic Red Grouper; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 53 Assessment webinar.

SUMMARY: The SEDAR 53 assessment of the South Atlantic stock of red grouper will consist of a series webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: A SEDAR 53 Assessment webinar will be held Wednesday, February 1, 2017, from 9 a.m. to 12 p.m.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. The product of the SEDAR webinar series will be a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Assessment webinar are as follows:

1. Participants will continue discussions to develop population models to evaluate stock status, estimate population benchmarks, and project future conditions, as specified in the Terms of Reference.

2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

3. Participants will prepare a workshop report and determine whether the assessment(s) are adequate for submission for review.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 4, 2017.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2017–00113 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Proposed Information Collection; Comment Request; Computer and Internet Use Supplement to the Census Bureau's Current Population Survey

AGENCY: National Telecommunications and Information Administration (NTIA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before March 10, 2017.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental

Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6612, 1401 Constitution Avenue NW., Washington, DC 20230 (or via email at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: NTIA has made a copy of the proposed information collection instrument available at *https://ntia.doc.gov/files/ntia/publications/november_2017_cps_supplement_draft_for_public_comment.pdf.* Additionally, requests for further information or copies of the proposed information collection instrument and instructions should be directed to Rafi Goldberg, Telecommunications Policy Analyst, Office of Policy Analysis and Development, NTIA, at (202) 482–4375 or *RGoldberg@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

NTIA proposes to add 58 questions to the U.S. Census Bureau's November 2017 Current Population Survey (CPS) to gather reliable data on broadband (also known as high-speed Internet) use by U.S. households through the Computer and Internet Use Supplement (''the Supplement''). The planned Supplement will be the fourteenth since NTIA began sponsoring such surveys in November 1994. Since that time, NTIA has continually revised the Supplement to reflect developments in Internet technology, applications, and connected devices.

As the digital economy's accelerating growth reinforces the Internet's importance to the nation's economic prosperity, policymakers, businesses, non-profits, communities, and other stakeholders increasingly rely on data about whether and how Americans use broadband in their routine activities. Recognizing that digitally-connected Americans provide the modern workforce, creative innovation, and growing customer base to help sustain our nation's global competitiveness, the Supplement will yield data that can inform investment decisions and resource allocations to advance full participation in the digital economy.

NTIA is working with Congress, the Federal Communications Commission (FCC), other federal agencies, state and local governments, as well as with industry and non-profits to develop and promote policies that foster broadband deployment and adoption. These policies help to ensure that the nation's businesses and consumers can obtain competitively priced high-speed Internet access and that everyone is able to gain the skills necessary to use the technology. Collecting current, systematic, and comprehensive information on broadband use and non-use by U.S. households is critical to enabling policymakers to gauge progress made to date, and also to identify specific areas and demographic groups in which broadband adoption is a concern with a specificity that permits carefully targeted and cost-effective responses.

The U.S. Census Bureau is widely regarded as a premier data collector based on centuries of experience and rigorous scientific methods. Collection of NTIA's requested broadband usage data will occur in conjunction with the U.S. Census Bureau's scheduled November 2017 CPS, thereby significantly reducing the potential burdens on the U.S. Census Bureau and on surveyed households.

The U.S. government has an increasingly pressing need for comprehensive broadband data. The U.S. Government Accountability Office (GAO), NTIA, and the FCC have issued reports noting the importance of useful broadband adoption data for policymakers. Moreover, Congress passed legislation—the Broadband Data Improvement Act in 2008 and the American Recovery and Reinvestment Act in 2009—wholly or in part to address this deficiency. Modifying the November 2017 CPS to include NTIA's requested broadband questions will enable the Commerce Department and NTIA to respond to congressional concerns and directives.

II. Method of Collection

The Supplement will be administered through personal visits and live telephone interviews using computer-assisted telephone interviewing and computer-assisted personal interviewing.

III. Data

OMB Control Number: 0660–0021.

Form Number(s): None.

Type of Review: Regular submission (Revision of a currently approved collection).

Affected Public: Individuals and households.

Estimated Number of Respondents: 54,000 households.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 9,000.

Estimated Total Annual Cost to Public: $0.

IV. Requests for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden on respondents of providing the requested information, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will be a matter of public record.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2017–00154 Filed 1–6–17; 8:45 am]

BILLING CODE 3510–60–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings Notice (Correction)

TIME AND DATE: Wednesday, January 11, 2017, 9:30 a.m.–12:30 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East-West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

MATTERS TO BE CONSIDERED:

1. *Decisional Matter:* Final Rule: Safety Standard for Sling Carriers (9:30 a.m.–11:00 a.m.)
2. *Briefing Matter:* Proposed Rule: Amendments to Fireworks Regulations (11:00 a.m.–12:00 p.m.)

A live webcast of the Meeting can be viewed at *www.cpsc.gov/live.*

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: January 5, 2017.

Todd A. Stevenson,

Secretary.

[FR Doc. 2017–00270 Filed 1–5–17; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2017–HQ–0001]

Proposed Collection; Comment Request

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Director Army Safety announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by March 10, 2017.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of the Army, Army Safety Office, Chief of Staff, DACS–SF, 9351 Hall Rd, Fort Belvoir, VA 22060, ATTN: Mr. Timothy Mikulski at (703) 697–1321.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Radiation Sources on Army Land; OMB Control Number 0702–0109.

Needs and Uses: The information collection requirement is necessary to regulate the use, storage, or possession of radiation sources by non- Army agencies (including their civilian contractors) on an Army installation. The non-Army applicant will apply by letter, email or facsimile with supporting documentation to the garrison commander through the appropriate tenant commander or garrison director.

The Army radiation permit application will specify the effective date and duration for the Army radiation permit and describe the purposes for which the Army radiation permit is being sought. The application will include identification of the trained operating personnel who will be responsible for implementation of the activities authorized by the permit and a summary of their professional qualifications; the point-of-contact name and phone number for the application; the applicant's radiation safety Standing Operating Procedures (SOPs); storage provisions when the radiation source is not in use; and procedures for notifying the installation of reportable incidents/accidents.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions; State, Local, or Tribal Government.

Annual Burden Hours: 470.

Number of Respondents: 235.

Responses per Respondent: 1.

Annual Responses: 235.

Average Burden per Response: 2 hours.

Frequency: On occasion.

Dated: January 4, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–00173 Filed 1–6–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2016–ICCD–0121]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Formula Grant EASIE (Electronic Application System for Indian Education)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 8, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0121. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 226–62, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kimberly Smith, 202–453–6469.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed

information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Formula Grant EASIE (Electronic Application System for Indian Education).

OMB Control Number: 1810–0021.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 11,300.

Total Estimated Number of Annual Burden Hours: 9,590.

Abstract: The Indian Education Formula Grant (CFDA 84.060A) requires the annual submission of the application from the local educational agency and/or tribe. The amount of each applicant's award is determined by formula, based upon the reported number of American Indian/Alaska Native students identified in the application, the state per pupil expenditure, and the total appropriation available. Applicants provide the data required for funding electronically, and the Office of Indian Education (OIE) is able to apply electronic tools to facilitate the review and analysis leading to grant awards. The system has been named Formula Grant Electronic Application System for Indian Education (EASIE), and is located in the EDFacts System (ESS) Web site.

Dated: January 4, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–00149 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; College Assistance Migrant Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information:

College Assistance Migrant Program (CAMP).

Notice inviting applications for new awards for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.149A.

Dates:

Applications Available: January 9, 2017.

Deadline for Transmittal of Applications: March 10, 2017.

Deadline for Intergovernmental Review: May 9, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of CAMP is to provide academic and financial support to help migrant and seasonal farmworkers and members of their immediate family complete their first year of college and continue in postsecondary education.

Priorities: This competition includes one competitive preference priority and two invitational priorities. In accordance with 34 CFR 75.105(b)(2)(iv), the competitive preference priority is from section 418A(e) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070d–2(e)).

Competitive Preference Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to 15 additional points to an application, depending on how well the applicant meets the competitive preference priority.

This priority is:

Prior Experience of Service Delivery (Up to 15 points).

For applicants with an expiring CAMP project, the Secretary will consider the applicant's prior experience in implementing its expiring CAMP project, based on information contained in documents previously provided to the Department, such as annual performance reports, project evaluation reports, site visit reports, and the previously approved CAMP application.

Under this competition, we also are particularly interested in applications that address the following invitational priorities.

Invitational Priorities: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—Science, Technology, Engineering, and Mathematics Education (STEM).

Projects that are designed to address one or more of the following priority areas:

(a) Providing students with increased access to rigorous and engaging coursework in STEM.

(b) Increasing the number and proportion of students prepared for postsecondary or graduate study and careers in STEM, with a specific focus on an increase in the number and proportion of students so prepared who are from groups traditionally underrepresented in STEM careers, including minorities, individuals with disabilities, and women.

Note: Applicants could, for example, propose providing students with increased access to coursework in STEM through such activities as mentoring, counseling, and tutoring in ways that motivate participants to pursue postsecondary education in the areas of STEM. Similarly, applicants could propose increasing the number and proportion of students prepared for postsecondary or graduate study and careers in STEM through activities such as referrals to STEM-oriented work-based learning experiences, exposure to academic programs and careers in STEM-related fields, and providing support services. These could include services to improve participants' academic skills and knowledge so that they may pursue studies and careers in STEM-related fields.

Invitational Priority 2—Faith-Based and Community Organizations.

Applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Program Authority: 20 U.S.C. 1070d–2.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34

CFR part 206. (e) The definitions of ''migratory agricultural worker'' in 34 CFR 200.81(f), ''migratory child'' in 34 CFR 200.81(g), and ''migratory fisher'' in 34 CFR 200.81(h). (f) The regulations in 20 CFR 669.110 and 669.320.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $4,537,279.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $180,000–$425,000.

Estimated Average Size of Awards: $412,479.

Maximum Award: We will reject any application that proposes a CAMP award exceeding $425,000 for any of the five single budget periods of 12 months as reflected in the applicant's ED 524 Budget Form, Section A, submitted as a part of the project application.

Minimum Award: We will reject any application that proposes a CAMP award that is less than $180,000 for any of the five single budget periods of 12 months as reflected in the applicant's ED 524 Budget Form, Section A, submitted as a part of the project application. Regardless of any other information in the application, the Department will interpret an ED 524 form that, in Part A, provides a blank budget summary for any of the five project years as the applicant's intent to seek ''$0'' for that year, and thus to not operate a project that year. Similarly, the Department will interpret any blank spaces on the ED 524 budget form as $0.

Estimated Number of Awards: 11.

Note: The Department is not bound by any estimates in this notice.

Project Period: Applicants must propose a project of 60 months (five years) in duration, and we will reject any application that does not do so as reflected on the applicant's ED 524 form, Section A, submitted as a part of the application. However, if an applicant receives an initial grant award, annual continuation funding is contingent upon availability of funds and the grantee having met minimum performance standards.

III. Eligibility Information

1. *Eligible Applicants:* IHEs or private non-profit organizations (including faith-based organizations) that plan their projects in cooperation with an IHE and propose to operate the project with the facilities of the IHE.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

3. *Other:* Projects funded under this competition must budget for a two-day Office of Migrant Education annual meeting for CAMP directors in the Washington, DC area during each year of the project period.

IV. Application and Submission Information

1. *Address to Request Application Package:* Emily Bank, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. Telephone: (202) 453–6389 or by email: *emily.bank@ed.gov.*

To obtain a copy via the Internet, use the following address: *www.ed.gov/programs/camp/applicant.html.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2.a. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part IV of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Panel readers will award points only for an applicant's response to a given selection criterion that is contained within the section of the application designated to address that particular selection criterion. Readers will not review, or award points for, a response to the selection criterion that is located in any other section of the application or the appendices. We will reject any application narrative that exceeds 25 pages or does not adhere to the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs. Charts, tables, figures, and graphs presented in the application narrative count toward the page limit.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch) throughout the entire application package.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted. The 25-page limit for the application narrative does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract. However, the page limit does apply to all of the application narrative.

Appendices must be limited to 20 pages and must include the following: Resumes, if applicable, and job descriptions of key personnel. Job descriptions must include duties and minimum qualifications. Items in the appendices will only be used by the program office; the items will not be read by reviewers.

b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the CAMP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: January 9, 2017.

Deadline for Transmittal of Applications: March 10, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We will not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: May 9, 2017.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a *SAM.gov* Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under CAMP, CFDA number 84.149A, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for CAMP at *www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.149, not 84.149A).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for

submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in read-only Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters).
- Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Emily Bank, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. FAX: (202) 205–0089.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.149A, LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.149A, 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* The Secretary will consider the need to provide an equitable geographic distribution of grants in selecting applications for awards, in accordance with section 418A of the HEA (20 U.S.C. 1070d–2(g)). In addition, we remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection

analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department developed the following performance measures to evaluate the overall effectiveness of CAMP: (1) The percentage of CAMP participants completing the first academic year of their postsecondary program, and (2) the percentage of CAMP participants who, after completing the first academic year of college, continue their postsecondary education.

Applicants must propose annual targets for these measures in their applications. The national target for GPRA measure 1 for FY 2017 is that 86 percent of CAMP participants will complete the first academic year of their postsecondary program. The national target for GPRA measure 2 for FY 2017 is that 85 percent of CAMP participants continue their postsecondary education after completing the first academic year of college. The national targets for subsequent years may be adjusted based on additional baseline data. The panel readers will score related selection criteria on the basis of how well an applicant addresses these GPRA measures. Therefore, applicants will want to consider how to demonstrate a sound capacity to provide reliable data on the GPRA measures, including the project's annual performance targets for addressing the GPRA performance measures, as is required by the Office of Management and Budget approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these GPRA performance measures.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Emily Bank, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. Telephone: (202) 453–6389 or by email: *emily.bank@ed.gov.*

If you use a TDD or TYY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 4, 2017.

Ann Whalen,

Delegated the authority to perform the functions and duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2017–00168 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

List of Correspondence From January 1, 2015 Through March 31, 2015 and April 1, 2015 Through June 30, 2015

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary is publishing the following list of correspondence from the U.S. Department of Education (Department) received by individuals during the first and second quarters of 2015. The correspondence describes the Department's interpretations of the Individuals with Disabilities Education Act (IDEA) or the regulations that implement the IDEA. This list and the letters or other documents described in this list, with personally identifiable information redacted, as appropriate, can be found at: *www2.ed.gov/policy/speced/guid/idea/index.html.*

FOR FURTHER INFORMATION CONTACT: Jessica Spataro or Mary Louise Dirrigl. Telephone: (202) 245–7605.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you can call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of this list and the letters or other documents described in this list in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting Jessica Spataro or Mary Louise Dirrigl at (202) 245–7605.

SUPPLEMENTARY INFORMATION: The following list identifies correspondence from the Department issued from January 1, 2015 through March 31, 2015 and April 1, 2015 through June 30, 2015. Under section 607(f) of the IDEA, the Secretary is required to publish this list quarterly in the **Federal Register**. The list includes those letters that contain interpretations of the requirements of the IDEA and its implementing regulations, as well as letters and other documents that the Department believes will assist the public in understanding the requirements of the law. The list identifies the date and topic of each letter and provides summary information, as appropriate. To protect the privacy interests of the individual or individuals involved, personally identifiable information has been redacted, as appropriate.

Part B—Assistance for Education of all Children With Disabilities

Section 612—State Eligibility

Topic Addressed: State Educational Agency General Supervisory Authority

- Dear Colleague Letter dated April 15, 2015, providing guidance on best practices for the appropriate use of IDEA's dispute resolution procedures and the importance of avoiding conflicting decisions when a public agency files a due process complaint on the same issues that are the subject of a parent's pending State complaint.
- Letter dated May 19, 2015, to Mississippi Department of Education, Special Assistant Attorney General Heather S. Deaton, regarding the State's

duty to implement corrective actions to address the findings in a State complaint decision, and the types of corrective actions that can be ordered when a parent subsequently files a due process complaint involving some of the same issues.

Section 615—Procedural Safeguards

Topic Addressed: Impartial Due Process Hearings

- Letter dated January 7, 2015, to Minnesota attorney Margaret O'Sullivan Kane, regarding two issues related to due process hearings in Minnesota.

Topic Addressed: Independent Educational Evalutions

- Letter dated February 23, 2015, to individual Debbie Baus, regarding a parent's right to request an independent educational evaluation at public expense in an area that was not previously assessed by the public agency, and the public agency's responsibilities after the parent makes the request.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 4, 2017.

Sue Swenson,

Deputy Assistant Secretary for Special Education and Rehabilitative Services, delegated the authority to perform the functions and duties of the Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2017–00172 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2017–ICCD–0001]

Agency Information Collection Activities; Comment Request; High School Equivalency Program (HEP) Annual Performance Report

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 10, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0001. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 226–62, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Tara Ramsey, 202–260–2063.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: High School Equivalency Program (HEP) Annual Performance Report.

OMB Control Number: 1810–0684.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 44.

Total Estimated Number of Annual Burden Hours: 1,408.

Abstract: The Office of Migrant Education is collecting information for the High School Equivalency Program Annual Performance Report in compliance with Higher Education Act of 1965, as amended, Title IV, Sec. 418A; 20 U.S.C. 1070d–2 (special programs for students whose families are engaged in migrant and seasonal farm work), the Government Performance Results Act (GPRA) of 1993, Section 4 (1115), and the Education Department General Administrative Regulations (EDGAR), 34 CFR 75.253. EDGAR states that recipients of multi-year discretionary grants must submit an Annual Performance Report demonstrating that substantial progress has been made towards meeting the approved objectives of the project. In addition, discretionary grantees are required to report on their progress toward meeting the performance measures established for the Department of Education grant program. The Office of Migrant Education requests an extension without change of a currently approved collection to continue the use of a customized Annual Performance Report that goes beyond the Department of Education generic form number 524B Annual Performance Report to facilitate the collection of more standardized and comprehensive data to inform GPRA, to improve the overall quality of data collected, and to increase the quality of data that can be used to inform policy decisions.

The proposed changes to the 2017 HEP APR are changes to the HEP

Instructions Form and Performance Report Data Form and OME made minor editorial language and formatting changes. OME aligned the directions to the performance report data form, and required grantees to disaggregate HSE attainers and HSE withdrawals into New and Returning participants.

Dated: January 4, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–00146 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Comprehensive Centers Program; CFDA Number: 84.283B

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary proposes to waive the requirements in 34 CFR 75.250(a) and 75.261(c)(2) of the Education Department General Administrative Regulations (EDGAR). Respectively, these provisions generally prohibit project periods exceeding five years and project period extensions involving the obligation of additional Federal funds. The proposed waivers would enable the 22 grantees under the Comprehensive Centers program that received awards in the fiscal year (FY) 2012 grant competition to continue to receive Federal funding for up to 24 months beyond the five-year limitation contained in 34 CFR 75.250(a).

DATES: We must receive your comments on or before February 8, 2017.

ADDRESSES: Address all comments about these proposed waivers to Britt Jung, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Ave. SW., Room 3E206, Washington, DC 20202–6400.

FOR FURTHER INFORMATION CONTACT: Britt Jung. Telephone: (202) 205–4513 or by email: *Britt.Jung@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice of proposed waivers.

During and after the comment period, you may inspect all public comments about this notice of proposed waivers by accessing *Regulations.gov.* You may also inspect the comments in person in Room 3E206, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week, except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed waivers. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background: Under the Comprehensive Centers program the Department of Education (Department) supports grants to operate regional technical assistance centers and national content centers as authorized by sections 203 through 207 of the Educational Technical Assistance Act of 2002 (ETAA) (20 U.S.C. 9602–9606).

The purpose of these centers is to provide technical assistance to States as States work to help local educational agencies (LEAs) and schools to close achievement gaps in core content areas and raise student achievement in schools. We are especially interested in helping LEAs that are implementing comprehensive support and improvement activities and targeted support and improvement activities under section 1111(d) of the Elementary and Secondary Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA).

Eligible applicants for Comprehensive Center grants are research organizations, institutions, agencies, institutions of higher education, partnerships among these types of entities, or individuals with the demonstrated ability or capacity to carry out the activities described in the notice inviting applications published in the **Federal Register** on June 6, 2012 (2012 NIA) (77 FR 33564) and corrected on August 15, 2012 (77 FR 48974). In FY 2012, the Department made five-year awards to 22 Comprehensive Centers. The project period for these Comprehensive Centers is currently scheduled to end on September 30, 2017.

We are proposing to waive the requirements in 34 CFR 75.250(a), which prohibit project periods exceeding five years, and the requirements in 34 CFR 75.261(c)(2), which limit the extension of a project period if the extension involves the obligation of additional Federal funds. This would allow the 22 current Comprehensive Center grantees to continue to receive Federal funding annually for project periods through FY 2017 and possibly through FY 2018.

We are proposing these waivers because we do not believe it would be in the public interest to hold a new competition under the Comprehensive Centers program until after the finalization of the Department's new regulations and guidance on the ESEA, as amended by the ESSA. One of the primary purposes of the Comprehensive Centers program is to provide technical assistance to States regarding the administration and implementation of programs under the ESEA. Delaying the next competition until after the Department has finished implementing the ESEA, as amended by the ESSA, would allow applicants to familiarize themselves with the new statutory requirements under the ESSA and submit proposals that will best serve States.

We have also concluded that it would be contrary to the public interest to have a lapse in the work of the Comprehensive Centers while the Department implements the components of the ESSA described above.

We intend to fund the extended project period for either one or two years by using the FY 2017 and, if necessary, FY 2018 funds that Congress appropriates under the current statutory authority.

Under this proposed waiver and extension of the project period—

(1) Current grantees will be authorized to receive continuation awards annually for up to two years.

(2) We would not announce a new competition or make new awards under the Comprehensive Centers program in FY 2017.

(3) During the extension period, any activities carried out must be consistent with, or be a logical extension of the scope, goals, and objectives of the grantee's approved application from the 2012 Comprehensive Centers competition.

(4) Each grantee who receives a continuation award must also continue to comply with the requirements established in the program regulations and the 2012 NIA.

The proposed waivers of 34 CFR 75.250(a) and 75.261(c)(2) would not affect the applicability of the requirements in 34 CFR 75.253 (continuation of a multi-year project

after the first budget period) to any current Comprehensive Centers grantee that receives a continuation award as a result of the waivers.

In addition, these proposed waivers would not exempt current Comprehensive Centers grantees from the account-closing provisions in 31 U.S.C. 1552(a), nor would they extend the availability of funds previously awarded to current Comprehensive Centers grantees. Under 31 U.S.C. 1552(a) appropriated funds may be used for payment of valid obligations for only five years after the expiration of their period of availability for Federal obligation. After that time, the U.S. Department of Education will cancel and return the unexpended balance of those funds to the U.S. Treasury Department and these funds will be unavailable for restoration for any purpose. The waivers proposed in this notice would not change this requirement.

Implementing these waivers, therefore, would ensure that the important services provided by the current Comprehensive Centers grantees can be continued uninterrupted, as the Department releases final regulations and guidance to support States in their transition to the ESSA. During this extension period the activities of the current Comprehensive Centers grantees would be modified through work plans, as necessary, to support States as they begin to implement the ESSA.

We will announce the final waivers, if any, in a notice in the **Federal Register**. We will determine the final waivers after considering responses to this notice and other information available to the Department.

Proposed Waivers—Comprehensive Centers Program

For the 22 Comprehensive Centers grantees that received awards in the FY 2012 competition, the Secretary proposes to waive the requirements in 34 CFR 75.250(a) and 75.261(c)(2) that prohibit project periods exceeding five years and extensions of project periods that involve the obligation of additional Federal funds.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed waivers would not have a significant economic impact on a substantial number of small entities.

The small entities that would be affected by these proposed waivers are:

(a) The FY 2012 grantees currently receiving Federal funds; and

(b) Entities that otherwise would have been eligible to apply for an award in FY 2017 under the Comprehensive Centers program if the Department had held that competition.

The Secretary certifies that the proposed waivers would not have a significant economic impact on these entities because the proposed waivers and the activities required to support the additional years of funding would not impose excessive regulatory burdens or require unnecessary Federal supervision. The proposed waivers would impose minimal requirements to ensure the proper expenditure of program funds, including requirements that are standard for continuation awards.

Paperwork Reduction Act of 1995

This notice of proposed waivers does not contain any information collection requirements.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 4, 2017.

Ann Whalen,

Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2017–00174 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; High School Equivalency Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information:

High School Equivalency Program (HEP)

Notice inviting applications for new awards for fiscal year (FY) 2017

Catalog of Federal Domestic Assistance (CFDA) Number: 84.141A.

Dates:

Applications Available: January 9, 2017.

Deadline for Transmittal of Applications: March 10, 2017.

Deadline for Intergovernmental Review: May 9, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of HEP are to help migrant and seasonal farmworkers and members of their immediate family: (1) Obtain a general education diploma that meets the guidelines for high school equivalency (HSE) established by the State in which the HEP project is conducted; and (2) gain employment or be placed in an institution of higher education (IHE) or other postsecondary education or training.

Priorities: This competition includes one competitive preference priority and two invitational priorities. In accordance with 34 CFR 75.105(b)(2)(iv), the competitive preference priority is from section 418A(e) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070d-2(e)).

Competitive Preference Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 15 points to an application, depending on how well the application meets this priority.

This priority is:

Prior Experience of Service Delivery (Up to 15 Points)

For applicants with an expiring HEP project, the Secretary will consider the applicant's prior experience in implementing its expiring HEP project, based on information contained in documents previously provided to the Department, such as annual performance reports, project evaluation reports, site visit reports, and the previously approved HEP application.

Under this competition, we also are particularly interested in applications that address the following invitational priorities.

Invitational Priorities: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—Science, Technology, Engineering, and Mathematics Education (STEM)

Projects that are designed to address one or more of the following priority areas:

(a) Providing students with increased access to rigorous and engaging coursework in STEM.

(b) Increasing the opportunities for high-quality preparation of, or professional development for, teachers or other educators of STEM subjects.

Note: Applicants could, for example, consider activities to better prepare program participants to transition into postsecondary education, such as preparing students to pass the sections of college entrance examinations in STEM-related subjects or providing mentoring, counseling, and tutoring services designed to motivate participants to pursue postsecondary education in STEM-related fields. Similarly, for the professional development priority area, applicants could propose activities to increase the opportunities for high-quality professional development for HSE instructors of STEM-related subjects that include, for example, training in intensive science teaching techniques presented by a professionally credentialed expert in science education.

Invitational Priority 2—Faith-Based and Community Organizations

Applications that propose to engage faith-based and community organizations in the delivery of services under this program.

Program Authority: 20 U.S.C. 1070d–2.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 206. (e) The definitions of ''migratory agricultural worker'' in 34 CFR 200.81(f), ''migratory child'' in 34 CFR 200.81(g), and ''migratory fisher'' in 34 CFR 200.81(h). (f) The regulations in 20 CFR 669.110 and 669.320.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $1,393,360.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $180,000–$475,000.

Estimated Average Size of Awards: $464,453.

Maximum Award: We will reject any application that proposes a HEP award exceeding $475,000 for any of the five single budget periods of 12 months as reflected in the applicant's ED 524 Budget Form, Section A, submitted as a part of the application.

Minimum Award: We will reject any application that proposes a HEP award that is less than $180,000 for any of the five single budget periods of 12 months as reflected in the applicant's ED 524 Budget Form, Section A, submitted as a part of the application. Regardless of any other information in the application, the Department will interpret an ED 524 Budget Form that, in Section A, provides a blank budget summary for any of the five project years as the applicant's intent to seek ''$0'' for that year, and thus to not operate a project that year. Similarly, the Department will interpret any blank spaces on the ED 524 budget form as $0.

Estimated Number of Awards: 3.

Note: The Department is not bound by any estimates in this notice.

Project Period: Applicants must propose a project of 60 months (five years) in duration, and we will reject any application that does not do so as reflected on the applicant's ED 524 Budget Form, Section A, submitted as a part of the application. However, if an applicant receives an initial grant award, annual continuation funding is contingent upon availability of funds and the grantee having met minimum performance standards.

III. Eligibility Information

1. *Eligible Applicants:* IHEs or private non-profit organizations (including faith-based organizations) that plan their projects in cooperation with an IHE and propose to operate some aspects of the project with the facilities of the IHE.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching. However, consistent with 34 CFR 75.700, which requires an applicant to comply with its approved application, an applicant that proposes non-Federal matching funds and is awarded a grant must provide those funds for each year that the funds are proposed.

3. *Other:* Projects funded under this competition must budget for a two-day Office of Migrant Education annual meeting for HEP Directors in the Washington, DC area during each year of the project period.

IV. Application and Submission Information

1. *Address to Request Application Package:* Emily Bank, U.S. Department of Education, Office of Migrant Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. Telephone: (202) 453–6389 or by email: *emily.bank@ed.gov.*

To obtain a copy via the Internet, use the following address: *www.ed.gov/programs/hep/applicant.html.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2. a. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part IV of the application) is where you, the applicant, address the selection

criteria that reviewers use to evaluate your application. Panel readers will award points only for an applicant's response to a given selection criterion that is contained within the section of the application designated to address that particular selection criterion. Readers will not review, or award points for, a response to the selection criterion that is located in any other section of the application or the appendices. We will reject any application narrative that exceeds 25 pages or does not adhere to the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs. Charts, tables, figures, and graphs presented in the application narrative count toward the page limit.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch) throughout the entire application package.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The 25-page limit for the application narrative does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract. However, the page limit does apply to all of the application narrative.

Appendices must be limited to 20 pages and must include resumes, if applicable, and job descriptions of key personnel. Job descriptions must include duties and minimum qualifications. Items in the appendices will only be used by the program office; the items will not be read by reviewers.

b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the HEP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Because we plan to make successful applications available to the public you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: January 9, 2017.

Deadline for Transmittal of Applications: March 10, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We will not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: May 9, 2017.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this

competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under HEP, CFDA number 84.141A, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for HEP at *www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.141, not 84.141A).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters).

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in

section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Emily Bank, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. FAX: (202) 205–0089.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.141A, LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.141A, 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* The Secretary will consider the need to provide an equitable geographic distribution of grants in selecting applications for awards, in accordance with section 418A of the HEA (20 U.S.C. 1070d–2(g)). In addition, we remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a

judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department developed the following performance measures to evaluate the overall effectiveness of HEP: (1) The percentage of HEP program participants exiting the program having received an HSE diploma (GPRA 1), and (2) the percentage of HSE diploma recipients who enter postsecondary education or training programs, upgraded employment, or the military (GPRA 2).

Applicants must propose annual targets for these measures in their applications. The national target for GPRA measure 1 for FY 2017 is that 69 percent of HEP program participants exit the program having received an HSE credential. The national target for GPRA measure 2 for FY 2017 is that 80 percent of HEP HSE diploma recipients will enter postsecondary education or training programs, upgraded employment, or the military. The national targets for subsequent years may be adjusted based on additional baseline data. The panel readers will score related selection criteria on the basis of how well an applicant addresses these GPRA measures. Therefore, applicants will want to consider how to demonstrate a sound capacity to provide reliable data on the GPRA measures, including the project's annual performance targets for addressing the GPRA performance measures, as is required by the Office of Management and Budget approved annual performance report that is included in the application package. All grantees will be required to submit, as part of their annual performance report, information with respect to these GPRA performance measures.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

For Further Information Contact: Emily Bank, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E338, Washington, DC 20202–6135. Telephone: (202) 453–6389 or by email: *emily.bank@ed.gov.*

If you use a TDD or TYY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under *For Further Information Contact* in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 4, 2017.

Ann Whalen,

Delegated the authority to perform the functions and duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2017–00170 Filed 1–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–178–000.
Applicants: Wisconsin River Power Company, Wisconsin Public Service Corporation, Wisconsin Power and Light Company.
Description: Supplement to September 9, 2016 Application of Wisconsin River Power Company, et al. for Approval of Transaction Under Section 203(a)(1) of the Federal Power Act.
Filed Date: 10/11/16.
Accession Number: 20161011–5348.
Comments Due: 5 p.m. ET 1/10/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2265–012; ER10–1580–016; ER10–1581–018; ER10–2383–008; ER10–2384–008; ER10–2888–021; ER11–2062–021; ER11–2107–012; ER11–2108–012; ER11–2508–020; ER11–2805–020; ER11–4307–021; ER11–4308–021; ER12–261–020; ER14–1818–012; ER14–2820–008; ER14–2821–008.
Applicants: NRG Power Marketing LLC, Boston Energy Trading and Marketing LLC, Energy Plus Holdings LLC, GenOn Energy Management, LLC, Green Mountain Energy Company, Independence Energy Group LLC, Long Beach Peakers LLC, Mountain Wind Power, LLC, Mountain Wind Power II, LLC, North Community Turbines LLC, North Wind Turbines LLC, Norwalk Power LLC, Reliant Energy Northeast LLC, RRI Energy Services, LLC, Saguaro Power Company, a Limited Partnership, Spring Canyon Energy II LLC, Spring Canyon Energy III LLC.
Description: Updated Market Power Analysis for the Northwest Region of NRG MBR Sellers.
Filed Date: 12/30/16.
Accession Number: 20161230–5232.
Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER10–2822–010; ER10–1291–021; ER10–1725–004; ER10–2285–006; ER10–2301–004; ER10–2306–004; ER10–2404–008; ER10–2423–008; ER10–2812–014; ER10–2828–004; ER10–2843–013; ER10–3001–005; ER10–3002–004; ER10–3004–005; ER10–3010–004; ER10–3031–004; ER10–3160–003; ER11–2112–008; ER12–2649–004; ER12–422–006; ER12–96–006; ER16–1250–002; ER16–1637–002; ER16–2285–002.
Applicants: Atlantic Renewable Projects II LLC, Blue Creek Wind Farm LLC, Casselman Windpower LLC, Central Maine Power Company, Desert Wind Farm LLC, Flat Rock Windpower LLC, Flat Rock Windpower II LLC, GenConn Devon LLC, GenConn Energy LLC, GenConn Middletown LLC, Groton Wind, LLC, Hardscrabble Wind Power LLC, Lempster Wind, LLC, Locust Ridge Wind Farm, LLC, Locust Ridge II, LLC, New England Wind, LLC, New York State Electric & Gas Corporation, Rochester Gas and Electric Corporation, South Chestnut LLC, Streator-Cayuga Ridge Wind Power LLC, The United Illuminating Company, UIL Distributed Resources, LLC, Providence Heights Wind, LLC, Avangrid Renewables, LLC.
Description: Updated Market Power Analysis for the Northeast Region of AVANGRID Northeast MBR Sellers.
Filed Date: 12/30/16.
Accession Number: 20161230–5228.
Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER17–608–001.
Applicants: NorthWestern Corporation.
Description: Tariff Amendment: Amendment to SA 760 2nd Rev—NITSA with Beartooth Electric Cooperative to be effective 3/1/2017.
Filed Date: 12/30/16.
Accession Number: 20161230–5167.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–728–000.
Applicants: Approved Energy II LLC.
Description: Baseline eTariff Filing: Approved Energy II LLC Market Based Rate Application to be effective 12/30/2016.
Filed Date: 12/30/16.
Accession Number: 20161230–5179.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–729–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: PJM TOs submit revisions to MISO–PJM JOA section 9.4 re TMEP Cost Allocations to be effective 12/31/9998.
Filed Date: 12/30/16.
Accession Number: 20161230–5190.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–730–000.
Applicants: NorthWestern Corporation.
Description: Tariff Cancellation: Notice of Cancellation: SA 781, Agreement with Montana DOT (Whitehall—South) to be effective 1/3/2017.
Filed Date: 12/30/16.
Accession Number: 20161230–5191.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–731–000.
Applicants: Green Mountain Power Corporation.
Description: Market-Based Triennial Review Filing: GMP Triennial for the Northeast Region to be effective 12/31/2016.
Filed Date: 12/30/16.
Accession Number: 20161230–5196.
Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER17–732–000.
Applicants: GridLiance West Transco LLC.
Description: Initial rate filing: GWT VEA NPC Third Amended and Restated Interconnection Agreement to be effective 3/1/2017.
Filed Date: 12/30/16.
Accession Number: 20161230–5198.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–733–000.
Applicants: PacifiCorp.
Description: Tariff Cancellation: Termination of Exelon Generation NITSA Rev 1 to be effective 12/31/2016.
Filed Date: 12/30/16.
Accession Number: 20161230–5199.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–734–000.
Applicants: Entergy Louisiana Power, LLC.
Description: Tariff Cancellation: Cancellation of CID to be effective 12/31/9998.
Filed Date: 12/30/16.
Accession Number: 20161230–5204.
Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: ER17–735–000.
Applicants: NEP Energy Services, Ltd.
Description: Baseline eTariff Filing: Baseline new to be effective 3/1/2017.
Filed Date: 12/30/16.
Accession Number: 20161230–5205.
Comments Due: 5 p.m. ET 1/23/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–00118 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–31–000]

Northern Illinois Municipal Power Agency v. PJM Interconnection, L.L.C.; Notice of Complaint

Take notice that on December 21, 2016, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h, and Rules 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212, Northern Illinois Municipal Power Agency (Complainant) filed a formal complaint against PJM Interconnection, L.L.C. (Respondent) alleging that Respondent is assessing duplicative congestion charges for pseudo-tied resources located in the adjoining balancing area of the Midcontinent Independent System Operator, Inc., all as more fully explained in the complaint.

Complainant certify that copies of the complaint were served on the contacts for Respondent, as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 10, 2017.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00066 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File Date	Presenter or Requester
Prohibited:		
1. CP15–554–000	12–12–2016	Vincent Russell.
2. CP15–554–000	12–12–2016	Eva Cosgrove.
3. CP15–500–000	12–12–2016	Eddy N.
4. CP15–554–000	12–13–2016	Vincent Russell.
5. CP15–17–000	12–19–2016	Mass Mailing.[1]
6. CP15–17–000	12–20–2016	Private Citizen.
7. CP16–10–000	12–23–2016	Caleb Laieski.
Exempt:		
1. CP15–558–000	12–12–2016	Delaware Township, New Jersey Mayor Susan Lockwood.
2. ER17–217–000	12–12–2016	U.S. House Representative Frank Pallone, Jr.
3. CP14–96–000	12–13–2016	U.S. Senator Elizabeth Warren.

Docket No.	File Date	Presenter or Requester
4. CP16–10–000	12–13–2016	U.S. Senator Bill Nelson.
5. ER17–217–000	12–14–2016	U.S. House Representative Frank Pallone, Jr.
6. CP16–454–000, CP16–455–000	12–19–2016	FERC Staff.[2]
7. CP15–138–000	12–20–2016	State of Pennsylvania House Representative Bryan Cutler.
8. CP15–138–000	12–20–2016	State of Pennsylvania House Representative Bryan Cutler.
9. CP15–138–000	12–20–2016	State of Pennsylvania House Representative Bryan Cutler.
10. CP15–138–000	12–20–2016	State of Pennsylvania House Representative Bryan Cutler.
11. CP16–10–000	12–22–2016	FERC Staff.[3]

[1] Three letters have been sent to FERC Commissioners and staff under this docket number.
[2] Conference call notes from December 6, 2016 call with Rio Grande LNG, LLC and Rio Bravo Pipeline, LLC.
[3] Memo forwarding letter dated December 21, 2016 from Advisory Council on Historic Preservation.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00072 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–138–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Availability of the Final Environmental Impact Statement for the Proposed Atlantic Sunrise Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Atlantic Sunrise Project, proposed by Transcontinental Gas Pipe Line Company, LLC (Transco) in the above-referenced docket. Transco requests authorization to expand its existing pipeline system from the Marcellus Shale production area in northern Pennsylvania to deliver an incremental 1.7 million dekatherms per day of year-round firm transportation capacity to its existing southeastern market areas.

The final EIS assesses the potential environmental effects of the construction and operation of the project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the project would result in some adverse environmental impacts; however, most of these impacts would be reduced to less-than-significant levels with the implementation of Transco's proposed mitigation and the additional measures recommended in the final EIS.

The U.S. Army Corps of Engineers and the U.S. Department of Agriculture's Natural Resources Conservation Service participated as cooperating agencies in the preparation of the final EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis. Although the U.S. Army Corps of Engineers and the Natural Resources Conservation Service provided input to the conclusions and recommendations presented in the final EIS, the agencies will present their own conclusions and recommendations in their respective records of decision or determinations for the project.

The final EIS addresses the potential environmental effects of the construction and operation of about 199.4 miles of pipeline composed of the following facilities:

- 185.9 miles of new 30- and 42-inch-diameter natural gas pipeline in Pennsylvania;
- 11.0 miles of new 36- and 42-inch-diameter pipeline looping in Pennsylvania;
- 2.5 miles of 30-inch-diameter replacements in Virginia; and
- associated equipment and facilities.

The project's proposed aboveground facilities include two new compressor stations in Pennsylvania; additional compression and related modifications to three existing compressor stations in Pennsylvania and Maryland; two new meter stations and three new regulator stations in Pennsylvania; and minor modifications at existing aboveground facilities at various locations in Pennsylvania, Virginia, Maryland, North Carolina, and South Carolina to allow for bi-directional flow and the installation of supplemental odorization, odor detection, and/or odor masking/deodorization equipment.

The FERC staff mailed copies of the final EIS to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding. Paper copy versions of this EIS were mailed to those specifically requesting them; all others received a CD version. In addition, the final EIS is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

In accordance with the Council on Environmental Quality's (CEQ) regulations implementing NEPA, no agency decision on a proposed action may be made until 30 days after the U.S. Environmental Protection Agency publishes a notice of availability of the final EIS in the **Federal Register**. However, the CEQ regulations provide an exception to this rule when an agency decision is subject to a formal internal appeal process that allows other agencies or the public to make their views known. In such cases, the agency decision may be made at the same time the notice of the final EIS is published, allowing both periods to run concurrently. The Commission decision for this proposed action is subject to a 30-day rehearing period.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP15–138). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676; for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings

by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp*.

Dated: December 30, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00073 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2822–011; ER11–2196–008; ER11–2462–007; ER11–2463–007; ER11–2464–007; ER11–2465–008; ER11–2466–007; ER11–2467–007; ER11–2468–007; ER11–2469–007; ER11–2470–007; ER11–2471–007; ER11–2472–007; ER11–2473–007; ER11–2474–009; ER11–2475–007; ER16–1250–003.

Applicants: Atlantic Renewable Projects II LLC, Avangrid Renewables, LLC, Big Horn Wind Project LLC, Big Horn II Wind Project LLC, Colorado Green Holdings LLC, Hay Canyon Wind LLC, Juniper Canyon Wind Power LLC, Klamath Energy LLC, Klamath Generation LLC, Klondike Wind Power LLC, Klondike Wind Power II LLC, Klondike Wind Power III LLC, Leaning Juniper Wind Power II LLC, Pebble Springs Wind LLC, San Luis Solar LLC, Star Point Wind Project LLC, Twin Buttes Wind LLC.

Description: Updated Market Power Analysis for the Northwest Region of AVANGRID Northwest MBR Sellers.

Filed Date: 12/30/16.

Accession Number: 20161230–5239.

Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER10–2906–008; ER10–2908–008; ER10–2910–008; ER10–2911–008; ER11–4666–002; ER11–4667–002; ER11–4669–002; ER11–4670–002; ER12–295–001; ER12–709–001.

Applicants: Morgan Stanley Capital Group Inc., MS Solar Solutions Corp., Naniwa Energy LLC, Power Contract Financing II, L.L.C., NaturEner Glacier Wind Energy 1, LLC, NaturEner Glacier Wind Energy 2, LLC, NaturEner Rim Rock Wind Energy, LLC, NaturEner Montana Wind Energy, LLC, NaturEner Power Watch, LLC, NaturEner Wind Watch, LLC.

Description: Updated Market Power Analysis for the Northwest Region and Notice of Change in Status of the Morgan Stanley Public Utilities, et al.

Filed Date: 12/30/16.

Accession Number: 20161230–5237.

Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER15–1952–003; ER16–853–002; ER16–855–002; ER16–856–002; ER16–857–002; ER16–858–002; ER16–860–002; ER16–861–002.

Applicants: Pavant Solar, LLC, Enterprise Solar, LLC, Escalante Solar I, LLC, Escalante Solar II, LLC, Escalante Solar III, LLC, Granite Mountain Solar East, LLC, Granite Mountain Solar West, LLC, Iron Springs Solar, LLC.

Description: Triennial Market Power Analysis for the Northwest Region of Pavant Solar, LLC, et al.

Filed Date: 12/30/16.

Accession Number: 20161230–5240.

Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER15–2351–002.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Alliant Energy Corp. Serv. Att AH SA 3066SO/Att AO SA 3071SO to be effective 10/1/2015.

Filed Date: 1/3/17.

Accession Number: 20170103–5090.

Comments Due: 5 p.m. ET 1/24/17.

Docket Numbers: ER16–328–003; ER10–2196–003; ER11–4027–008; ER12–1275–003; ER12–952–004; ER13–1141–003; ER13–1142–003; ER13–1143–004; ER13–1144–004; ER15–1657–004; ER16–918–002.

Applicants: Cogentrix Virginia Financing Holding Company, LLC, Essential Power, LLC, Essential Power Massachusetts, LLC, Essential Power Newington, LLC, Essential Power OPP, LLC, Essential Power Rock Springs, LLC, James River Genco, LLC, Lakewood Cogeneration, L.P., Red Oak Power, LLC, Rhode Island State Energy Center, LP, SEPG Energy Marketing Services, LLC.

Description: Updated Market Power Analysis for the Northeast Region of Cogentrix Virginia Financing Holding Company, LLC, et al.

Filed Date: 12/30/16.

Accession Number: 20161230–5230.

Comments Due: 5 p.m. ET 2/28/17.

Docket Numbers: ER17–736–000.

Applicants: Quantum Power Corp.

Description: Compliance filing: Market Based Rate Tariff Baseline Filing to be effective 1/1/2017.

Filed Date: 1/3/17.

Accession Number: 20170103–5095.

Comments Due: 5 p.m. ET 1/24/17.

Docket Numbers: ER17–737–000.

Applicants: Viridity Energy Solutions Inc.

Description: Baseline eTariff Filing: VES MBR Application to be effective 1/4/2017.

Filed Date: 1/3/17.

Accession Number: 20170103–5150.

Comments Due: 5 p.m. ET 1/24/17.

Docket Numbers: ER17–738–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3125R4 Basin Electric Power Cooperative NITSA and NOA to be effective 12/1/2016.

Filed Date: 1/3/17.

Accession Number: 20170103–5186.

Comments Due: 5 p.m. ET 1/24/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–00119 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF16–10–000]

WBI Energy Transmission, Inc.; Supplemental Notice of Intent To Prepare an Environmental Assessment for the Planned Valley Expansion Project and Request for Comments on Environmental Issues

On November 23, 2016, the Commission issued a ''*Notice of Intent to Prepare an Environmental Assessment for the Planned Valley Expansion Project and Request for Comments on Environmental Issues*'' (NOI) and an Errata Notice for the NOI on November 28, 2016. It has come to our attention that the environmental mailing list was not provided copies of the NOI or the Errata Notice; therefore, we are issuing this Supplemental NOI to extend the scoping period and provide

additional time for interested parties to file comments on environmental issues.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Valley Expansion Project involving construction and operation of facilities by WBI Energy Transmission, Inc. (WBI Energy) in Clay County, Minnesota and Cass, Burleigh, Stutsman, and Barnes Counties, North Dakota. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. The NOI identified December 23, 2016 as the close of the scoping period. Please note that the scoping period is now extended and will close on January 27, 2017.

If you sent comments on this project to the Commission before the opening of this docket on October 17, 2016, you will need to file those comments in Docket No. PF16–10–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF16–10–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Planned Project

WBI Energy plans to construct 38 miles of new 16-inch-diameter pipeline between Mapleton, North Dakota and Felton, Minnesota. WBI Energy also plans to construct a new 2,600-horsepower electric-driven compressor station in Cass County, North Dakota, farm taps, valve settings, and ancillary facilities. Additionally, WBI Energy plans to replace two existing town border station delivery points and construct one regulator station in Burleigh, Stutsman, and Barnes Counties, North Dakota in order to increase in the maximum allowable operating pressure of a portion of its Line Section 24. According to WBI Energy, the project would provide an additional 40 million cubic feet per day of firm transportation on its system.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Construction of the project would affect a total of about 530 acres of land, including the pipeline construction right-of-way, additional temporary workspace, staging areas, temporary and permanent access roads, and aboveground facilities. The total acreage required for operation of the project is approximately 235 acres, including the new permanent pipeline easement, permanent access roads, and permanent aboveground facilities' footprint.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us[2] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA, we will discuss impacts that could occur as a result of the construction and operation of the planned project under these general headings:

- Geology and soils;
- water resources, fisheries, and wetlands;
- vegetation and wildlife;
- endangered and threatened species;
- cultural resources;
- socioeconomics;
- land use;
- air quality and noise;
- public safety; and
- cumulative impacts.

We will also evaluate possible alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the planned facilities and the environmental information provided by WBI Energy. This preliminary list of issues may change based on your comments and our analysis, but currently includes:

- Drain tiles;
- deep topsoil and poor quality subsoils (salinity/sodium or lime);
- prime farm land;
- federally listed species, including the whooping crane, gray wolf, Dakota skipper, northern long-eared bat, western prairie fringed orchid, and the powershiek skipperling;
- cultural resources; and
- crossing methods of the Rush River, Red River of the North, and the Buffalo River.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

Once WBI Energy files its application with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF16–10). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription, which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00071 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Atlantic Coast Pipeline, Supply Header Project, and Capacity Lease Proposal

	Docket Nos.
Atlantic Coast Pipeline, LLC.	CP15–554–000, CP15–554–001
Dominion Transmission, Inc.	CP15–555–000
Piedmont Natural Gas Company, Inc.	CP15–556–000

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft environmental impact statement (EIS) for the Atlantic Coast Pipeline (ACP) and Supply Header Project (SHP) as proposed by Atlantic Coast Pipeline, LLC (Atlantic) and Dominion Transmission, Inc. (DTI), respectively, in the above-referenced dockets. Atlantic and DTI request authorization to construct and operate a total of 641.3 miles of natural gas transmission pipeline and associated facilities, and three new natural gas-fired compressor stations, and to modify four existing compressor stations. The projects would provide about 1.44 billion cubic feet per day of natural gas to electric generation, distribution, and end use markets in Virginia and North Carolina. In addition, Atlantic and Piedmont Natural Gas Co., Inc. (Piedmont) request authorization to allow Atlantic to lease capacity on Piedmont's existing pipeline distribution system in North Carolina for use by Atlantic (Capacity Lease Proposal). No construction or facility modifications are proposed with the Capacity Lease Proposal.

The draft EIS assesses the potential environmental effects of the construction and operation of the projects in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the projects would have some adverse and significant environmental impacts; however, the majority of impacts would be reduced to less-than-significant levels with the implementation of the Atlantic's and DTI's proposed mitigation and the additional measures recommended in the draft EIS.

The U.S. Department of Agriculture—Forest Service (FS); U.S. Army Corps of Engineers; U.S. Environmental Protection Agency; U.S. Fish and Wildlife Service—Great Dismal Swamp National Wildlife Refuge; West Virginia Department of Environmental Protection; and West Virginia Division of Natural Resources participated as cooperating agencies in the preparation of the draft EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposals and participate in the NEPA analysis. Further, the FS may use the EIS when it considers amendments to Land and Resource Management Plans (LRMPs) for the proposed crossings of the Monongahela National Forest (MNF) and George Washington National Forest (GWNF). Although the cooperating agencies provide input to the conclusions and recommendations presented in the draft EIS, each agency will present its own conclusions and recommendations in its respective record of decision or determination for the projects.

The draft EIS addresses the potential environmental effects of the construction and operation of the following proposed project facilities:

The ACP includes:

- 519.1 miles of new 42- and 36-inch-diameter natural gas pipeline in West Virginia, Virginia, and North Carolina;
- 84.6 miles of 20- and 16-inch-diameter natural gas pipeline in Virginia and North Carolina;
- three new compressor station in Lewis County, West Virginia; Buckingham County, Virginia; and Northampton County, North Carolina; and
- nine meter stations, along with pig launchers/receivers and mainline valves.

The SHP includes:

- 37.5 miles of new 36-inch-diameter natural gas pipeline in Pennsylvania and West Virginia;
- modifications at four existing compressor stations in Westmoreland and Green Counties Pennsylvania and Marshall and Wetzel Counties West Virginia;
- abandonment of existing compressor units and associated facilities in Wetzel County, West Virginia; and
- one meter station, along with pig launchers/receivers and mainline valves.

Actions of the Forest Service

The FS's purpose and need for the proposed action is to respond to a special use application submitted by Atlantic on November 12, 2015, to allow the construction and operation of the ACP on national forest system (NFS) lands managed by the MNF and the GWNF. If the FS decides to authorize the pipeline crossing of NFS lands and issue a special use permit, the FS has determined that amendments to each national forest LRMP would be needed.

Project-specific plan amendments would be needed to deviate from the precise wording of forest plan standards for the construction and operation of the ACP. These amendments are considered ''project-specific'' amendments because they would not change FS requirements for other projects or authorize any other actions. Additionally, if the proposed route is authorized and a special use permit issued, the GWNF LRMP would need to be amended to change the current management prescriptions in the pipeline's operational corridor to Management Prescription Area (Rx) 5C-Designated Utility Corridors. The MNF does not have LRMP direction that would require a similar plan amendment to reallocate management prescriptions. Therefore, this amendment is considered a ''plan-level'' amendment and would change future management direction for the lands reallocated to the new management prescription. The FS has also identified other potential amendments that may be required, pending survey information and analyses that are not currently available.

Pursuant to Title 40 of the Code of Federal Regulations, Part 1506.3(c) (40 CFR 1506.3(c)), the FS may adopt and use the EIS developed by FERC to consider authorization for the construction and operation of the ACP crossing NFS lands. Further, the FS may use this EIS when it considers amendments to the LRMPs that would be required for the proposed crossings of the MNF and GWNF. The FS will prepare separate Records of Decision for the authorization decision and for the plan amendments decisions, after issuance of the FERC final EIS.

The following amendments have been proposed by the FS as part of the proposed action in the FERC draft EIS:

Monongahela National Forest

The type of amendment applicable to the MNF would be a project-specific amendment. This amendment would not change FS requirements for other projects or authorize any other actions.

Potential Amendment 1: The MNF LRMP may need to be amended to allow construction of the ACP to temporarily exceed standards identified under management direction for soils and water, specifically forest-wide standards SW06 and SW07, provided that design criteria, mitigation measures, project requirements, and/or monitoring activities agreed upon by the FS are

implemented as needed to achieve adequate slope and soil stability.

Other potential amendments may be needed pending the outcome of ongoing analyses and development of project design and mitigation.

George Washington National Forest

The first type of LRMP amendment applicable to the GWNF would be a plan-level amendment that would change land allocations. This would change future management direction for the lands reallocated to the new Rx and is required by LRMP Standards FW–243 and FW–244.

Proposed Amendment 1: The LRMP would be amended to reallocate 102.3 acres to the Rx 5C-Designated Utility Corridors from these Rxs: 7E1-Dispersed Recreation Areas (7 acres), and 13-Mosaics of Habitat (95 acres). Rx 11-Riparian Corridors would remain embedded within the new Rx 5C area.

Rx 5C-Designated Utility Corridors contains special uses which serve a public benefit by providing a reliable supply of electricity, natural gas, or water essential to local, regional, and national economies. The new Rx 5C land allocation would be 53.5 feet wide, the width of the final operational right-of-way of the ACP. The area would not cross into the Rx 4A-Appalachian National Scenic Area but would stop and start at the existing Rx 4A boundary. The Rx4A would continue to be managed for the Appalachian National Scenic Trail.

The second type of amendment applicable to the GWNF would be a project-specific amendment that would apply only to the construction and operation of the ACP. The following standards would require a temporary waiver to allow the project to proceed. These amendments would not change LRMP requirements for other projects or authorize any other actions.

Proposed Amendment 2: The LRMP would be amended to allow construction of the ACP to exceed restrictions on soil conditions and riparian corridor conditions as described in LRMP Standards FW–5, FW–15, FW–16, FW–17, and 11–019, provided that mitigation measures or project requirements agreed upon by the FS are implemented as needed.

Proposed Amendment 3: The LRMP would be amended to allow the ACP to cross the Appalachian National Scenic Trail in Augusta County, Virginia (reference LRMP Standard 4A–025).

Potential Amendment 4: The LRMP may need to be amended to allow the removal of old growth trees within the construction corridor of ACP (reference LRMP Standard FW–85).

Potential Amendment 5: The LRMP may need to be amended to allow major reconstruction of a NFS road within the Rx 2C3 area to provide access for pipeline construction. This is contingent on the final location of access roads (reference LRMP Standard 2C3–015).

Potential Amendment 6: The LRMP may need to be amended to allow the ACP to not immediately meet Scenic Integrity Objectives; however, mitigation measures, including vegetation management and restoration actions, are expected to improve visual quality over an extended timeframe (reference LRMP Standard FW–182).

The FS is requesting public comments on the authorization of the ACP on NFS lands and the draft proposed and potential amendments of the LRMPs that would allow the ACP to cross the MNF and GWNF. All comments must be submitted to the FERC as directed in this notice. The FS decision to authorize the ACP will be subject to FS predecisional administrative review procedures established in 36 CFR 218. The MNF Potential Amendment 1, GWNF Proposed Amendments 2 and 3, and Potential Amendments 4, 5, and 6 were developed in accordance with 36 CFR 219 (2012 version) regulations but will be subject to the administrative review procedures under 36 CFR 218 regulations Subparts A and B, per 36 CFR 219.59(b). GWNF Proposed Amendment 1 was developed in accordance to 36 CFR 219 (2012) regulations and will be subject to the administrative review procedures under 36 CFR 219 Subpart B. Refer to the applicable administrative review regulations for eligibility requirements.

All comments must be submitted to the FERC, the lead federal agency, within the timeframe stated in this Notice of Availability. Refer to Docket No. CP15–554–000 (ACP) in all correspondence to ensure that your comments are correctly filed in the record. You may submit your comments to the FERC using one of the four methods listed below.

Distribution and Comments on the Draft Environmental Impact Statement

The FERC staff mailed copies of the draft EIS to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project areas; and parties to this proceeding. Paper copy versions of this draft EIS were mailed to those specifically requesting them; all others received a CD version. In addition, the draft EIS is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the draft EIS are available for distribution and public inspection at:

Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the draft EIS may do so. To ensure consideration of your comments on the proposals in the final EIS, it is important that the Commission receive your comments by April 6, 2017.

For your convenience, there are four methods you can use to submit your comments to the Commission. In all instances, please reference the appropriate docket numbers (CP15–554–000 and CP15–554–001 for ACP; CP15–555–000 for SHP; or CP15–556–000 for Capacity Lease) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project.

(2) You can file your comments electronically by using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type.

(3) You can file a paper copy of your comments by mailing them to the following address:

Nathaniel J. Davis, Sr., Deputy Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

(4) In lieu of sending written or electronic comments, the Commission invites you to attend one of the public comment sessions its staff will conduct in the project area to receive comments on the draft EIS. We encourage interested groups and individuals to attend and present oral comments on

the draft EIS. The sessions are scheduled as follows:

Date and time	Location
Monday, February 13, 2017, 5:00–9:00 p.m	Doubletree Hotel, 1965 Cedar Creek Road, Fayetteville, NC 28312.
Tuesday, February 14, 2017, 5:00–9:00 p.m	Forest Hills Middle School, 1210 Forest Hills Road, Wilson, NC 27893.
Wednesday, February 15, 2017, 5:00–9:00 p.m	Hilton Garden Inn Roanoke Rapids, 111 Carolina Crossroads Parkway, Roanoke Rapids, NC 27870.
Thursday, February 16, 2017, 5:30–9:30 p.m	Hilton Garden Inn Conference Center, 100 East Constance Road, Suffolk, VA 23434.
Tuesday, February 21, 2017, 5:00–9:00 p.m	Moton Museum, 900 Griffin Boulevard, Farmville, VA 23901.
Wednesday, February 22, 2017, 5:00–9:00 p.m	Nelson County High School, 6919 Thomas Nelson Highway, Route 29, Lovingston, VA 22949.
Thursday, February 23, 2017, 5:00–9:00 p.m	Holiday Inn Hotel and Conference, 152 Fairway Lane, Staunton, VA 24401.
Tuesday, February 28, 2017, 5:00–9:00 p.m	Highland Center, 61 Highland Center Drive, Monterey, VA 24465.
Wednesday, March 1, 2017, 5:00–9:00 p.m	Gandy Dance Theater, 359 Beverly Pike, Elkins, WV 26241.
Thursday, March 2, 2017, 5:00–9:00 p.m	Marlinton Community Wellness Center, 320 9th Street, Marlinton, WV 24954.

There will not be a formal presentation by Commission staff at any of the ten public comment sessions, although a format outline handout will be made available. All sessions will begin at 5:00 p.m., with the exception of the session on Thursday, February 16, 2017, which will begin at 5:30 p.m. If you wish to provide verbal comments, the Commission staff will hand out numbers in the order of your arrival. Number distribution will be discontinued at 8:00 p.m. in order to ensure all comments are received by the session closing time. Comments will be taken until 9:00 p.m. (or 9:30 p.m. at the February 16 session). However, if no additional numbers have been handed out *and* all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 8:00 p.m., or after the last comment is taken.

The primary goal of the public sessions is to allow individuals to provide verbal comments on the draft EIS. Individual verbal comments will be taken on a one-on-one basis with a Court Reporter (with FERC staff or representative present), called up in the order of the numbers received. Because we anticipate considerable interest from concerned citizens, this format is designed to receive the maximum amount of verbal comments, in a convenient way during the timeframe allotted. If many people are interested in providing verbal comments in the one-on-one setting at any particular session, a time limit of 3 minutes may be implemented for each commenter.

Your verbal comments will be recorded by the Court Reporter. Transcripts of all comments from the sessions will be placed into the dockets for the projects, which are accessible for public viewing on the FERC's Web site (at *www.ferc.gov*) through our eLibrary system.

Commission staff will be available at each venue of the public sessions to answer questions about our environmental review process. It is important to note that written comments mailed to the Commission and those submitted electronically are reviewed by staff with the same scrutiny and consideration as the verbal comments given at the public sessions.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR part 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Questions?

Additional information about the projects is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP15–554, CP15–555, or CP15–556). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676; for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp* to subscribe.

[1] See the previous discussion on the methods for filing comments.

Dated: December 30, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00068 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–737–000]

Viridity Energy Solutions Inc.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request For Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Viridity Energy Solutions Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of

future issuances of securities and assumptions of liability, is January 23, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–00122 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–29–000]

American Municipal Power, Inc. v. Midcontinent Independent System Operator, Inc.; Notice of Complaint

Take notice that on December 19, 2016, pursuant to Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and sections 206 and 309 of the Federal Power Act, (FPA) [1] American Municipal Power, Inc. (AMP or Complainant) filed a formal complaint against Midcontinent Independent System Operator, Inc. (MISO or Respondent) alleging that MISO violated its Open Access Transmission, Energy and Operating Reserve Markets Tariff by improperly charging AMP for certain congestion and scheduling fees associated with the transmission of energy from its facility, as more fully explained in the complaint.

The Complainant certifies that a copies of the complaint were served on the contacts for MISO as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 18, 2017.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00075 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

[1] 16 U.S.C. 824(e) and 825(h).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[EL17–33–000]

Great River Energy; Notice of Filing

Take notice that on December 29, 2016, Great River Energy submitted an updated revenue requirement for Reactive Power Service provided under Schedule 2 of the Midwest ISO Tariff.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 19, 2017.

Dated: December 30, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00074 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–32–000]

Old Dominion Electric Cooperative and Direct Energy Business, LLC on Behalf of Itself and Its Affiliate, Direct Energy Business Marketing, LLC and American Municipal Power, Inc. v. PJM Interconnection, L.L.C.; Notice Of Complaint

Take notice that on December 23, 2016, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h, and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Old Dominion Electric Cooperative (ODEC) and Direct Energy Business, LLC, on behalf of itself and its affiliate, Direct Energy Business Marketing, LLC, and American Municipal Power, Inc. (collectively, Complainants) filed a formal complaint against PJM Interconnection, L.L.C. (PJM or Respondent) alleging, among other things, that certain provisions in the Respondent's Open Access Transmission Tariff and the Reliability Assurance Agreement among Load Serving Entities in the PJM Region, regarding Seasonal Capacity Performance Resources in the RPM auctions, are no longer just and reasonable, all as more fully explained in the complaint.

Complainants certify that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 18, 2017.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00067 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–735–000]

NEP Energy Services, Ltd.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of NEP Energy Services, Ltd.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 23, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–00121 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–478–000]

Gulf South Pipeline Company, LP; Notice of Schedule for Environmental Review of the St. Charles Parish Expansion Project

On July 11, 2016, Gulf South Pipeline Company, LP (Gulf South) filed an application in Docket No. CP16–478–000 requesting a Certificate of Public Convenience and Necessity pursuant to section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed project is known as the St. Charles Parish Expansion (Project), and involves the construction and operation of natural gas pipeline and compression facilities by Gulf South in St. Charles and St. John the Baptist Parishes, Louisiana.

On July 18, 2016, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal

authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project.

Schedule for Environmental Review

Issuance of EA—March 3, 2017
90-day Federal Authorization Decision Deadline—June 1, 2017

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project purpose is to provide 133,333 dekatherms per day to serve Entergy Louisiana, LLC's proposed natural gas-fired power plant facility located near Montz, Louisiana. Gulf South proposes to construct a new 5,000 horsepower compressor station near Montz, Louisiana (Montz Compressor Station), about 900 feet of new 16-inch-diameter pipeline, and auxiliary facilities.

The proposed Montz Compressor Station would be on the border of St. Charles and St. John the Baptist Parishes. Gulf South plans to begin construction of the Project in the fall of 2017 and place the facilities in-service by September 1, 2018.

Background

On August 24, 2016, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed St. Charles Parish Expansion Project and Request for Comments on Environmental Issues* (NOI). The NOI was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the NOI, the Commission received comments from the U.S. Environmental Protection Agency and the Choctaw Nation of Oklahoma. The primary issues raised by the commentors are air quality, impacts on wetlands, tribal coordination, the availability of cultural surveys, and environmental justice impacts.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP16–478), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: December 30, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00069 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–681–000]

Enel Trading North America, Inc.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Enel Trading North America, Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 17, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00070 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–30–000]

Nogales Transmission, L.L.C., Nogales Frontier Operations, L.L.C.; Notice of Petition for Declaratory Order

Take notice that on December 21, 2016, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] Nogales Transmission, L.L.C. (Nogales Transmission) and Nogales Frontier Operations, L.L.C. (Nogales Operations) filed a petition for declaratory order: (1)

[1] 18 CFR 385.207(a)(2) (2016).

Finding that Nogales Transmission is a passive entity and therefore not a ''public utility'' under the Federal Power Act, or an ''electric utility company'' under the Public Utility Holding Company Act of 2005; (2) granting Nogales Operations negotiated rate authority; (3) approving Nogales Operations' capacity allocation methodology; and (4) granting certain waivers of Commission regulations, all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.or* call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on January 20, 2017.

Dated: December 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–00065 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–728–000]

Approved Energy II LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request For Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Approved Energy II LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 23, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 3, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–00120 Filed 1–6–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2014–0471; FRL–9958–00–OAR]

RIN 2060–AS26

Granting Petitions To Add n-Propyl Bromide to the List of Hazardous Air Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is publishing a draft notice of the rationale for granting petitions to add n-propyl bromide (nPB), also known as 1-bromopropane (1–BP), (Chemical Abstract Service No. 106–94–5) to the list of hazardous air pollutants (HAP) contained in section 112(b)(1) of the Clean Air Act (CAA). The Halogenated Solvents Industry Alliance (HSIA) and New York State Department of Environmental Conservation (NYSDEC) submitted petitions requesting that nPB be added to the list of HAP. In response to the EPA requests for additional data, HSIA subsequently supplemented its petition. Petitions to add a substance to the list of HAP are permitted under the CAA section 112(b)(3).

Based on the EPA's evaluation of the petitioners' showing concerning potential hazards, emissions, and atmospheric dispersion modeling that provided estimates of ambient concentrations of nPB, the EPA has determined that there is adequate evidence to support a determination that emissions and ambient concentrations of nPB may reasonably be anticipated to cause adverse health effects.

DATES: Comments must be received on or before March 10, 2017.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0471, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Elineth Torres, Sector Policies and Programs Division, Policies and Strategies Group (D205–02), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4347; email address: *torres.elineth@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2014–0471. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at: *http://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Instructions: All submissions must include agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. Direct your comments to Docket ID No. EPA–HQ–OAR–2014–0471. The EPA's policy is that all comments received will be included in the public docket and may be made available online at: *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be CBI, or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment, and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/dockets.*

Acronyms. A number of acronyms are used in this document. To ease the reading of the document and for reference purposes, the following acronyms are defined as follows:

1–BP 1-Bromopropane (also known as n-propyl bromide, nPB)
ATSDR Agency for Toxic Substances and Disease Registry
CAA Clean Air Act
CBI Confidential Business Information
EPA U.S. Environmental Protection Agency
EPCRA Emergency Planning and Community Right-to-Know Act
ETI Enviro Tech International
HAP Hazardous Air Pollutants
HSIA Halogenated Solvents Industry Alliance
IRIS Integrated Risk Information System
nPB n-Propyl Bromide (also known as 1-bromopropane, 1–BP)
NESHAP National Emissions Standards for Hazardous Air Pollutants
NTP National Toxicology Program
NYSDEC New York State Department of Environmental Conservation
OMB Office of Management and Budget
PPA Pollution Prevention Act
PERC Perchloroethylene
SNAP Significant New Alternatives Policy
TCE Trichloroethylene
TRI Toxics Release Inventory

Organization of This Document. The information presented in this document is organized as follows:

I. General Information
A. What should I consider as I prepare my comments for the EPA?
B. Where can I get a copy of this document?
II. Background Information
A. What is the list of HAP?
B. CAA Authority: Petitions To Modify the List of HAP
C. Criteria for Listing
III. Summary of Petitions
A. Background
B. Public Comments Received on EPA's Notice of Complete Petition
IV. EPA's Technical Review of the Petitions
A. Chemical Characteristics, Uses, Sources, and Emissions of nPB
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C. Potential Human Exposure and Cancer Risk
V. EPA's Decision To Grant the Petitions
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A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

I. General Information

A. What should I consider as I prepare my comments for the EPA?

Submitting CBI. Do not submit information that you consider to be CBI electronically through *http://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address: OAQPS Document Control Officer (Room C404–02), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; Attn: Docket ID No. EPA–HQ–OAR–2014–0471.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information marked as CBI

will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document.

B. Where can I get a copy of this document?

In addition to being available in the docket, the electronic copy of this document will be available on the World Wide Web. Following signature, a copy of this document will be posted on at the following address: *https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications.*

II. Background Information

A. What is the list of HAP?

The list of HAP, which can be found in CAA section 112(b)(1), is a list of a wide variety of organic and inorganic substances that Congress identified as hazardous air pollutants in the 1990 CAA Amendments. These HAP have been associated with a wide variety of adverse health effects, including cancer, neurological effects, reproductive effects, and developmental effects. The health effects associated with various HAP differ depending upon the toxicity of the individual HAP and the particular circumstances of exposure, such as the amount of chemical present, the length of time a person is exposed, and the stage of life at which the person is exposed. The CAA directs the EPA to first identify and list source categories that emit HAP and then to set emission standards for those listed source categories. Standards promulgated under CAA section 112(d) are commonly referred to as National Emission Standards for Hazardous Air Pollutants (NESHAP).

B. CAA Authority: Petitions To Modify the List of HAP

CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP contained in CAA section 112(b)(1) by adding or deleting a substance. CAA section 112(b)(3)(B) sets out the substantive criteria for granting a petition. It calls for the Administrator to add a substance to the CAA section 112(b)(1) list ''upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.'' The Administrator is required under CAA section 112(b)(3)(A) to either grant or deny a petition within 18 months of the receipt of a complete petition by publishing a written explanation of the reasons for the Administrator's decision. The Administrator may not deny a petition solely on the basis of inadequate resources or time for review.

CAA section 112(b)(2) gives the Administrator authority to add to the CAA section 112(b)(1) list ''pollutants which present, or may present through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances, which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition or otherwise.'' CAA section 302(k) defines an air pollutant as ''any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive . . . substance or matter which is emitted into or otherwise enters the ambient air.'' CAA section 112(a)(7) specifically defines the term ''adverse environmental effect'' as ''any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.''

The EPA reviews petitions to add substances to the HAP list in two phases: (1) A completeness determination and (2) a substantive technical review. During the completeness determination, we conduct a broad review of the petition to determine whether the necessary subject areas have been addressed and whether reasonable information and analyses are present for each of the subject areas. Once we determine the petition complete, we publish a notice of receipt of a complete petition in the **Federal Register** and request public comment and/or additional data.

During the technical review, we conduct an evaluation of both the petition and the information received from the public in response to the **Federal Register** notice of complete petition to determine whether the data, analyses, interpretations, and conclusions in the petition are adequate. Based on this review, we decide whether the petition satisfies the requirements of CAA section 112(b)(3)(B) and adequately supports a decision to grant the petition. Upon conclusion of this review, we publish a draft notice in the **Federal Register** with the written explanation of the Administrator's decision to grant the petition. After considering the comments received on the draft document, we publish a final notice in the **Federal Register**. A final notice granting a petition to add a pollutant to the HAP list in CAA section 112(b)(1) brings sources emitting that HAP into consideration in the EPA's program to promulgate NESHAP.

Finally, under CAA section 112(e)(4), the Administrator's action to add a pollutant to the CAA section 112(b)(1) HAP list is not a final agency action subject to judicial review, except that any such action may be reviewed when the Administrator promulgates applicable CAA section 112(d) standards for the pollutant. Thus, any final decision to grant petitions to add nPB to the HAP list would not be subject to review until the Administrator promulgates applicable CAA section 112(d) standards addressing emissions of nPB.

C. Criteria for Listing

As previously explained, CAA section 112(b)(3)(A) allows any person to petition the EPA to modify the CAA section 112(b)(1) list of HAP by adding or deleting a substance. A petitioner must make ''a showing . . . that there is adequate data on the health or environmental effects of the pollutant or other evidence adequate to support the petition.'' CAA section 112(b)(3)(A). Thus, this section places the burden on a petitioner to demonstrate that the data sufficiently support an affirmative determination that the substantive criteria contained in CAA section 112(b)(3)(B) have been met. In other words, a petitioner bears the burden of showing that emissions, ambient concentrations, bioaccumulation or deposition of a substance are known to cause or may reasonably be anticipated to result in adverse human health or environmental effects. ''The statutory language unambiguously places on a [ ]listing petitioner the burden to make a 'showing' that 'there is adequate data' about a substance to determine exposure to it 'may . . . reasonably be anticipated to cause' adverse effects.'' *Am. Forest & Paper Ass'n* v. *EPA,* 294 F.3d 113, 119 (D.C. Cir. 2002) (emphasis in original). The statute does not further define what constitutes adequate data and we believe that by employing the term

''adequate,'' the statute acknowledges the limitations of data on human health and environment and gives the Administrator discretion to determine what constitutes sufficient or adequate information for purposes of a listing petition. We also note that CAA section 112(b)(4) allows the Administrator to ''acquire'' information ''when she determines that information on the health or environmental effects of a substance is not sufficient to make a determination,'' under CAA section 112(b)(3). Moreover, Congress could have provided, but did not provide, specific criteria to guide the Administrator's exercise of her discretion in deciding whether the data presented are sufficient under CAA section 112(b)(3)(A).[1] Thus, we interpret the statutory silence in CAA section 112(b)(3)(A) as allowing the Administrator to apply her expertise when reviewing data/information provided by the petitioner to make the demonstration required by CAA section 112(b)(3)(B), as well as to consider limitations and difficulties inherent in information on public health, welfare, and/or the environment.

As previously noted, CAA section 112(b)(3)(B) calls for the Administrator to add to the CAA section 112(b)(1) list of HAP a substance that is shown to be ''an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.'' CAA section 112(b)(2) provides additional guidance on how the Administrator's decision is to be formed by identifying carcinogenicity, mutagenicity, teratogenicity, neurotoxicity, reproductive dysfunction, and acute or chronic toxicity as types of adverse health effects. Further, the language used in CAA section 112(b)(3)(B) does not call for either complete substantiation or require absolute certainty that a substance will cause adverse effects to human health or the environment. In fact, it calls for listing a substance that ''may reasonably be anticipated to cause'' certain impacts. The EPA interprets this language as recognizing the limitations and difficulties associated with information on public health and environment. Typically, questions as to whether a substance presents adverse health and welfare effects and the types of effects border on the frontiers of scientific knowledge and are given to uncertainty because there is either insufficient or inconsistent data. For example, there might be limited scientific knowledge of exposure effects on human health and the environment. Some substances have no known safe level. There might also be limited emissions data on a substance that is considered for addition to the list given that it would be largely unregulated.

Moreover, the CAA is a protective or preventive statute. One of its stated purposes is ''to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare.'' CAA section 101(b)(1). Relevant legislative history also provides support for this stated purpose. (The CAA is ''to assure that regulatory action can effectively prevent harm before it occurs; to emphasize the predominant value of protection of public health.'' H.R. Rep. No. 95–294, 95th Cong., 1st Sess. 49 (1977)). Such statutes do not call for certainty of harm, but rather accord a decision maker flexibility in taking regulatory action that is protective of public health and the environment. They allow a decision maker to exercise discretion when forming her judgement, which would likely involve balancing of factors that are uniquely within her expertise and policy choices, and predictions on the frontiers of scientific knowledge. (''[A]n agency [has] latitude to exercise its discretion in accordance with the remedial purposes of the controlling statute where relevant facts cannot be ascertained or are on the frontiers of scientific inquiry.'' *Nat'l Lime Ass'n* v. *EPA,* 627 F.2d 416, 454 (D.C. Cir. 1980)).

Further, requiring data/information that provides absolute certainty of the adverse health effects of a substance would likely result in making listing decisions similar to the risk- and health-based approach employed prior to the 1990 CAA Amendments. See S. Rep. No. 101–228 at 3, 128 (1989); see also H.R. Rep. No. 101–490, pt. 1, at 322 (1990). Up until then, the EPA was required to list HAP for regulation based on a conclusion that they could ''cause or contribute to, an increase in mortality, an increase in serious irreversible, or incapacitating reversible illness.'' Section 112(a)(1), CAA, Pub. L. 91–604, 84 Stat. 1676, 1685 (1970).[2] In doing so, the EPA would consider emissions levels at which health effects have previously been observed and factor in an ample margin of safety to protect public health. This approach proved unsatisfactory in achieving the goal of improved public health and in the 1990 CAA Amendments, Congress dispensed with this provision, listed 189 HAP in CAA section 112(b)(1) for regulation, and provided for modifications of the HAP list either by petition or on the Administrator's determination in CAA sections 112(b)(3)(A) and (B). Thus, we interpret CAA section 112(b)(3)(B) as invoking the Administrator's expertise in considering information/data that addresses the potential or likelihood of harm rather than concrete proof of actual harm. We also believe that CAA section 112(b)(3)(B) would allow the Administrator to act in the face of uncertainty as to the proven health effects of a substance, draw inferences from the data before her, as well as err on the side of caution in determining whether the data are sufficient to support listing a substance. This determination would likely take into account the risks associated with not taking an action as compared to taking action and granting the petition to add a substance to the CAA section 112(b)(1) HAP list.

We note that the Administrator's discretion is neither unbounded nor limitless, but rather constrained by the EPA's duty to protect human health and welfare. See *Massachusetts* v. *EPA,* 127 S. Ct. 1438, 1462. (The goal of the CAA is ''to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population.'' CAA section 101(b)(1)). Therefore, we believe that CAA section 112(b)(3) would allow the Administrator to make a comparative assessment of adverse health or environment effects of a substance, projections, or predictions of future possibilities of harm, consideration of uncertainties, and extrapolation of limited and even imperfect scientific data. We also believe that it would allow the Administrator to balance the likelihood of adverse health effects against limited scientific data and to err on the side of caution in making her decision in light of uncertainties in scientific data. Any projections, assessments, and estimations, however, must be

[1] This is in contrast to various provisions in the CAA that specify listing criteria for pollutants(See for example, CAA section 108(a)(2), which states that within 12 months of the listing of a pollutant under CAA section 108(a), the Administrator must issue ''air quality criteria'' that ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.'').

[2] Additionally, until 1990, a HAP was defined as an ''air pollutant . . . which in the judgment of the Administrator cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.'' Section 112(a)(1), CAA, Public Law 91–604, 84 Stat. 1676, 1685 (1970).

reasonable and not based on conjecture. She must also make any necessary policy choices and considerations. Therefore, we do not read CAA section 112(b)(3)(B) as requiring a bright-line test on how a CAA section 112(b)(1) listing decision should be made. The Administrator will neither require nor base her determination solely on a single parameter or measure, *i.e.,* in arriving at her decision, no one set of data will outweigh the other. Rather, the Administrator's decision to list a HAP would be made on a case-by-case basis and involve a thorough and comprehensive review of factual issues, scientific evidence, and data provided in support of a petition to add a substance to the CAA section 112(b)(1) HAP list.

In summary, we read CAA section 112(b)(3)(B) as allowing the Administrator to exercise her expertise to decide, based on all relevant considerations, whether the data presented in a petition are adequate to support a decision to add a substance to the CAA section 112(b)(1) list of HAP. In other words, to determine whether a petitioner has shown that emissions of a substance cause or may reasonably be anticipated to cause adverse effects to human health or the environment. The Administrator would also likely assess potential or probable public health and environmental risks rather than proof of actual harm and consider necessary policy issues. The burden, however, remains on a petitioner to provide data sufficient to support an affirmative determination that emissions of a substance may cause or may reasonably be anticipated to cause adverse human health or environmental effects. Thus, a petitioner must provide a detailed assessment of the available data concerning the substance's potential adverse human health and environmental effects and, where appropriate, characterize the potential for human and environmental exposures resulting from emissions of the substance. We expect that such data would most likely demonstrate that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may reasonably be anticipated to cause adverse effects to human health or the environment. We believe this is a reasonable and proper manner of giving effect to the Administrator's duty to address public health and environmental effects under CAA section 112(b)(3).

III. Summary of Petitions

A. Background

HSIA and NYSDEC submitted petitions to add nPB, also known as 1–BP, to the CAA section 112(b)(1) list of HAP on October 28, 2010, and November 24, 2011, respectively. On November 28, 2012, in response to the EPA's requests for additional data, HSIA supplemented its petition. The petitions to add nPB to the list of HAP presented the following information:

- Background data on nPB, including chemical properties, physical properties, production data, and use data;
- Toxicological evidence describing the human health effects of nPB;
- Estimation of an inhalation unit risk;
- nPB emissions estimates and atmospheric dispersion modeling estimating potential ambient concentrations of nPB adjacent to facilities that emit it; and
- Characterization of potential risks to human health due to potential exposure to ambient air concentrations of nPB.

We discuss in detail the information presented in the petitions in section IV of this document, titled EPA's Technical Review of the Petitions.

Following the receipt of the petitions, the EPA conducted a review to determine whether the petitions were complete according to the agency criteria. After reviewing these petitions and supplemental information, the EPA determined that the petitions addressed all of the necessary subject areas for the agency to assess whether emissions, ambient concentrations, bioaccumulation, or deposition of nPB are known to cause or may reasonably be anticipated to cause adverse human health effects or adverse environmental effects. The EPA determined the petitions to add nPB to the list of HAP to be complete and published a notice of receipt of a complete petition in the **Federal Register** on February 6, 2015, and invited the public to comment on the technical merits of these petitions and to submit any information relevant to the technical review of the petitions.

B. Public Comments Received on EPA's Notice of Complete Petition

We received 17 submissions in response to the request for comments and additional information. The submissions are in the docket. Almost all the submissions agreed with the EPA's completeness determination of the petitions to add nPB to the CAA section 112(b)(1) HAP list. The majority of commenters referenced the National Toxicology Program (NTP) Report on Carcinogens (RoC), 13th Edition, 2014 (NTP, 2014) in which the NTP classified nPB, identified as 1–BP, as being reasonably anticipated to be a human carcinogen.

Both petitioners, HSIA and NYSDEC, provided comments and additional information on occupational hazards and toxicity of nPB to support their petitions. Albemarle Corporation and Enviro Tech International (ETI), a manufacturer and a supplier of nPB respectively, disagreed with the EPA's completeness determination and provided their own evaluation of the emissions estimates, nPB carcinogenicity, as well as the exposure and cancer risk assessment included in the HSIA petition. Both Albemarle and ETI did not support the granting of petitions to add nPB to the HAP list based on their risk assessment. Submissions from various states, the city of Philadelphia, and groups representing state air pollution control agencies supported the EPA's completeness determination, presented state-specific information regarding the uses of nPB in dry cleaning and as a solvent in adhesives and degreaser operations, provided information on nPB state-specific studies and regulations, and supported the granting of the petitions to add nPB to the HAP list.

Submissions from national environmental organizations and other members of the public provided the EPA with additional references to studies on nPB's carcinogenic potential and neurotoxicity as well as information relevant to the NTP's peer-reviewed report on the carcinogenicity of nPB, and to the occupational exposure limits for nPB. These commenters also referenced the EPA's addition of nPB to the list of toxic chemicals subject to reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and section 6607 of the Pollution Prevention Act (PPA). We considered all comments in our technical review.

IV. EPA's Technical Review of the Petitions

In this section, we present the EPA's evaluation of the evidence provided by the petitioners and information submitted by commenters beyond what was provided in the petitions relevant to our technical review. The purpose of this evaluation is to determine whether the data, analyses, interpretations, and conclusions in the petitions are adequate and whether they support a determination under CAA section 112(b)(3) that the substance is an air

pollutant and that emissions, ambient concentrations, bioaccumulation, or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.

The EPA's technical review focuses on the evidence provided by petitioners and commenters regarding emissions, ambient concentrations, and health effects of nPB. We are seeking comments on the EPA's technical review of the HSIA and NYSDEC petitions, on whether the criteria for listing have been met, and the agency's rationale for the decision to grant these petitions.

A. Chemical Characteristics, Uses, Sources, and Emissions of nPB

nPB, also known as 1–BP or 1-propyl bromide (CAS # 106–94–5), is a brominated organic colorless liquid that is insoluble in water, but soluble in ethanol and ether. Both petitioners and public commenters provided background information regarding nPB's chemical properties, physical properties, production, and usage. nPB is used as an intermediate chemical in the manufacture of pharmaceuticals and agricultural products, as well as a carrier solvent in aerosols and adhesives. The petitioners presented information on specific applications of nPB, including its use in aerosol solvents, adhesives, dry cleaning, and for open vapor degreasing applications in electronic, metal, and precision cleaning operations. Many commenters raised concerns with the use of nPB as a replacement of perchloroethylene (PERC), a HAP, in the dry cleaning industry and as replacement for HAP chlorinated solvents, like trichloroethylene (TCE), in solvent cleaning operations. Commenters pointed out that nPB's vapor pressure (146 millimeters of mercury (mm Hg) at 20 °C) is higher than the vapor pressure for PERC (14 mm Hg at 20 °C) and TCE (58 mm Hg at 20 °C) and that indoor and outdoor air emissions associated with nPB use are likely to be higher than those caused by similar use of other solvents with lower vapor pressure.

The petitioners expressed the difficulty in obtaining data on production, uses, and emissions of nPB due to the lack of publically available data. HSIA estimated the global production of nPB in 2007 was 20,000–30,000 metric tons and projected the use of nPB as a solvent in the U.S. to be growing at a rate of 15–20 percent per year (5,000 metric tons or 5,511 short tons). ETI commented on the HSIA's estimates and presented its own data on the use of nPB in the U.S. in the precision cleaning industry sector, dry cleaning industry, and the adhesive, coatings, and inks sectors. Per ETI, in 2014 the U.S. used a total of 4,080 short tons of nPB within these three sectors.

The EPA agrees with the petitioners that since nPB has not been a regulated pollutant under CAA section 112 and reporting data under the Toxics Release Inventory (TRI) Program will not be available until July 2017,[3] it is difficult to ascertain public data on usage, sources, and emissions. Nevertheless, in evaluating the information included in the petitions regarding uses and sources of nPB, the EPA compared the information with previous assessments of nPB performed by the EPA for the Significant New Alternatives Policy (SNAP) program and TRI. Based on this review, the EPA finds that the petitioner's showing of information regarding nPB uses and sources is reasonable.

To assess nPB air emissions, HSIA estimated nPB emissions for five facilities: A narrow tube manufacturing/degreasing operation, two dry cleaners, and two furniture manufacturing/spray adhesive facilities. HSIA's emission estimates are based on the internal concentration of nPB as measured by industrial hygiene studies or based on permit files and assuming that nPB is emitted in quantities similar to what would be expected for volatile organic compounds, TCE, or PERC. HSIA acknowledged in their petition that since the emission estimates have been made without access to the facilities, specific nPB use data provided by the facilities, or stack testing data, actual nPB emissions for these facilities could be different from the emission estimates. In their comments, Albemarle presented their own nPB emissions estimates for the same facilities included in the HSIA petition. The EPA believes the emissions estimates provided by HSIA and Albemarle represent a reasonable range of potential nPB emissions, with HSIA providing more conservative (higher) emissions estimates. The EPA finds that HSIA has presented adequate evidence to support the determination that nPB is an air pollutant as defined by CAA section 302(k).

B. nPB Health Effects

To support their request for listing nPB as a HAP, the petitioners provided citations for peer-reviewed published papers and reports describing health effects of nPB. The summary from HSIA's original petition focused on reproductive effects, carcinogenicity, and neurotoxicity. When the EPA requested additional information, HSIA supplemented the information with additional scientific literature on these primary health outcomes. The NYSDEC's petition addressed these same health effects. The petitioners submitted summaries of 2-year bioassays in rats and mice, along with recommendations of the NTP Technical Reports Review Subcommittee, as evidence of carcinogenic activity (NTP, 2011). Claims of neurotoxicity are supported by the laboratory animal studies, as well as occupational studies and case reports of altered peripheral nerve function in workers exposed to concentrations of nPB as low as 1–3 parts per million (ppm). Developmental and reproductive effects, which were described by the EPA SNAP rule (72 FR 30142, May 30, 2007), were referenced by the petitioners. The petitioners claimed that the data are sufficient to conclude that nPB can and does produce adverse human health outcomes. Public comments mostly concurred with this description of health effects. In particular, Dr. Adam Finkel (a subject-matter expert on chemical toxicology) provided comments expanding upon the submitted evidence to lend more support and explanations of nPB toxicity. Regarding these health effects, Albemarle provided comments and summaries of additional studies to refute conclusions of carcinogenicity and to discount methods used in one human occupational study.

1. Cancer Effects

The petitions included a draft report of the NTP Technical Reports Review Subcommittee, followed by the final NTP report summarizing the carcinogenicity bioassays in rats and mice (NTP, 2011).[4] This NTP report concluded ''clear evidence of carcinogenicity'' of nPB based on increased incidences of alveolar/bronchiolar neoplasms in female mice and intestinal adenomas in female rats and ''some evidence of carcinogenicity'' based on skin neoplasms and intestinal adenomas in male rats. There were also increased incidences of non-neoplastic lesions in both rats and mice. More recently the NTP has synthesized information from the existing animal and mechanistic studies, public comments, and peer review and

[3] The final rule adding 1–BP to the list of toxic chemicals subject to reporting under section 313 of the EPCRA and section 6607 of the PPA, 80 FR 72906, November 23, 2015, became effective on November 30, 2015. The reporting year began on January 1, 2016, with reports due on July 1, 2017.

[4] References used in the evaluation of nPB health effects are available in the docket of this action.

concluded that nPB is ''reasonably anticipated to be a human carcinogen'' in the NTP's 13th RoC (NTP, 2014). The EPA has reviewed that assessment to assure its consistency with the EPA Guidelines for Carcinogen Risk Assessment and agreed with the conclusions and classification by the NTP (U.S. EPA Office of Environmental Information, 2014); the details of the EPA's review of these data were presented in the proposed (80 FR 20189, April 15, 2015) and final (80 FR 72906, November 23, 2015) documents to add nPB to the TRI list.

Comments submitted by Albemarle regarding these HAP listing petitions are the same as those submitted on the EPA's proposed TRI action (80 FR 20189, April 15, 2015). Detailed responses by the EPA to these comments are described therein. Albemarle disputed the use of the alveolar/bronchiolar adenomas in the cancer assessment, suggesting a lack of human relevance of these mouse tumors. While this topic has been debated in the scientific literature and was the topic of a technical workshop convened by the EPA (U.S. EPA, 2014),[5] there is no cross-chemical consensus on the human relevance of mouse lung tumors; each chemical will need to be judged separately regarding relevance. Furthermore, the NTP conclusions, supported by the EPA, do not rely solely on the lung tumor data, but rather on the totality of the available information. The commenter also claimed that the EPA has not considered potential uncertainties in the mutagenicity, genotoxicity, and carcinogenicity data for nPB. The NTP review, however, assessed available mutagenicity data in its review. This took into account reports of mutations in bacterial and mammalian cells and limited data on DNA damage in nPB-exposed workers. Furthermore, it is noted that metabolic pathways are similar in humans and experimental animals, and several metabolites of nPB have been identified as mutagens and are known to cause DNA damage. Results from some of these in vitro assays are mixed, and confounding factors may include the volatility of nPB or active metabolites. Finally, the commenter provided a summary of an unpublished study they commissioned showing negative results in the Ames assay; however, the EPA is not persuaded, and these results do not change the conclusion regarding the mutagenicity of nPB and its metabolites. Another commenter (Dr. Adam Finkel) provided counter-arguments to each of Albemarle's points and strongly encouraged the EPA to grant the petitions and to add nPB to the CAA 112(b)(1) list of hazardous pollutants. Considering the available information, including that presented in the petitions and in public comments, the EPA continues to agree with NTP's conclusion that nPB is ''reasonably anticipated to be a human carcinogen.''

2. Non-Cancer Effects

a. Developmental/Reproductive Toxicity

In a previous SNAP ruling (72 FR 30142, May 30, 2007), the EPA reviewed a two-generation study (WIL Research, 2001) and concluded that reproductive toxicity, specifically changes in sperm motility and estrus cycles, was the most sensitive effect of nPB. The petition repeated this information, added references to literature studies that replicated these changes, and suggested that a metabolite may be responsible for the spermatotoxicity (Liu et al., 2009; Banu et al., 2007; Garner et al., 2007; Yamada et al., 2003). These effects are reported at inhalation exposures ≥ 200 ppm in rats and ≥ 50 ppm in mice. The petition also summarized the deliberations of the NTP Center for the Evaluation of Risks of Human Reproduction (NTP–CERHR), an expert panel that evaluated the available scientific literature on the potential for nPB to adversely affect human reproduction or development (NTP–CERHR, 2003). That monograph summarized nPB effects, including alterations in sperm count and motility, estrus cyclicity, follicular count, and reproductive organ weights. The impact of these changes is evident in the two-generation study that reported decreased fertility, increased post-implantation loss, and decreased number of litters, and live litter size. Decreased fetal weight and skeletal abnormalities, as well as depressed postnatal weight gain have also been reported in the literature. Using a weight-of-evidence approach, the panel concluded that there is clear evidence of adverse developmental/reproductive toxicity in laboratory animals and serious concern for adverse effects in humans at levels of occupational exposures.

The EPA has previously reviewed the reproductive and developmental data and agreed with the NTP panel's conclusions. In its SNAP ruling (72 FR 30142, May 30, 2007), the descriptions and evaluations of these data were provided in considerable detail. At that time the data on sperm counts and estrus cyclicity were used for derivations of acceptable exposure levels. In a recent draft report (81 FR 12099, March 8, 2016), the EPA again described nPB-induced reproductive and developmental toxicity, supplemented with studies made available after the 2003 NTP report (NTP–CERHR, 2003). These studies confirm and extend the findings of spermatotoxicity, alterations in estrous cycles, and decreased reproductive organ weights. In this recent report, the EPA considered decreased live litter size (WIL Research, 2001) to be among the most sensitive endpoints for dose-response modeling. Public comments received on the **Federal Register** notice of complete petition (80 FR 6676, February 6, 2015) supported and reiterated concern for this health outcome and noted that nPB is listed as a developmental/reproductive toxicant under Proposition 65 in California.

Given the available information in the petitions, and as described by the EPA in other agency actions on nPB,[6] the EPA concludes that there is clear evidence that nPB produces adverse developmental and reproductive effects.[7]

b. Neurotoxicity

The petitions presented data from published studies in humans and laboratory animals that demonstrate that both the peripheral and central nervous systems are sensitive targets of nPB exposure. The petitions described case reports of severe neurotoxicity requiring hospitalization and potentially irreversible effects (Perrone et al., 2008; Majersik et al., 2007; Sclar, 1999). There are also epidemiological studies that describe concentration-related neurological impacts at relatively low levels; these findings were initially reported in small worker populations while later studies expanded testing to larger groups from several Chinese production facilities (Li et al., 2010; Ichihara et al., 2004; Ichihara et al., 2002). Measurements used in these occupational studies included tuning fork vibration sensitivity and neurophysiological measures of

[5] U.S. EPA. Summary Report: State-of-the-Science Workshop on Chemically-Induced Mouse Lung Tumors: Applications to Human Health Assessments. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–14/002, 2014. Available at *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=291094&CFID=67867665&CFTOKEN=37343828.*

[6] See 72 FR 30142, May 30, 2007; 80 FR 20189, April 15, 2015; 80 FR 72906, November 23, 2015; and 81 FR 12098, March 8, 2016.

[7] In January, 2016, the Agency for Toxic Substances and Disease Registry published a Draft Toxicological Profile for nPB that includes an analysis of the available data on the toxicity of nPB that provides further support for the evidence presented in this notice on the adverse health effects of nPB. The document can be found at *https://www.atsdr.cdc.gov/ToxProfiles/tp209.pdf.*

conduction velocity and latency in motor and sensory nerves. Li et al. (2010) allocated exposure levels (measured by passive sampling) into tertiles with medians of 1.28 to 22.58 ppm for female workers and conducted the analyses using time-weighted averages and cumulative exposures. Vibration sensitivity, the most sensitive endpoint, significantly decreased in all exposure groups, and tibial motor distal latency and sural nerve conduction velocity were altered in the middle and/or high exposure groups. Hematological and hormonal changes were also reported in some or all groups.

The petitions also referenced a number of animal studies showing hind limb weakness, altered neurophysiological measures, and ataxic gait from nPB exposure, which are qualitatively similar to the reported human neurological outcomes. Behavioral measures of neuromuscular function are sensitive measures of nPB neurotoxicity (Banu et al., 2007; Honma et al., 2003; Ichihara et al., 2000). Significant changes were documented at exposures as low as 50 ppm for 21 days (Honma et al., 2003) and changes may be slow or not reversible (Banu et al., 2007). Motor nerve conduction velocity and latency measured in the rat tail nerve were altered at higher concentrations with progressive changes from 4 to 12 weeks of exposure (Yu et al., 2001; Ichihara et al., 2000). Studies of very high exposures report severely altered gait, weakness or loss of hind limb control, convulsions, and death (Banu et al., 2007; Yu et al., 2001; Ichihara et al., 2000; Ohnishi et al., 1999), as well as peripheral nerve degeneration, myelin sheath abnormalities, and spinal cord axonal swelling (Wang et al., 2002; Yu et al., 2001; Ichihara et al., 2000). The petitions included studies of potential mechanisms including neurotransmitter dysregulation (Suda et al., 2008; Wang et al., 2002) and disinhibition in paired-pulse stimulation of hippocampal slices (Fueta et al., 2007).

Some of these neurotoxic effects were described in the EPA's SNAP ruling (72 FR 30142, May 30, 2007), and the conclusions of that review are in agreement with the claims of the petitioners. Since then, the EPA has reviewed the larger literature on the neurotoxicity of nPB and has described the physiological, behavioral, and biochemical measures that characterize and develop exposure-response data for neurological effects (81 FR 12098, March 8, 2016). The EPA has concluded that the concordance of outcomes across humans and laboratory rodents provides striking evidence of neurotoxic effects.

One commenter (Albemarle) expressed concerns regarding the validity and conduct of the tuning fork test of peripheral neuropathy (Li et al., 2010) for risk assessment purposes. The EPA is not persuaded by these objections given that electrophysiological measures of peripheral nerve function were also altered in that and other studies, and, furthermore, considerations regarding hazard do not rely solely on that endpoint. The conclusion of nPB neurotoxicity is supported by the EPA's review of numerous human reports and the preponderance of studies in laboratory animals.

3. Inhalation Unit Risk

HSIA and Albemarle each submitted separate quantitative estimates of cancer unit risk. In addition, the 2010 HSIA petition recommended a non-cancer reference value based on a larger composite uncertainty factor than was used in the SNAP rule's acceptable exposure level. When using quantitative reference values for determining risk from chronic cancer and non-cancer effects, for CAA section 112 actions, the EPA uses only final values that have undergone a rigorous development and review process,[8] *i.e.,* the EPA Integrated Risk Information System (IRIS), the Agency for Toxic Substances and Disease Registry (ATSDR)[9] and the California Office of Environmental Health Hazards Assessment. At this time, there are no final dose-response values for chronic cancer and non-cancer effects for nPB from these sources. Notwithstanding, the EPA acknowledges that the petitioners have shown that adequate information exists to develop such values and that this provides additional support for the potential cancer and non-cancer hazards from exposure to nPB.

C. Potential Human Exposure and Cancer Risk

The petition submitted by HSIA, including supplemental information and analyses submitted through February 2016, contains an exposure assessment and estimates of lifetime potential cancer risks for populations downwind of the five facilities discussed in section IV.A of this document. The petitioner's assessment used the latest version of the EPA's Human Exposure Model (HEM)[10] to model estimated facility emissions and account for the effects on plume dispersion from building downwash and whether the facility was located in an urban or rural area. Census block centroids from the 2010 Census are used as model receptors in HEM and are surrogates for locations of human exposure. The petitioner supplemented these default receptor locations with the locations of actual residences near the facilities. The petitioner applied its derived cancer unit risk estimate to the modeled ambient concentrations to estimate potential lifetime individual cancer risks and population risks. The petitioner's estimates of potential risk range from 5-in-1 million to 40-in-1 million, with about 9,000 people estimated to have cancer risk greater than 1-in-1 million.

A commenter (Albemarle) noted issues with several aspects of the estimation of ambient concentration and potential cancer risks originally submitted by the petitioner, including the use of an outdated model, which used old census and meteorological data, failure to consider the urban heat island effect, incorrect source release parameters, and failure to diurnally vary source emissions. Most of the concerns raised by this commenter have been addressed by the petitioner's use of the latest model version in its most recently submitted assessment, which used current census data, recent meteorological data from a larger library of meteorological stations, and specified urban or rural dispersion for each facility. Although the petitioner did not make any revisions to source release parameters nor temporalize source emissions, the EPA concludes that the petitioner's assessment is to be viewed less as a refined assessment of these specific facilities, but rather as an indication that it is reasonable that nPB emissions and ambient concentrations have the potential to cause elevated risks. It is important to note that the commenter's own assessment of the facilities modeled by the petitioner indicate cancer risk estimates as high as 10-in-1 million.

Moreover, as explained earlier in section II.C of this document, CAA section 112(b)(3)(B) does not specifically require an exposure assessment as a criterion for listing a substance. Rather it requires the EPA to consider whether ''emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be

[8] *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

[9] In January 2016 ATSDR published a draft toxicological profile for nPB. The document can be found at the effects of nPB. The document can be found at *https://www.atsdr.cdc.gov/ToxProfiles/tp209.pdf.*

[10] *https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem.*

anticipated to cause adverse effects to human health or adverse environmental effects.'' In contrast, EPCRA section 313(d)(2)(A) mandates that the EPA consider whether ''a chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries.'' The contrast demonstrates that when Congress intends to specifically require a risk assessment, it does so. It decided not to do so in CAA section 112(b)(3). The CAA is silent on the issue of noncancer hazards and quantitative cancer risk evaluation and does not explicitly prohibit the EPA from considering it when making a determination under CAA section 112(b)(3)(B). As previously explained in section II.C, the EPA also believes that in meeting its obligation under CAA section 112(b)(3)(B), the Administrator has discretion in forming her decision to either grant or deny a petition to add a substance to the CAA section 112(b)(1) HAP list. We believe this discretion would allow her, where appropriate, to consider risk evaluation of a substance in order to make the requisite determination as to whether a substance is ''known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects,'' under CAA section 112(b)(3)(B).

Thus, the EPA concludes that the petitioners have met the CAA section 112(b)(3)(A) requisite showing of adequate data by estimating nPB emissions and ambient concentrations that are likely to result beyond a facility's fence line and providing adequate evidence of adverse health effects of nPB. Because the EPA is granting the petition for reasons stated above, the agency does not find it necessary to make determinations regarding other elements of the petition, such as a petitioner's noncancer hazards and quantitative cancer risk evaluation, or whether nPB presents adverse environmental effects.

V. EPA's Decision To Grant the Petitions

Based on the EPA's evaluation of the petitions submitted by HSIA and NYSDEC, we conclude that the petitioners have provided sufficient information demonstrating the adverse health effects of nPB. The documented adverse health effects of nPB, which are based on established sound scientific principles, include carcinogenicity, reproductive toxicity, and neurotoxicity. The EPA also concludes that the petitioner's assessment regarding estimates of potential ambient concentrations of nPB that are likely to result at a facility's fence line and process emissions related information and chemical usage information representative of normal operating conditions are reasonable. The EPA concludes that there is adequate evidence to support a determination that nPB is an air pollutant and that emissions and ambient concentrations of nPB may reasonably be anticipated to cause adverse effects to human health. As mentioned above, we are seeking comments on all aspects of this notice, including EPA's technical review of the HSIA and NYSDEC petitions, whether the criteria for listing have been met, and the agency's rationale for the decision to grant these petitions.

VI. Statutory and Executive Order Review

Additional information about this Executive Order can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

Accordingly, the EPA is issuing this draft notice announcing the decision to grant petitions to add nPB to the CAA section 112(b)(1) HAP list.

Dated: December 28, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2017–00158 Filed 1–6–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, January 12, 2017 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Draft Advisory Opinion 2016–21: Great America PAC

Draft Advisory Opinion 2016–23: Socialist Workers Party

Revised Proposal To Launch Rulemaking To Ensure That U.S. Political Spending is Free From Foreign Influence

January–July 2017 Meeting Dates

Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Dayna C. Brown,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2017–00321 Filed 1–5–17; 4:15 pm]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–17–17IY]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS)

ACTION: Notice with comment period; withdrawal.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR) in the Department of Health and Human Services (HHS) announces the withdrawal of the notice published under the same title on December 30, 2016 for public comment.

DATES: Effective January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: On December 30, 2016 ATSDR published a notice in the **Federal Register** titled ''Proposed Data Collection Submitted for Public Comment and Recommendations'' (Vol. 81, No. 251 FR Doc. 2016–31738, Pages 96454–96456). ATSDR prematurely and inadvertently published this notice. The notice is being withdrawn immediately for public comment.

A new and corrected notice published on January 3, 2017 under the same title

(Vol. 82, No. 1 FR Doc. 2016–31772, Pages 124–126, Docket No. ATSDR–2016–0007) for public comment.

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–00080 Filed 1–6–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6059–N6]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children's Health Insurance Program in those states.

DATES: Effective January 29, 2017.

FOR FURTHER INFORMATION CONTACT: Steve Manning, (410) 786–1691.

News media representatives must contact CMS' Public Affairs Office at (202) 690–6145 or email them at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Implementation of Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 **Federal Register** (76 FR 5862), CMS published a final rule with comment period titled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,'' which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services' Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular geographic locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a **Federal Register** document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied as a result of the imposition of a temporary moratorium (see § 424.514(d)(2)(v)(C)).

Based on this authority and our regulations at § 424.570, we initially imposed moratoria to prevent enrollment of new home health agencies, subunits, and branch locations [1] (hereafter referred to as HHAs) in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Medicare Part B ground ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339).[2] We exercised this authority again in a notice published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded them to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties. Then, we further extended these moratoria in documents issued on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444). On August 3, 2016 (81 FR 51120), we extended the current moratoria for an additional 6 months and expanded them to statewide for the

[1] As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, CMS–6028–FC (76 FR 5870), home health agency subunits and branch locations are subject to the moratoria to the same extent as any other newly enrolling home health agency.

[2] CMS has identified an error in the provider and beneficiary saturation data described in our July 31, 2013 **Federal Register** notice (78 FR 46339). We have subsequently revised the methodology by which we determine provider and beneficiary saturation. Following these revisions to the methodology, we simulated application of our current 2016 methodology to the 2013 data, and determined that the 2013 decision to impose the moratorium would not have been impacted had the revised methodology been applied. Provider saturation remains one of the criteria used to determine whether to implement a moratorium. CMS has made market saturation data publicly available at *https://data.cms.gov/market-saturation.*

enrollment of new HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas. Our August 3, 2016 publication also announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers.[3]

B. Determination of the Need for Moratoria

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. CMS' determination of a high risk of fraud, waste, or abuse in these provider and supplier types within these geographic locations was then confirmed by CMS' data analysis, which relied on factors the agency identified as strong indicators of risk. (For a more detailed explanation of this determination process and of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

Because fraud schemes are highly migratory and transitory in nature, many of CMS' program integrity authorities and anti-fraud activities are designed to allow the agency to adapt to emerging fraud in different locations. The laws and regulations governing CMS' moratoria authority give us flexibility to use any and all relevant criteria for future moratoria, and CMS may rely on additional or different criteria as the basis for future moratoria.

1. Application to Medicaid and the Children's Health Insurance Program (CHIP)

The February 2, 2011, final rule also implemented section 1902(kk)(4) of the Act, establishing new Medicaid regulations at § 455.470. Under § 455.470(a)(1) through (3), the Secretary may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency must impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries' access to medical assistance and so notifies the Secretary. The final rule also implemented section 2107(e)(1)(D) of the Act by providing, at § 457.990 of the regulations, that all of the provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act, as well as the implementing regulations, also apply to CHIP.

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid, and/or CHIP, ''if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.'' While there may be exceptions, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. Many of the new anti-fraud provisions in the Affordable Care Act reflect this concept of ''reciprocal risk'' in which a provider that poses a risk to one program poses a risk to the other programs. For example, section 6501 of the Affordable Care Act titled, ''Termination of Provider Participation under Medicaid if Terminated Under Medicare or Other State Plan,'' which amends section 1902(a)(39) of the Act, requires State Medicaid agencies to terminate the participation of an individual or entity if such individual or entity is terminated under Medicare or any other State Medicaid plan. Additional provisions in title VI, Subtitles E and F of the Affordable Care Act also support the determination that categories of providers and suppliers pose the same risk to Medicaid as to Medicare. Section 6401(a) of the Affordable Care Act required us to establish levels of screening for categories of providers and suppliers based on the risk of fraud, waste, and abuse determined by the Secretary. Section 6401(b) of the Affordable Care Act required State Medicaid agencies to screen providers and suppliers based on the same levels established for the Medicare program. This reciprocal concept is also reflected in the Medicare moratoria regulations at § 424.570(a)(2)(ii) and (iii), which permit CMS to impose a Medicare moratorium based solely on a State imposing a Medicaid moratorium. Accordingly, CMS has determined that there is a reasonable basis for concluding that a category of providers or suppliers that poses a risk to Medicare also poses a similar risk to Medicaid and CHIP, and that a moratorium in all of these programs is necessary to effectively combat this risk.

2. Consultation With Law Enforcement

In consultation with the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS previously identified two provider and supplier types in nine geographic locations that warrant a temporary enrollment moratorium. For a more detailed discussion of this consultation process, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475).

3. Data Analysis

In addition to consulting with law enforcement, CMS also analyzed its own data to identify specific provider and supplier types within geographic locations with significant potential for fraud, waste or abuse, therefore warranting the imposition of enrollment moratoria.

4. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its State partners, and CMS carefully evaluated access for the target moratorium locations with every imposition and extension of the moratoria. Prior to imposing and extending these moratoria, CMS reviewed Medicare data for these areas and found no concerns with beneficiary access to HHAs or ground ambulance suppliers. CMS also consulted with the appropriate State Medicaid Agencies and with the appropriate State Departments of Emergency Medical Services to determine if the moratoria would create access to care concerns for Medicaid and CHIP beneficiaries. All of CMS' State partners were supportive of CMS' analysis and proposals, and together with CMS, determined that *continuation of* these moratoria would not create access to care issues for Medicaid or CHIP beneficiaries.

5. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to any of the following: (1) Changes in practice location (2) changes in provider or supplier information, such as phone number or address; or (3) changes in ownership (except changes in ownership of HHAs that require initial enrollment under § 424.550). Also, in

[3] CMS also concurrently announced a demonstration under the authority provided in section 402(a)(l)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-l(a)(l)(J)) that allows for access to care-based exceptions to the moratoria in certain limited circumstances after a heightened review of that provider has been conducted. This exception process also applies to Medicaid and CHIP providers in each state. This announcement may be found in the **Federal Register** document issued on August 3, 2016 (81 FR 51116).

accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that a Medicare contractor has already approved, but has not yet entered into the Provider Enrollment, Chain, and Ownership System (PECOS) at the time the moratorium is imposed.

6. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended, CMS will publish a document regarding such extensions in the **Federal Register**.

As provided in § 424.570(d), CMS may lift a moratorium at any time if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, if circumstances warranting the imposition of a moratorium have abated, if the Secretary has declared a public health emergency, or if, in the judgment of the Secretary, the moratorium is no longer needed.

Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be designated to CMS' high screening level under §§ 424.518(c)(3)(iii) and 455.450(e)(2) for 6 months from the date the moratorium was lifted.

II. Extension of Home Health and Ambulance Moratoria—Geographic Locations

CMS currently has in place moratoria on newly enrolling HHAs in Florida, Illinois, Michigan, and Texas and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas.

As provided in § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under this authority, CMS is extending the temporary moratoria on the Medicare enrollment of HHAs and Part B non-emergency ground ambulance providers and suppliers in the geographic locations discussed herein. Under the regulations at § 455.470 and § 457.990, these moratoria also apply to the enrollment of HHAs and non-emergency ground ambulance providers and suppliers in Medicaid and CHIP in those locations. Under § 424.570(b), CMS is required to publish a document in the **Federal Register** announcing any extension of a moratorium, and this extension of moratoria document fulfills that requirement.

CMS consulted with the HHS–OIG regarding the extension of the moratoria on new HHAs and Part B non-emergency ground ambulance providers and suppliers in all of the moratoria states, and HHS–OIG agrees that a significant potential for fraud, waste, and abuse continues to exist regarding those provider and supplier types in these geographic areas. The circumstances warranting the imposition of the moratoria have not yet abated, and CMS has determined that the moratoria are still needed as we monitor the indicators and continue with administrative actions to combat fraud and abuse, such as payment suspensions and revocations of provider/supplier numbers. (For more information regarding the monitored indicators, see the February 4, 2014 moratoria document (79 FR 6475)).

Based upon CMS' consultation with the relevant State Medicaid agencies, CMS has concluded that extending these moratoria will not create an access to care issue for Medicaid or CHIP beneficiaries in the affected states at this time. CMS also reviewed Medicare data for these states and found there are no current problems with access to HHAs or ground ambulance providers or suppliers. Nevertheless, the agency will continue to monitor these locations to make sure that no access to care issues arise in the future.

Based upon our consultation with law enforcement and consideration of the factors and activities described previously, CMS has determined that the temporary enrollment moratoria should be extended for an additional 6 months.

III. Summary of the Moratoria Locations

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to extend and implement temporary enrollment moratoria on HHAs for all counties in Florida, Illinois, Michigan, and Texas, as well as Part B non-emergency ground ambulance providers and suppliers for all counties in New Jersey, Pennsylvania, and Texas.

IV. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act states that there shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed on the enrollment of new providers of services and suppliers if the Secretary determines that the moratorium is necessary to prevent or combat fraud, waste, or abuse. Accordingly, our regulations at 42 CFR 498.5(l)(4) state that for appeals of denials based on a temporary moratorium, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review. Our regulations do not limit the right to seek judicial review of a final agency decision that the temporary moratorium applies to a particular provider or supplier. In the preamble to the February 2, 2011 (76 FR 5918) final rule with comment period establishing this regulation, we explained that ''a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review.'' We are clarifying that providers and suppliers that have received unfavorable decisions in accordance with the limited scope of review described in § 498.5(l)(4) may seek judicial review of those decisions after they exhaust their administrative appeals. However, we reiterate that section 1866(j)(7)(B) of the Act precludes judicial review of the agency's basis for imposing a temporary moratorium.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

CMS has examined the impact of this document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects ($100 million or more in any 1 year). This document will prevent the enrollment of new home health providers and Part B non-emergency ground ambulance suppliers in Medicare, Medicaid, and CHIP in certain states. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Since the imposition of the initial moratoria on July 31, 2013, 1,147 HHAs and 19 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area (MSA) for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: December 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–32007 Filed 1–6–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Request for Information

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for information (RFI).

SUMMARY: This Request for Information (RFI) seeks recommendations for future work with and on behalf of American Indian and Alaska Native (AI/AN) leadership, tribes, tribal organizations, and populations in accord with ACF's vision of ''children, youth, families, individuals, and communities who are resilient, safe, healthy, and economically secure.''

DATES: Submit responses by March 10, 2017.

ADDRESSES: Written comments may be submitted through any of the methods specified below. However, electronic submission is preferred. Please do not submit duplicate comments.

▪ *Electronic submission* through *https://www.regulations.gov* portal. Follow the instructions for submitting electronic comments. Attachments, if any, should be in Microsoft Word or Microsoft Excel. You can find this RFI by typing ACF–2016–0002 in the Search window. Then click on the ''Comment Now!'' button on the Search Results page. This will open up a Comment form where you can enter your comment on the form, attach files (up to 10MB each), as well as your personal information, when applicable. Be sure to complete all required fields. Please note that information entered on the web form may be viewable publicly. Once you reach the ''Your Preview'' screen, the information that will be viewable publicly is displayed directly on the form under the section titled: ''This information will appear on *Regulations.gov*.'' To complete your comment, you must first agree to the disclaimer and check the box. This will enable the ''Submit Comment'' button. Upon completion, you will receive a Comment Tracking Number for your comment. To learn more about comment submission, visit the Submit a Comment section of the ''How to Use Regulations.gov'' pages.

▪ *Electronic submission* through email to *ANAComments@acf.hhs.gov*.

All comments received before the close of the comment period will be available for public inspection, including any information that is included in a comment. All electronically submitted comments posted through the *https://www.regulations.gov* portal received before the end of the comment period will be available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Camille Loya, Director, Division of Policy, Administration for Native Americans, *Camille.Loya@acf.hhs.gov,* 202–401–5964.

SUPPLEMENTARY INFORMATION:

I. Background information

Executive Order 13175, dated November 6, 2000, established policymaking criteria applicable to federal agencies, to the extent permitted by law, when formulating and implementing policies that have tribal implications, including special requirements for legislative proposals and consultation. Subsequently, President Obama issued a Presidential Memorandum on Tribal Consultation, dated November 5, 2009, affirming that ''meaningful dialogue between Federal officials and tribal officials has greatly improved Federal policy toward Indian

tribes.'' Finally, ACF recently issued the *ACF Principles for Working with Federally Recognized Indian Tribes,* effective October 20, 2016, that affirmed ACF's commitment to receive input from elected tribal representatives as well as ''to otherwise ensure human services coordination around issues affecting AI/AN populations.''

Consistent with the above affirmative statements of the value of feedback from AI/AN partners and stakeholders, ACF is requesting information from AI/AN tribes, tribal organizations, and stakeholders (including grantees). The purpose is to identify issues and challenges facing AI/AN populations as well as to inform ACF of tribes' and tribal organizations' recommendations, promising practices, and innovations to address the needs of AI/AN children, youth, families, and communities. This information may, in turn, be used by ACF in the development of future rulemaking and technical assistance, formation of legislative proposals and research agendas, and strategic planning in consultation with tribes.

II. Request for Information

As President Obama stated in his Presidential Proclamation—National Native American Heritage Month (2016):

> Let us continue to build on the advancements we have made, because enduring progress will depend on our dedication to honoring our trust and treaty responsibilities. With sustained effort and unwavering optimism, we can ensure a vibrant and resilient Indian Country filled with possibility and prosperity.

In this RFI, we seek feedback and recommendations related to how ACF partners with tribes and how to make progress in the future. The following questions are not exhaustive, and we encourage commenters to provide any additional information they believe relevant to ACF's work with and on behalf of American Indians and Alaska Natives. You may provide general comments, respond to all questions posed in section II of this RFI, or respond to one or more questions. If you respond to any of the questions in section II, please identify the number that corresponds to the question(s) you are responding to. Include our agency name and the docket number on all submissions. Please do not include confidential information, or otherwise sensitive or protected information with your responses.

(1) Are there challenges to AI/AN tribes and tribal organizations posed by non-federal match or cost sharing requirements in any applicable ACF programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(2) Are there challenges to AI/AN tribes and tribal organizations posed by administrative cost caps required under some ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(3) Are there instances for which you believe waiver authority, additional waiver authority allowed under block grants, would benefit tribes under any ACF programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing challenges or difficulties posed and any specific recommendations you wish to provide.

(4) For ACF programs that currently have waiver authority for tribes, do you recommend ACF streamline the processes under which AI/AN tribes and tribal organizations apply for or request waivers of statutory or regulatory requirements across ACF grant programs? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing where you believe additional streamlining is needed, along with any specific recommendations you wish to provide.

(5) Are there regulatory or administrative barriers that present challenges to AI/AN tribes and tribal organizations in the implementation of ACF grant programs? Please be specific about what those regulatory or administrative barriers are as well as recommendations for addressing them.

(6) Can you identify practices, policies, and procedures in ACF or elsewhere that are particularly effective in meeting the needs of AI/AN tribes, tribal organizations, families, and communities? Please be specific as to the program or programs you are referring to as well as provide as much detail as possible in describing effective and responsive practices, policies, and procedures.

(7) Related to data, what would you recommend ACF either collect (if it does not already) or analyze that would be most useful to inform our work with AI/AN tribes and tribal organizations? Please be specific and provide as much detail as possible.

(8) Do you have recommendations for how ACF could better share data related to AI/AN grantee program performance, outcomes, and sustainability? Please be specific, including recommended use of technological or other means of data sharing.

(9) Are there elements of the application process that could potentially discourage AI/AN tribes or organizations from applying for ACF grants? If so, please specify what those elements are and explain why those elements could potentially discourage prospective AI/AN applicants and any recommendations for addressing such barriers.

III. Response to Comments

Because of the large number of public comments we normally receive, we are not able to acknowledge or respond to them individually. However, comments will be accepted on this RFI through *https://www.Regulations.gov* where you will be able to track your own comments and view other comments we receive.

Dated: January 3, 2017.

Mark H. Greenberg

Acting Assistant Secretary for Children and Families.

Dated: January 3, 2017.

Stacey Ecoffey,

Acting Deputy Assistant Secretary for Native American Affairs and Acting Commissioner Administration for Native Americans.

[FR Doc. 2017–00111 Filed 1–6–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2537]

Submission of Quality Metrics Data; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of revised draft guidance availability that appeared in the **Federal Register** of November 25, 2016. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of revised draft guidance availability published on November 25, 2016 (81 FR 85226). Submit either electronic or written comments by March 27, 2017.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2537 for ''Submission of Quality Metrics Data; Revised Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993–0002, 301–796–3257 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 2016, FDA published a notice of revised draft guidance availability with a 60-day comment period. Comments on the notice of revised draft guidance availability will inform FDA's development and proposed implementation of a voluntary phase of the quality metrics program.

FDA is extending the comment period for an additional 60 days, until March 27, 2017. The Agency believes that a 60-day extension of the comment period for the notice of revised draft guidance availability will provide adequate time for interested persons to submit comments without significantly delaying Agency decision making on these important issues.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00094 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on February 23, 2017, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington, DC/North, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's phone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993–0002, *Evella.Washington@fda.hhs.gov,* 301–796–6683, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/*

default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On February 23, 2017, the committee will discuss and make recommendations on clinical information related to the *de novo* request for the Sentinel® Cerebral Protection System, a first of a kind embolic protection device to be used with transcatheter aortic valve replacement (TAVR) procedures.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 9, 2017. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 1, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 2, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 4, 2017.

Janice M. Soreth,

Associate Commissioner, Special Medical Programs.

[FR Doc. 2017–00143 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4586]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by ELITechGroup Inc. Molecular Diagnostics. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of December 9, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a

determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

II. EUA Request for an In Vitro Diagnostic Device for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On November 28, 2016, ELITechGroup Inc. Molecular Diagnostics requested, and on December 9, 2016, FDA issued, an EUA for the Zika ELITe MGB® Kit U.S., subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *https://www.regulations.gov/*.

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of Zika virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 9, 2016

Terry Trimingham
Senior Regulatory Affairs Specialist
ELITechGroup Inc. Molecular Diagnostics
21720 23rd Drive SE, Suite 150
Bothell, WA 98021

Dear Mr. Trimingham:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of ELITechGroup Inc. Molecular Diagnostics' ("EGI MDx") Zika ELITe MGB® Kit U.S. for the qualitative detection of RNA from Zika virus in human serum and EDTA plasma from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum, following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

[1] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."
[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on November 16, 2016).
[3] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of significant potential for a public health emergency.
[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Zika ELITe MGB® Kit U.S. (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Zika ELITe MGB® Kit U.S. for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Zika ELITe MGB® Kit U.S., when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Zika ELITe MGB® Kit U.S. for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Zika ELITe MGB® Kit U.S. for detecting Zika virus and diagnosing Zika virus infection.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Zika ELITe MGB® Kit U.S. by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

The Authorized Zika ELITe MGB® Kit U.S.

The Zika ELITe MGB® Kit U.S. is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, EDTA

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

plasma and other authorized specimen types. The Zika ELITe MGB® Kit U.S. uses a primer set and single uniquely labeled probe to amplify and detect the NS3 protein encoding gene of Zika virus.

The Zika ELITe MGB® Kit U.S. is performed using the ELITe InGenius™ instrument or other authorized instruments. The ELITe InGenius™ instrument automates the nucleic acid extraction, amplification and detection. The RNA is extracted and purified from the patient specimen before it is reverse transcribed into cDNA which is then amplified using the primer set and detected using the specific probe.

The Zika ELITe MGB® Kit U.S. includes the following materials or other authorized materials: 20x Zika PreMix, PCR MasterMix, RT EnzymeMix, PCR Grade Water, Negative Control, MS2 RNA Internal Control, Zika – Positive Control. The Zika ELITe MGB® Kit U.S. also requires the use of additional materials and ancillary reagents that are not include with the test but are commonly used in clinical laboratories and are described in the authorized Zika ELITe MGB® Kit U.S. Instructions for Use.

The Zika ELITe MGB® Kit U.S. requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Zika ELITe MGB® Kit U.S. Instructions for Use:

- Zika - Positive Control: Synthetic Zika RNA stabilized in a guanidinium buffer, requires extraction – run in place of a sample daily. Monitors for failures of rRT-PCR reagents and reaction conditions.
- Negative Control: DNase and RNase-free water – run in place of a sample on every batch run. Monitors for reagent and system contamination.
- MS2 RNA Internal Control: MS2 RNA stabilized in a guanidinium buffer, requires extraction – added automatically to each sample and control during the extraction step. The MS2 RNA is co-extracted and co-amplified with the target nucleic acid, and monitors for integrity of the kit reagents, equipment function and the presence of amplification inhibitors in the samples.

The above described Zika ELITe MGB® Kit U.S., when labeled consistently with the labeling authorized by FDA entitled "Zika ELITe MGB® Kit U.S." (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by EGI MDx in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Zika ELITe MGB® Kit U.S. is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Zika ELITe MGB® Kit U.S. Test Results
- Fact Sheet for Patients: Understanding Results from the Zika ELITe MGB® Kit U.S.

As described in Section IV below, EGI MDx and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized Zika ELITe MGB® Kit U.S. that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Zika ELITe MGB® Kit U.S. in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Zika ELITe MGB® Kit U.S. may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized Zika ELITe MGB® Kit U.S., when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Zika ELITe MGB® Kit U.S. under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Zika ELITe MGB® Kit U.S. described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Zika ELITe MGB® Kit U.S. during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Zika ELITe MGB® Kit U.S.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ELITechGroup Inc. Molecular Diagnostics and Its Authorized Distributor(s)

A. EGI MDx and its authorized distributor(s) will distribute the authorized Zika ELITe MGB® Kit U.S. with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. EGI MDx and its authorized distributor(s) will provide to authorized laboratories the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients.

C. EGI MDx and its authorized distributor(s) will make available on their websites the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients.

D. EGI MDx and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. EGI MDx and its authorized distributor(s) will ensure that the authorized laboratories using the authorized Zika ELITe MGB® Kit U.S. have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

F. Through a process of inventory control, EGI MDx and its authorized distributor(s) will maintain records of device usage.

[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that EGI MDx, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

G. EGI MDx and its authorized distributor(s) will collect information on the performance of the test. EGI MDx will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which EGI MDx becomes aware.

H. EGI MDx and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Zika ELITe MGB® Kit U.S. that is consistent with, and does not exceed, the terms of this letter of authorization.

ELITechGroup Inc. Molecular Diagnostics

I. EGI MDx will notify FDA of any authorized distributor(s) of the Zika ELITe MGB® Kit U.S., including the name, address, and phone number of any authorized distributor(s).

J. EGI MDx will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. EGI MDx may request changes to the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Healthcare Providers and the authorized Zika ELITe MGB® Kit U.S. Fact Sheet for Patients. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. EGI MDx may request the addition of other instruments for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. EGI MDx may request the addition of other extraction methods for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. EGI MDx may request the addition of other specimen types for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. EGI MDx may request the addition and/or substitution of other control materials for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. EGI MDx may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized Zika ELITe MGB® Kit U.S. Such requests will be made by EGI MDx in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. EGI MDx will assess traceability[7] of the Zika ELITe MGB® Kit U.S. with FDA-

[7] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, EGI MDx will update its labeling to reflect the additional testing.

R. EGI MDx will track adverse events and report to FDA under 21 CFR Part 803.

Authorized Laboratories

S. Authorized laboratories will include with reports of the results of the Zika ELITe MGB® Kit U.S. the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories will perform the Zika ELITe MGB® Kit U.S. on the ELITe InGenius™ instrument, or other authorized instruments.

U. Authorized laboratories will perform the Zika ELITe MGB® Kit U.S. on human serum, EDTA plasma, or other authorized specimen types.

V. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

W. Authorized laboratories will collect information on the performance of the test and report to EGI MDx any suspected occurrence of false positive or false negative results of which they become aware.

X. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

ELITechGroup Inc. Molecular Diagnostics, Its Authorized Distributor(s) and Authorized Laboratories

Y. EGI MDx, its authorized distributor(s), and authorized laboratories, will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

Z. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika ELITe MGB® Kit U.S. shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that EGI MDx, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

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AA. All advertising and promotional descriptive printed matter relating to the use of the authorized Zika ELITe MGB® Kit U.S. shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Zika ELITe MGB® Kit U.S. may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Zika ELITe MGB® Kit U.S. as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00084 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–1196 and FDA–2016–E–1197]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADYNOVATE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ADYNOVATE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 10, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for

extension acted with due diligence during the regulatory review period by July 10, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–E–1196 and FDA–2016–E–1197 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ADYNOVATE.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these Acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product ADYNOVATE (antihemophilic factor (recombinant), PEGylated). ADYNOVATE is indicated in adolescent and adult patients (12 years and older) with Hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes, and routine prophylaxis to reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received patent term restoration applications for ADYNOVATE (U.S. Patent Nos. 7,199,223 and 8,247,536) from Nektar Therapeutics, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ADYNOVATE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ADYNOVATE is 1,061 days. Of this time, 707 days occurred during the testing phase of the regulatory review period, while 354 days occurred during the approval phase. These periods of

time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* December 19, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2012.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: November 25, 2014. FDA has verified the applicant's claim that the biologics license application (BLA) for ADYNOVATE (BLA 125566) was initially submitted on November 25, 2014.

3. *The date the application was approved:* November 13, 2015. FDA has verified the applicant's claim that BLA 125566 was approved on November 13, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 708 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00095 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–1198]

Determination of Regulatory Review Period for Purposes of Patent Extension; EMPLICITI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EMPLICITI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 10, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 10, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–E–1198 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EMPLICITI.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product EMPLICITI (elotuzumab). EMPLICITI is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies. Subsequent to this approval, the USPTO received a patent term restoration application for EMPLICITI (U.S. Patent No. 7,709,610) from AbbVie Biotherapeutics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of EMPLICITI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for EMPLICITI is 3,400 days. Of this time, 3,245 days occurred during the testing phase of the regulatory review period, while 155 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* August 11, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 11, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 29, 2015. FDA has verified the applicant's claim that the biologics license application (BLA) for EMPLICITI (BLA 761035) was initially submitted on June 29, 2015.

3. *The date the application was approved:* November 30, 2015. FDA has verified the applicant's claim that BLA 761035 was approved on November 30, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,095 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00108 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4508]

Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and public comment, in anticipation of the passage of Generic Drug User Fee Amendments reauthorization (GDUFA II), relevant to FDA's planned approach for administering generic drug program fees under that legislation for fiscal year (FY) 2018. This includes requests for comment and information regarding FDA's initial inventory of approved abbreviated new drug application sponsors and application numbers. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA program fees in a timely manner.

DATES: Submit written or electronic comments and information by March 10, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–4508 for ''Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristan Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In anticipation of the enactment and implementation of GDUFA II, FDA has begun taking steps to ensure efficient administration of GDUFA for FY 2018. It is projected that the GDUFA II legislation will include an annual program fee for which holders of approved abbreviated new drug applications (ANDAs) will be responsible.

Under GDUFA II, it is anticipated that affiliated companies will be grouped together and counted as a single entity for purposes of assessing the program fee. The proposed legislation defines the term ''affiliate'' in the same way it was defined in GDUFA. An ''affiliate'' is defined as a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls, or has the power to control, the other business entity; or a third party controls, or has the power to control, both of the business entities. As set forth in the proposed legislation, the program fee will be allocated among three tiers of application holders:

• Large (companies with 20 or more approved ANDAs);

• Medium (companies with between 6 and 19 approved ANDAs); and,

• Small (companies with 5 or fewer approved ANDAs).

To assess program fees in an accurate and timely manner if these provisions are enacted, FDA seeks to identify how many approved ANDAs belong to each application holder, and which application holders are affiliates for purposes of assessing GDUFA II program fees. In furtherance of this effort, FDA requests comments and information regarding FDA's initial inventory of approved ANDA sponsors and application numbers. The current spreadsheet containing this initial inventory and instructions on how to use it are available at *http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm.*

II. Request for Information and Comment

FDA is seeking information and public comment, in anticipation of the passage of GDUFA II, relevant to FDA's planned approach for administering generic drug program fees under that legislation for FY 2018. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA Program Fees in a timely manner. Interested persons are invited to comment, in general, on any aspect of FDA's planned approach for administering these generic drug program fees under GDUFA II. FDA is particularly interested in comments and information addressing the accuracy and completeness of the information in the previously mentioned spreadsheet containing FDA's initial inventory of approved ANDA sponsors and application numbers. In addition, FDA is interested in any information that could be relevant to determining whether two or more companies that are currently listed separately in that spreadsheet should be considered to be affiliated for purposes of assessing the anticipated program fee. As a general matter, FDA does not consider affiliates

to be confidential commercial information.

After receiving feedback and comments on the spreadsheet, FDA anticipates publishing a **Federal Register** notice and making available a revised spreadsheet that will incorporate information received in the comments on this notice. FDA plans to seek comment on the revised spreadsheet before compiling the final information regarding affiliated entities that will be used as the basis for determining and assessing FY 2018 program fees in the event that GDUFA II is enacted.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00081 Filed 1–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 8, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Advanced Education Nursing Traineeship (AENT) Program Specific Data Collection Forms for Use with the New Advanced Nursing Education Workforce (ANEW) Program.

OMB No. 0915–0375—Revision

Abstract: The Advanced Nursing Education Workforce (ANEW) Program is a new program that incorporates elements of HRSA's Advanced Education Nursing Traineeship (AENT) and Advanced Nursing Education (ANE) programs. The current OMB approved Program Specific Data Collection Forms for the former AENT Program will be simplified and used for the ANEW program. HRSA provides advanced education nursing grants to educational institutions to increase the numbers of advanced education nurses through the ANEW Program. The ANEW Program is authorized by Title VIII, Section 811 of the Public Health Service Act (42 U.S.C. 296j). This renewal with revision request includes the Project Abstract, Program Narrative, Attachments, and Tables. The proposed ANEW Tables are very similar to the previous AENT Tables and include information on program participants such as the projected number of enrollees/trainees receiving traineeship support; projected number of graduates receiving traineeship support for the previous fiscal year; the types of programs they are enrolling into and/or from which enrollees/trainees are graduating, and the distribution of primary care nurse practitioners (NP), primary care clinical nurse specialists (CNS); and nurse-midwives who plan to practice in rural and underserved settings. To reduce the reporting burden for applicants, HRSA simplified the Tables to focus on the types of providers and practice settings that are included in the statute in order to determine whether applicants qualify for the preference or special consideration in making awards for this program.

Need and Proposed Use of the Information: HRSA will use this information in determining the eligibility for the statutory funding preference and special consideration, and to succinctly capture data for the number of projected students for subsequent years in the project period.

Likely Respondents: Likely respondents are potential applicants for the ANEW program. Eligible applicants for the ANEW program include entities that provide registered nurses with primary care NP, primary CNS, and nurse-midwife education. Such programs may include accredited schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities authorized by the Secretary of HHS to confer degrees to registered nurses for primary care NP, primary care CNS, or nurse-midwife education. Federally recognized Indian Tribal Government and Native American Organizations as well as faith-based or community-based organizations may apply if they are otherwise eligible.

Eligible state government entities include the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total estimated annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
ANEW Application including the ANEW Program Specific Tables and Attachments	236	1	236	7	1,652

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total	236	1	236	7	1,652

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017–00277 Filed 1–6–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bacterial Pathogenesis.

Date: January 12, 2017.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 3, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00089 Filed 1–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Lung Cellular, Molecular, and Immunobiology Study Section.

Date: February 1–2, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: George M Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: February 1–2, 2017.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Row Hotel, 2015 Massachusetts Avenue NW., Washington, DC 20036.

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Biophysics of Neural Systems Study Section.

Date: February 2, 2017.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn San Francisco Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

Contact Person: Geoffrey G Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Cellular and Molecular Immunology—B Study Section.

Date: February 2–3, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301–435–1223, *haydenb@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Musculoskeletal Rehabilitation Sciences Study Section.

Date: February 2–3, 2017.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435–1222, *nurminskayam@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Interventions to Prevent and Treat Addictions.

Date: February 3, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 3, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00088 Filed 1–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored Training in Comparative and Veterinary Medicine.

Date: February 3, 2017.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 5213, Bethesda, MD 20892, 301–455–2364, *tatiana.cohen@nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Neurodegeneration Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA 94133.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Molecular and Cellular Hematology Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6183, MSC 7804, Bethesda, MD 20892, 301–495–1213, *espinozala@mail.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, 301–435–0677, *mannl@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Development—2 Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular Neuropharmacology and Signaling Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–408–9129, *lewisdeb@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 3, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00090 Filed 1–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification and Clarification of the National Customs Automation Program Tests Regarding Post-Summary Corrections and Periodic Monthly Statements; Republication With Correction and Further Clarification

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice; republication with correction and further clarification.

SUMMARY: On December 12, 2016, U.S. Customs and Border Protection (CBP) published in the **Federal Register** a document announcing CBP's plans to modify and clarify the National Customs Automation Program (NCAP) test regarding Post-Summary Correction (PSC) claims to entry summaries that are filed in the Automated Commercial Environment (ACE), as well as the Periodic Monthly Statement (PMS) test. The notice liberalized and eliminated some requirements needed for the filing of PSCs; however, it also placed burdens on the importer in the form of a restriction and a prohibition.

Subsequently, CBP decided to remove the restriction imposed on all PSC filings to make payments within three business days of submitting the PSC, with the exception of entry type 03 filings, and to remove the prohibition of filing additional PSCs until additional

duties, fees and taxes are deposited. This document republishes and supersedes the document published on December 12 with these corrections and clarifications. Except to the extent expressly announced or modified by this document, all aspects, rules, terms and conditions announced in notices previous to this notice and the December 12 publication regarding the tests remain in effect.

DATES: The changes made by this notice are effective January 14, 2017.

ADDRESSES: Comments concerning these test programs may be submitted via email to Monica Crockett at *ESARinfoinbox@dhs.gov* with a subject line identifier reading, ''Post-Summary Corrections and Periodic Monthly Statements.''

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact Randy Mitchell, Director, Commercial Operations, Trade Policy and Programs, Office of Trade, at *Randy.Mitchell@cbp.dhs.gov.* For technical questions related to ABI transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Representative Branch at (703) 650–3500.

SUPPLEMENTARY INFORMATION: On December 12, 2016, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** (81 FR 89482) announcing plans to modify and clarify, effective on January 14, 2017, the National Customs Automation Program (NCAP) test regarding Post-Summary Correction (PCS) claims, and the Periodic Monthly Statement (PMS) test. The notice announced seven changes to the PSC test. Subsequently, CBP decided not to implement two of the changes. One of the changes relates to the requirement of submitting additional duties, fees and taxes within three business days of filing a PSC. This notice alleviates the requirement imposed on all PSC filings and limits the restriction of submitting payment to PSC filings declaring an increase of liability for antidumping/countervailing duties and associated fees and taxes. This notice also removes the prohibition of filing additional PSCs until the duties, fees and taxes are deposited. With this notice, CBP modifies section 3 (''Deposit of Duties, Fees and Taxes With PSC Showing Increase in Liability'') and removes section 5 (''Elimination of CBP's Policy of Rejecting a PSC When There is No Deposit of Antidumping and/or Countervailing Duties at Time of Submission of PSC'') of the published notice on December 12.

This document also provides the correct CBP point of contact for making a deposit, and clarifies the method and location of payment of additional deposits of duties, fees and taxes. In addition, this notice clarifies how CBP will determine the time of payment of duties, fees and taxes.

For ease of reference, the December 12 document is republished below with the aforementioned changes.

I. Background

Post-Summary Correction (PSC) and Periodic Monthly Statement (PMS) Test Programs

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement (NAFTA) Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE), the planned successor to the Automated Commercial System (ACS) as the CBP-authorized electronic data interchange (EDI) system. ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for CBP and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality designed to replace specific legacy ACS functions and add new functionality. Section 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)) provides for the testing of NCAP components. *See* T.D. 95–21, 60 FR 14211 (March 16, 1995). A list of ACE tests is provided in Section III below.

1. PSC Test Program

On June 24, 2011, CBP published a notice in the **Federal Register** (76 FR 37136) that announced a plan to conduct an NCAP test concerning new ACE capabilities which allow importers to file a PSC for certain entry summaries using the Automated Broker Interface (ABI). Importers and brokers are also allowed to use ABI to file a PSC to those pre-liquidation ACE entry summaries that were accepted by CBP, fully paid, and under CBP control. On November 19, 2013, CBP published a notice in the **Federal Register** modifying and clarifying the terms and conditions of the PSC test. *See* 78 FR 69434.

2. PMS Test Program

On February 4, 2004, CBP published a notice in the **Federal Register** (69 FR 5362) that announced a plan to conduct an NCAP test concerning PMS which allows importers to deposit estimated duties, fees and taxes on a monthly basis. CBP modified and clarified the PMS test in seven subsequent **Federal Register** notices published on: September 8, 2004 (69 FR 54302); February 1, 2005 (70 FR 5199); August 8, 2005 (70 FR 45736); September 22, 2005 (70 FR 55623); January 20, 2006 (71 FR 3315); June 2, 2006 (71 FR 32114); and October 17, 2008 (73 FR 61891).

II. Test Modifications and Clarifications

This document announces numerous modifications and clarifications to the PSC and PMS tests. Each modification and clarification is discussed separately below. This document supersedes the December 12 notice and, except to the extent expressly announced or modified by this document, all aspects, rules, terms, requirements, obligations and conditions announced in notices previous to this notice and the December 12 publication regarding the PSC and PMS tests remain in effect.

A. Modifications and Clarifications of the PSC Test

1. Expansion of Entry Types

This document announces that CBP is expanding the type of entries that may be corrected by filing a PSC, in addition to the current entry types 01 (Consumption—Free and Dutiable) and 03 (Consumption—Antidumping/Countervailing Duty). The additional entry types are as follows:

- 02—Consumption—Quota/Visa.
- 06—Consumption—Foreign Trade Zone (FTZ).
- 07—Consumption—Antidumping/Countervailing Duty and Quota/Visa Combination.
- 21—Warehouse.
- 22—Re-Warehouse.
- 23—Temporary Importation Bond (TIB).
- 31—Warehouse Withdrawal—Consumption.
- 32—Warehouse Withdrawal—Quota.

- 34—Warehouse Withdrawal—Antidumping/Countervailing Duty.
- 38—Warehouse Withdrawal—Antidumping/Countervailing Duty & Quota/Visa Combination.
- 51—Defense Contract Administration Service Region (DCASR).
- 52—Government—Dutiable.

2. Merchandise Subject to Quota

When filing a PSC for an entry of merchandise subject to quota, the date and time of submission will be considered the date and time of presentation of the merchandise to CBP. If a PSC is filed on an entry with merchandise subject to quota, and the quota is full or nearly full at threshold, the PSC filer must do two things. The filer must follow the Entry Summary Business Rules and Process Document on *www.CBP.gov* and also, within 24 hours of making the correction, contact Headquarters Quota Branch, either by phone: (202) 863–6560 (public phone number), or email: *HQQuota@cbp.dhs.gov,* regardless of whether the correction concerns merchandise subject to quota.

3. Deposit of Duties, Fees and Taxes With PSC Showing Increase in Liability

This document announces that when a PSC is filed declaring an increase in the importer's liability for antidumping or countervailing duties and associated fees and taxes, the importer must mail or deliver a check to the CBP port of entry with those additional antidumping or countervailing duties and associated fees and taxes within three business days of submitting the PSC. Furthermore, CBP will no longer reject a PSC declaring an increase in liability for antidumping or countervailing duties and associated fees and taxes when the additional duties, fees and taxes are not deposited at the time of submitting the PSC. This is a change in CBP policy.

If a check is mailed, CBP will consider the additional deposit made based on the date of postmark indicating the check was mailed. When a PSC is filed that results in an increase in the importer's liability for regular duties, fees and taxes and the importer wishes to deposit them, the importer must mail or deliver a check to the port of entry.

4. Change of Entry Type When Antidumping and/or Countervailing Duties Are Involved

Previously, a filer under the PSC test could not change a type 03 entry to a type 01 entry. *See* 76 FR 37136. This document announces that a PSC may declare that a previously filed entry which stated that merchandise covered by that entry was subject to antidumping and/or countervailing duties is not, in fact, subject to such duties. For instance, a PSC may declare that a previously filed 03 entry type is corrected to indicate it is a 01 entry type.

5. No Filing of PSC To Make a Post-Importation Claim under 19 U.S.C. 1520(d)

On June 24, 2011, CBP announced in the **Federal Register** (76 FR 37136) that one of the data elements that may not be modified via a PSC is the NAFTA indicator. This notice clarifies that such prohibition applies not only to a post-importation NAFTA claim under 19 U.S.C. 1520(d), but also to a claim made under other free trade agreements covered by 19 U.S.C. 1520(d).

6. PSC Submission Within the Time Limitations Authorized by This Test

On November 19, 2013, CBP published a notice in the **Federal Register** (78 FR 69434) that stated that a PSC cannot be filed when any merchandise covered by the original entry has been conditionally released and its right to admission has not been determined. This restriction was overly broad and prevented importers from filing a PSC because all goods are conditionally released and their admissibility is not legally determined until liquidation. This notice announces that this restriction does not prevent the filing of a PSC within the time periods allowed as long as all other requirements and limitations are met. The time limits authorized by this test are set forth in notices published in the **Federal Register** on June 24, 2011 (76 FR 37136) and November 19, 2013 (78 FR 69434). This clarification is in line with current practice.

B. Modification to the PMS Test

This notice announces that CBP will consider a PMS as paid, in the event the importer uses the Automated Clearing House (ACH) debit process, when CBP receives confirmation from the Treasury Department that funds are available and transferred to CBP from the financial institution designated by the importer for payment of the ACH debit authorization. Prior to this modification, CBP considered a PMS as paid when CBP transmitted the debit authorization to the designated financial institution. *See* 69 FR 5362 (February 4, 2004). This change will result in a delay of approximately two working days in the time that CBP uses to consider a PMS as paid. It is important to note that this modification applies only to importers who participate in the test program. For all other importers, the current regulation, 19 CFR 24.25(c)(4), still applies which means CBP will consider a statement as paid upon acceptance of the ACH debit authorization.

III. Development of ACE Prototypes

A chronological listing of **Federal Register** publications detailing ACE test developments is set forth below.

- ACE Portal Accounts and Subsequent Revision Notices: 67 FR 21800 (May 1, 2002); 69 FR 5360 and 69 FR 5362 (February 4, 2004); 69 FR 54302 (September 8, 2004); 70 FR 5199 (February 1, 2005).
- ACE System of Records Notice: 71 FR 3109 (January 19, 2006).
- Terms/Conditions for Access to the ACE Portal and Subsequent Revisions: 72 FR 27632 (May 16, 2007); 73 FR 38464 (July 7, 2008).
- ACE Non-Portal Accounts and Related Notice: 70 FR 61466 (October 24, 2005); 71 FR 15756 (March 29, 2006).
- ACE Entry Summary, Accounts and Revenue (ESAR I) Capabilities: 72 FR 59105 (October 18, 2007).
- ACE Entry Summary, Accounts and Revenue (ESAR II) Capabilities: 73 FR 50337 (August 26, 2008); 74 FR 9826 (March 6, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR III) Capabilities: 74 FR 69129 (December 30, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR IV) Capabilities: 76 FR 37136 (June 24, 2011).
- Post-Entry Amendment (PEA) Processing Test: 76 FR 37136 (June 24, 2011).
- ACE Announcement of a New Start Date for the National Customs Automation Program Test of Automated Manifest Capabilities for Ocean and Rail Carriers: 76 FR 42721 (July 19, 2011).
- ACE Simplified Entry: 76 FR 69755 (November 9, 2011).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS): 77 FR 20835 (April 6, 2012).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Simplified Entry: Modification of Participant Selection Criteria and Application Process: 77 FR 48527 (August 14, 2012).
- Modification of National Customs Automation Program (NCAP) Test Regarding Reconciliation for Filing Certain Post-Importation Preferential Tariff Treatment Claims under Certain FTAs: 78 FR 27984 (May 13, 2013).
- Modification of Two National Customs Automation Program (NCAP)

Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE): 78 FR 44142 (July 23, 2013).

• Modification of Two National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE); Correction: 78 FR 53466 (August 29, 2013).

• Modification of National Customs Automation Program Test Concerning Automated Commercial Environment (ACE) Cargo Release (formerly known as Simplified Entry): 78 FR 66039 (November 4, 2013).

• Post-Summary Corrections to Entry Summaries Filed in ACE Pursuant to the ESAR IV Test: Modifications and Clarifications: 78 FR 69434 (November 19, 2013).

• National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message Set Through the Automated Commercial Environment (ACE): 78 FR 75931 (December 13, 2013).

• Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Ocean and Rail Carriers: 79 FR 6210 (February 3, 2014).

• Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release to Allow Importers and Brokers to Certify From ACE Entry Summary: 79 FR 24744 (May 1, 2014).

• Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Truck Carriers: 79 FR 25142 (May 2, 2014).

• Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System: 79 FR 36083 (June 25, 2014).

• Announcement of eBond Test: 79 FR 70881 (November 28, 2014).

• eBond Test Modifications and Clarifications: Continuous Bond Executed Prior to or Outside the eBond Test May Be Converted to an eBond by the Surety and Principal, Termination of an eBond by Filing Identification Number, and Email Address Correction: 80 FR 899 (January 7, 2015).

• Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System Relating to Animal and Plant Health Inspection Service (APHIS) Document Submissions: 80 FR 5126 (January 30, 2015).

• Modification of National Customs Automation Program (NCAP) Test Concerning the use of Partner Government Agency Message Set through the Automated Commercial Environment (ACE) for the Submission of Certain Data Required by the Environmental Protection Agency (EPA): 80 FR 6098 (February 4, 2015).

• Announcement of Modification of ACE Cargo Release Test to Permit the Combined Filing of Cargo Release and Importer Security Filing (ISF) Data: 80 FR 7487 (February 10, 2015).

• Modification of NCAP Test Concerning ACE Cargo Release for Type 03 Entries and Advanced Capabilities for Truck Carriers: 80 FR 16414 (March 27, 2015).

• Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: 80 FR 39790 (July 10, 2015).

• National Customs Automation Program (NCAP) Concerning Remote Location Filing Entry Procedures in the Automated Commercial Environment (ACE) and the Use of the Document Image System for the Submission of Invoices and the Use of eBonds for the Transmission of Single Transaction Bonds: 80 FR 40079 (July 13, 2015).

• Modification of National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Partner Government Agency (PGA) Message Set Regarding Types of Transportation Modes and Certain Data Required by the National Highway Traffic Safety Administration (NHTSA): 80 FR 47938 (August 10, 2015).

• Automated Commercial Environment (ACE) Export Manifest for Vessel Cargo Test: 80 FR 50644 (August 20, 2015).

• Modification of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency Message Set through the Automated Commercial Environment (ACE): 80 FR 52051 (August 27, 2015).

• Automated Commercial Environment (ACE) Export Manifest for Rail Cargo Test: 80 FR 54305 (September 9, 2015).

• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Document Image System (DIS) Regarding Future Updates and New Method of Submission of Accepted Documents: 80 FR 62082 (October 15, 2015).

• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Cargo Release for Entry Type 52 and Certain Other Modes of Transportation: 80 FR 63576 (October 20, 2015).

• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Entry Summary, Accounts and Revenue (ESAR) Test of Automated Entry Summary Types 51 and 52 and Certain Modes of Transportation: 80 FR 63815 (October 21, 2015).

• Modification of the National Customs Automation Program Test Concerning the Automated Commercial Environment Portal Account to Establish the Exporter Portal Account: 80 FR 63817 (October 21, 2015).

• Modification of National Customs Automation Program Test Concerning the Automated Commercial Environment Partner Government Agency Message Set Regarding the Toxic Substances Control Act Certification Required by the Environmental Protection Agency: 81 FR 7133 (February 10, 2016).

• Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Certain Electronic Entry and Entry Summary Filings: 81 FR 10264 (February 29, 2016).

• Modification of the National Customs Automation Program (NCAP); Test Concerning the Partner Government Agency Message Set for Certain Data Required by the Environmental Protection Agency (EPA): 81 FR 13399 (March 14, 2016).

• Cessation of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency (PGA) Message Set Through the Automated Commercial Environment (ACE): 81 FR 18634 (March 31, 2016).

• Automated Commercial Environment (ACE); Announcement of National Customs Automation Program Test of the In-Transit Manifest Pilot Program: 81 FR 24837 (April 27, 2016).

• Announcement of National Customs Automation Program (NCAP) Test Concerning the Submission through the Automated Commercial Environment (ACE) of Certain Import

Data and Documents Required by the U.S. Fish and Wildlife Service: 81 FR 27149 (May 5, 2016).

• Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Certain Electronic Entry and Entry Summary Filings Accompanied by Food and Drug Administration (FDA) Data: 81 FR 30320 (May 16, 2016).

• Notice Announcing the Automated Commercial Environment (ACE) as the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Entry and Entry Summary Filings: 81 FR 32339 (May 23, 2016).

• Notice Announcing the Automated Commercial Environment (ACE) Protest Module as the Sole CBP-Authorized Method for Filing Electronic Protests: 81 FR 49685 (July 28, 2016).

• Modification of the National Customs Automation Program (NCAP) Test Concerning the Automated Commercial Environment (ACE) Portal Accounts to Establish the Protest Filer Account and Clarification that the Terms and Conditions for Account Access Apply to all ACE Portal Accounts: 81 FR 52453 (August 8, 2016).

• National Customs Automation Program (NCAP) Test Concerning Electronic Filing of Protests in the Automated Commercial Environment (ACE): 81 FR 53497 (August 12, 2016).

• Modification of the National Customs Automation Program (NCAP) Test Regarding Reconciliation and Transition of the Test From the Automated Commercial System to the Automated Commercial Environment (ACE): 81 FR 89486 (December 12, 2016).

• Modification and Clarification of the National Customs Automation Program (NCAP) Test Regarding Post-Summary Corrections and Periodic Monthly Statements: 81 FR 89482 (December 12, 2016).

• Effective Date for the Automated Commercial Environment (ACE) Being the Sole CBP-Authorized Electronic Data Interchange (EDI) System for Processing Electronic Drawback and Duty Deferral Entry and Entry Summary Filings: 81 FR 89486 (December 12, 2016).

Dated: January 4, 2017.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2017–00128 Filed 1–6–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2003–14610]

Revision of Agency Information Collection Activity Under OMB Review: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0027, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice soliciting comments for a 60-day period on August 16, 2016, 81 FR 54585. The collection involves applicant submission of biometric and biographic information for TSA's security threat assessment required before obtaining the hazardous materials endorsement (HME) on a commercial driver's license (CDL) issued by the States and the District of Columbia.

DATES: Send your comments by February 8, 2017. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0027.

Forms(s): TSA Form 2214; HME Threat Assessment Program (HTAP).

Affected Public: Drivers seeking a hazardous material endorsement (HME) on their commercial driver's license (CDL).

Abstract: This collection supports the implementation of sec. 1012 of the USA PATRIOT Act (Pub. L. 107–56, 115 Stat. 272, 396, Oct. 26, 2001) (49 U.S.C. 5103a), which mandates that no State or the District of Columbia may issue an HME on a CDL unless TSA has first determined the driver is not a threat to transportation security. TSA's regulations at 49 CFR part 1572 describe the procedures, standards, and eligibility criteria for security threat assessments on individuals seeking to obtain, renew, or transfer a HME on a CDL. In order to conduct the security threat assessment, States (or a TSA designated agent in States that elect to have TSA perform the collection of information) must collect information in addition to that already collected for the purpose of HME applications, which will occur once approximately every five years. The driver is required to submit an application that includes personal biographic information (for instance, height, weight, eye and hair color, date of birth); information concerning legal status, mental health defects history, and criminal history;

and biometrics such as fingerprints. In addition, 49 CFR part 1572 requires States to maintain a copy of the driver application for a period of one year.

TSA is revising the collection of information to allow for recurrent criminal history vetting. Applicants' fingerprints and associated information will be provided to the Federal Bureau of Investigation (FBI) for the purpose of comparing their fingerprints to other fingerprints in the FBI's Next Generation Identification (NGI) system or its successor systems, including civil, criminal, and latent fingerprint repositories. The FBI may retain applicants' fingerprints and associated information in NGI after the completion of their application and, while retained, their fingerprints may continue to be compared against other fingerprints submitted to or retained by NGI. TSA will also transmit applicants' biometrics for enrollment into the Department of Homeland Security Automated Biometrics Identification System (IDENT).

In addition, TSA is revising the collection of information to expand enrollment options and the potential use of biographic and biometric (*e.g.,* fingerprints, iris scans, and/or photo) information. This revision would allow for facilitation of the security threat assessment and future use of the information collected for additional comparability determinations, such as allowing the HME applicant to participate in a program such as the TSA Pre✓® Application Program, TSA's expedited screening program for air travelers, or obtain a Transportation Worker Identification Credential (TWIC) without requiring an additional background check.

TSA is currently revising its fee for the HME Threat Assessment Program as well as the fee for comparable security threat assessments in light of changes to the FBI's fingerprint processing fee and TSA's costs related to conducting the security threat assessment (STA). The FBI's fee and STA fee are two out of three segments of the HME Threat Assessment Program's overall fee. The HME fee contains segments for enrollment, the STA, and FBI fees, most recently $38.00 for vendor enrollments (amount varies by State for State enrollments), $34.00 for the STA of each applicant and $14.50 for the FBI processing each enrollment, respectively.

On February 1, 2015, the FBI reduced its fingerprint-based criminal history record check fee by $1.75 based on recommendations from a required user fee study (75 FR 18751). Effective October 1, 2016, the FBI again reduced its fingerprint-based criminal history record check fee, this time by $2.75 based on recommendations from a required user fee study (81 FR 45535). Section 1572.501(b)(3) states that if the FBI amends its fee for criminal history records checks, TSA will collect the amended FBI fee. By contrast, TSA will increase the STA segment of the standard HME fee in the amount of $3.00. TSA has identified, in accordance with the methodologies described in the 2013 final fee rule, threat assessment service costs related to the STA segment of the standard HME fee that exceed the expected STA segment revenue. The majority of these costs relate to technology infrastructure and operating costs. In addition to increased technology costs, the number of HME applicants has been in decline, leaving fewer applicants from which costs may be recovered. These two factors necessitate an increase in cost recovery in the ongoing operation of the HME program. The enrollment segment of the HME Threat Assessment Program's overall fee will remain at $38.00 for enrollments conducted by TSA's vendor. As a result of the FBI's fee decreases ($4.50 over the FBI's past two fee changes) and the increase in the STA segment of the standard HME fee ($3.00), the overall HME standard enrollment fee ($86.50) for applicants enrolled by TSA's vendor will be reduced by $1.50 to the new fee of $85.00 ($10.00 + $37.00 + $38.00), effective upon publication of TSA's Notice of Fee Adjustment. For applicants who enroll through a State in States that choose not to use TSA's enrollment vendor, the revised fees for the FBI and STA segments of the overall fee for State enrollments will be the same as for enrollments conducted by TSA's vendor ($10.00 and $37.00, respectively); however, because each State that conducts its own enrollments charges its own fee (over which TSA has no control) TSA cannot provide a revised overall enrollment fee for State enrollments.

TSA will also decrease the amount of the STA segment of the reduced HME fee by $1.00, from $29.00 to $28.00, which applies to both vendor and state enrollment methods. TSA is decreasing this segment of the reduced HME fee because TSA has identified, in accordance with the methodologies described in the 2013 final fee rule, threat assessment service revenue related to the STA segment of the reduced fee that exceeds the expected STA segment costs. Thus, the HME reduced enrollment fee ($67.00) will be reduced to the new fee of $66.00 for vendor enrollments, effective upon publication of TSA's Notice of Fee Adjustment. Again, because each state that conducts its own enrollments charges its own fee for its enrollment segment, it is not possible to give a revised overall reduced HME fee for state enrollments.

Number of Respondents: 268,295.

Estimated Annual Burden Hours: An estimated 524,746 hours annually.

Dated: January 3, 2017.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2017–00155 Filed 1–6–17; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5915–N–14]

60-Day Notice of Proposed Information Collection: Supportive Services Demonstration Resident Assessment Form

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* March 10, 2017.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email

Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Supportive Services Demonstration Resident Assessment Form.

OMB Approval Number: Pending.

Type of Request: New.

Form Number: No forms.

Description of the Need for the Information and Proposed Use: HUD assists a large vulnerable senior population in its Section 202 and other elderly-designated properties. By virtue of their advanced ages, low-incomes and other demographic characteristics, residents in these communities have complex social, health and functional situations. The quality affordable housing provided by HUD provides a fundamental base for these individuals to age safely in their community. With housing as a key social determinant of health, HUD wishes to leverage its properties as a platform for the coordination and delivery of services to better address the interdependent health and supportive service needs of its older residents. The Fiscal Year (FY) 2014 Consolidated Appropriations Act gave HUD the authority to develop a demonstration to test a model of housing and supportive services for low-income elderly residents in HUD-assisted housing. In FY 2015, HUD announced the availability of a funding opportunity under the Supportive Services Demonstration that will provide grants to property owners to participate in the demonstration. The purpose of this demonstration is to test a model of housing and supportive services with the potential to delay nursing home care for low-income elderly residents in HUD-assisted housing. HUD aims to better manage residents' health, decrease emergency room and hospital utilization, and maintain residents' independence in their homes for a longer period of time, thus delaying or preventing transfers to a higher level of care.

Conducting this research will require the Implementation Team (The Lewin Group and our partners from Leading Age and the National Center for Healthy Aging, under HUD contract HHSP23337002T) to collect self-reported information from demonstration participants. The Implementation Team will leverage existing validated tools combined together in one comprehensive Resident Needs Assessment. The Resident Needs Assessment requests information on demographics, health status and ability to complete Activities of Daily Living (ADLs), and Instrumental Activities of Daily Living (IADLs), as well as other social and medical service information.

The Resident Needs Assessment will occur face-to-face in a private setting administered by trained enhanced service coordinators or wellness nurses. The assessment interview is expected to last an average of 90 minutes.

Respondents: This information collection will affect approximately 4,000 individuals residing in units of 40 funded demonstration sites (approximately 100 residents per property; 40 properties in total). Respondents are expected to be low-income seniors who currently reside in HUD-assisted multi-family properties. All respondents will be presented with an IRB approved informed consent form prior to participation in the demonstration. In their consent, individuals agree to the collection of data about their health and wellness. Upon consent, respondents will be requested to complete a Resident Needs Assessment within 45 days of enrollment in the demonstration.

Information will be collected in a secure web-based platform that meets all required federal regulations to track general health and service use information. Information will be attributed to individuals by name. Names and information collected in a project-specific web-based platform will link to HUD's administrative data, which HUD can be linked to Medicare and possibly Medicaid data for program evaluation purposes. All collected information will be self-reported and will inform the development of individualized healthy aging plans and property-wide health education/promotion activities and programs, including selection of specific evidence-based interventions to be implemented within demonstration sites. Additionally, results will support the evaluation of the demonstration in meeting HUD's goals and desired outcomes for the national demonstration.

The table below estimates the total burden to the public for the proposed information collection, assuming an hourly cost per response, based on the income levels of respondents. Hourly costs were estimated using FY 2016 income limits from the Office of Policy Development and Research through HUD's Web site located at *https://www.huduser.gov/portal/datasets/il/il16/index.html.*

HUD tiers the income levels for funded recipients at three levels: Extremely low, very low, and low. For purposes of burden estimate, we selected the ''low income'' tier to identify a median income level.

Further delineation of the burden estimates requires income adjustments based on the number of individuals residing with the respondent. Using HUD data to conduct data analysis, we estimate that:

- 66% of potential respondents will live alone (2650 respondents)
- 17% will reside with a spouse (690 respondents)
- 8% will reside with three people (330 respondents)
- 8% will reside with four people (330 respondents)

For HUD, the baseline for median income is based on a four-person household. For FY 2016 this was adjusted at $65,800. Adjustments for number of residents are legislated by Congress.

- A single household is adjusted at 70% of income of baseline ($46,060)
- Living with spouse is adjusted at 80% of income of baseline ($52,640)
- Living in a three-person household is adjusted at 90% of income of baseline ($59,220)

These income adjustments, based on both probability of residence status as well as adjustments based on the income baseline, are used to estimate burden of information collection in the table below.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
HUD Residents living alone (single household)	2,650	3	1	1.5	3,975	$33.21	$132,009.75

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
HUD Residents living with spouse (2-person household)	690	3	1	1.5	1,035	37.97	39,298.95
HUD Residents in 3-person household	330	3	1	1.5	495	42.71	21,141.45
HUD Residents in 4-person household	330	3	1	1.5	495	47.45	23,487.75
Total	4,000				6,000		215,937.90

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: December 23, 2016.

Matthew Ammon,

General Deputy, Assistant Secretary for Policy Development and Research.

[FR Doc. 2017–00163 Filed 1–6–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R7–ES–2014–0060; FF07CAMM00 FXES11130700000]

Endangered and Threatened Wildlife and Plants; Notice of Availability of Polar Bear Conservation Management Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of our Polar Bear Conservation Management Plan (Polar Bear Plan). The polar bear is listed as threatened under the Endangered Species Act of 1973, as amended (ESA), and is also considered ''depleted'' under the Marine Mammal Protection Act of 1972, as amended (MMPA). The Polar Bear Plan identifies objective, measurable ESA recovery criteria, site-specific recovery actions, as well as time and cost estimates. It also serves as an MMPA conservation plan.

ADDRESSES: An electronic copy of the Polar Bear Plan is available for viewing at *https://ecos.fws.gov/ecp0/profile/speciesProfile?spcode=A0IJ* or at *www.regulations.gov* at Docket No. FWS–R7–ES–2014–0060. Copies of the Polar Bear Plan are also available by request from the U.S. Fish and Wildlife Service, Marine Mammals Management Office, 1011 East Tudor Road, MS–341, Anchorage, AK 99503; telephone (907) 786–3800; facsimile (907) 786–3816. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

FOR FURTHER INFORMATION CONTACT: Hilary Cooley, Polar Bear Lead, Marine Mammals Management, by telephone at 907–786–3800; by U.S. mail at Marine Mammals Management, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, AK 99503; or by email at *Hilary_Cooley@fws.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We announce the availability of our Polar Bear Conservation Management Plan (Polar Bear Plan). The polar bear (*Ursus maritimus*) is listed throughout its range as threatened under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.,* ESA). Because of its threatened status under the ESA, the species is also considered ''depleted'' under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.,* MMPA). As required under the ESA section 4(f), the Polar Bear Plan identifies ''objective, measurable'' recovery criteria and site-specific recovery actions with estimations of the time and costs to carry out those actions. The Polar Bear Plan also serves as a conservation plan under section 115(b) of the MMPA with a goal of conserving and restoring polar bears to their optimum sustainable population level, and will contribute to our international polar bear conservation efforts under the 1973 Agreement on the Conservation of Polar Bears (T.I.A.S. No. 8409).

Background

We listed the polar bear as threatened under the ESA on May 15, 2008 (73 FR 28212). For a description of the taxonomy, distribution, status, breeding biology, and habitat, and a summary of factors affecting the species, please see Appendix A of the Polar Bear Plan. Recovery of endangered or threatened animals and plants is a primary goal of our endangered species program and the ESA. To help guide the recovery effort, we prepare recovery plans for most listed species native to the United States. Further, the ESA requires that we develop recovery plans for listed species, unless such a plan would not promote the conservation of a particular species, and that we provide public notice and an opportunity for public review and comment during recovery plan development. Recovery plans describe actions considered necessary for the conservation and survival of the species, establish criteria for delisting listed species, and estimate time and cost for implementing needed recovery measures.

MMPA Conservation Plans have the purpose of conserving and restoring a species or stock to its optimum sustainable population. The MMPA further provides that Conservation Plans shall be modeled on ESA recovery plans. Therefore, the Polar Bear Plan provides recommended management actions for the survival and recovery of the species and to conserve and restore the species to its optimum sustainable population.

To invite public review and comment on the draft Polar Bear Plan, we published a notice of availability initiating a 45-day public comment period for the draft Polar Bear Plan on July 6, 2015 (80 FR 38458); we extended that comment period an additional 30 days on August 14, 2015 (80 FR 48908). The final Polar Bear Plan and the associated documents reflect the comments and recommendations the U.S. Fish and Wildlife Service received on that draft.

Polar bears evolved to utilize the Arctic sea ice niche. They are distributed throughout most ice-covered seas of the United States, Canada, the Russian Federation, Norway, and Greenland/Denmark (collectively the Range States), in the Northern Hemisphere and are managed in 19 subpopulations around the Arctic (see Figure 1 of the Polar Bear Plan). The current global polar bear population is estimated to be 22,000 to 31,000.

Ongoing and projected loss of the polar bear's crucial sea ice habitat threatens the species throughout all of its range. The projected loss of sea ice will diminish productivity, abundance, and availability of ice seals, the polar bear's primary prey base, and increase energetic requirements of polar bears for movement and obtaining food. It will also affect access to traditional denning areas. In turn, these factors will cause declines in the condition of polar bears from nutritional stress and reduced productivity. The eventual effect of this loss of sea ice is that the polar bear population will decline. The rate and magnitude of decline will vary geographically, based on differences in the rate, timing, and magnitude of impacts. However, within the foreseeable future, the worldwide population will be affected, and the species is likely to become in danger of extinction throughout all of its range (73 FR 28292–28293, May 15, 2008). Global climate change resulting from greenhouse gas emissions is the root cause of the loss of Arctic sea ice.

The Plan

The Polar Bear Plan addresses both the MMPA and the ESA, as they relate to polar bear conservation and recovery; it also reflects the input and values of stakeholders closely connected with polar bears and their habitat, including the State of Alaska, the North Slope Borough, Alaska Native peoples, the Polar Bear Range States, conservation groups, and the oil and gas industry, as well as the general public. All of these sources informed the Polar Bear Plan's fundamental goals, which focus on conservation of polar bears while recognizing values associated with subsistence take, human safety, and economic activity. The goals will be used to guide management, research, monitoring, and communication into the future. Although the fundamental goals target three geographic scales (rangewide, intermediate (ecoregion), and subpopulation (stock)), specific actions under the Polar Bear Plan pertain primarily to the polar bear subpopulations present in Alaska. The Polar Bear Plan also contains specific recovery criteria, expressed in fundamental, demographic, and threats-based terms, to determine when the polar bear should be considered for delisting under the ESA and fundamental and demographic criteria to guide conservation efforts associated with the MMPA.

Conservation and recovery actions are specified in the Polar Bear Plan. The single most important action for the recovery of polar bears is global reduction of atmospheric greenhouse gases, which, if achieved, should result in reduced global climate change, including Arctic warming and sea ice loss. Along with communicating that fact, the Polar Bear Plan identifies a suite of high-profile actions designed to ensure that polar bears remain in sufficient number and diversity so that they are in a position to recover once climate change is addressed. Those actions include the following:

- Limit global atmospheric levels of greenhouse gases to levels appropriate for supporting polar bear recovery and conservation, primarily by reducing greenhouse gas emissions;
- Support international conservation efforts through the Range States relationships;
- Manage human–bear conflicts;
- Collaboratively manage subsistence harvest;
- Protect denning habitat;
- Minimize risks of contamination from spills;
- Conduct strategic monitoring and research.

The full cost of implementing the Polar Bear Plan over the next 5 years is approximately $66,720,000.

Authority: We developed our Polar Bear Plan under the authority of ESA section 4(f), 16 U.S.C. 1533(f), as well as section 115(b) of the MMPA, 16 U.S.C. 1383b(b). We publish this notice under ESA section 4(f) (16 U.S.C. 1531 *et seq.*).

Dated: December 20, 2016.

Gregory Siekaniec,

Regional Director, Alaska Region, U.S. Fish and Wildlife Service.

[FR Doc. 2017–00127 Filed 1–6–17; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–17–001]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 18, 2017 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None
2. Minutes
3. Ratification List
4. Vote in Inv. No. 731–TA–718 (Fourth Review)(Glycine from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by January 31, 2017.
5. Vote in Inv. Nos. 731–TA–825 and 826 (Third Review)(Polyester Staple Fiber from Korea and Taiwan). The Commission is currently scheduled to complete and file its determinations and views of the Commission by January 31, 2017.
6. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.
Issued: January 4, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–00279 Filed 1–5–17; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–565 and 731–TA–1341 (Preliminary)]

Hardwood Plywood From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of hardwood plywood from China,

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

provided for in subheadings 4412.10, 4412.31, 4412.32, 4412.39, 4412.94, and 4412.99 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On November 18, 2016, the Coalition for Fair Trade of Hardwood Plywood and its individual members [2] filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV and subsidized imports of hardwood plywood from China. Accordingly, effective November 18, 2016, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–565 and antidumping duty investigation No. 731–TA–1341 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 28, 2016 (81 FR 85639). The conference was held in Washington, DC, on December 9, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on January 3, 2017. The views of the Commission are contained in USITC Publication 4661 (January 2017), entitled *Hardwood Plywood from China: Investigation Nos. 701–TA–565 and 731–TA–1341 (Preliminary).*

By order of the Commission.

Issued: January 3, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–00126 Filed 1–6–17; 8:45 am]

BILLING CODE 7020–02–P

[2] Columbia Forest Products, Greensboro, North Carolina; Commonwealth Plywood Inc., Whitehall, New York; Murphy Plywood Co., Eugene, Oregon; Roseburg Forest Products Co., Roseburg, Oregon; States Industries, Inc., Eugene, Oregon; and Timber Products Company, Springfield, Oregon.

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0018]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Federal Firearms License (ATF F 7(5310.12)/7 CR (5310.16))

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** 81 FR 57616, on August 23, 2016, allowing for a 60-day comment period. This information collection OMB 1140–0018 (Application for Federal Firearms License)—ATF Form 7 (5310.12) is being revised and combined with OMB 1140–0038 (Application for Federal Firearms License (Collector of Curios and Relics))—ATF Form 7 CR (5310.16); thereby eliminating the need for a separate application form for Type 03, Collector of Curios and Relics FFL (1140–0038). The proposed information collection is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for an additional 30 days until February 8, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Tracey Robertson, Chief, Federal Firearms Licensing Center, either by mail at 244 Needy Road, Martinsburg, WV 25405, or by email at *tracey.robertson@atf.gov.* Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Federal Firearms License.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF F 7(5310.12)/7 CR (5310.16).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households.

Abstract: The law of 18 U.S.C. Section 923(a)(1), requires a person wishing to transport, ship, or receive firearms in interstate or foreign commerce to pay a fee, to file an application and to obtain a license before engaging in business. ATF F 5310.12/7 CR 5310.16 will be for the purpose of ensuring this collection of information is necessary to insure that the person who wishes to be licensed as required by Section 923 meets the requirements of the section for the license. Additionally, this form will be used by the public when applying for a Federal firearms license to collect curios and relics to facilitate a personal collection in interstate and foreign commerce. The information requested on the form establishes eligibility for all license types.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 15,000 respondents will utilize the form, and it will take each respondent 60 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 15,000 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: January 4, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–00110 Filed 1–6–17; 8:45 am]

BILLING CODE 4410–14–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2017–020]

Records Management; General Records Schedule (GRS); GRS Transmittal 27

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of new General Records Schedule (GRS) Transmittal 27.

SUMMARY: NARA is issuing a new set of General Records Schedules (GRS) via GRS Transmittal 27. The GRS provides mandatory disposition instructions for administrative records common to several or all Federal agencies. Transmittal 27 announces changes we have made to the GRS since we published Transmittal 26 in August and September 2016. We are concurrently disseminating Transmittal 27 (the memo and the accompanying records schedules and documents) directly to each agency's records management official and have also posted it on NARA's Web site.

DATES: This transmittal is effective the date it publishes in the **Federal Register**.

ADDRESSES: You can find this transmittal on NARA's Web site at *http://www.archives.gov/records-mgmt/grs/.* You can download the complete current GRS, in PDF format, from NARA's Web site at *http://www.archives.gov/records-mgmt/grs.html.*

FOR FURTHER INFORMATION CONTACT: For more information about this notice or to obtain paper copies of the GRS, contact Kimberly Keravuori, External Policy Program Manager, at *regulation_comments@nara.gov,* or by telephone at 301.837.3151.

You may contact NARA's GRS Team with general questions about the GRS at *GRS_Team@nara.gov.* Writing and maintaining the GRS is the GRS Team's responsibility. This team is part of Records Management Services in the National Records Management Program, Office of the Chief Records Officer at NARA.

Your agency's records officer may contact the NARA appraiser or records analyst with whom your agency normally works for support in carrying out this transmittal and the revised portions of the GRS. You may access a list of the appraisal and scheduling work group and regional contacts on our Web site at *http://www.archives.gov/records-mgmt/appraisal/index.html.*

SUPPLEMENTARY INFORMATION: GRS Transmittal 27 announces changes to the General Records Schedules (GRS) made since NARA published GRS Transmittal 26 in September 2016. The GRS provide mandatory disposition instructions for records common to several or all Federal agencies. We are more than half-way through a 5-year plan to completely rewrite the GRS. With Transmittal 27, 61% of old items are now superseded.

Transmittal 27 introduces a significant change in the way we publish transmittals and indeed the entire GRS. Transmittal 26 included all current schedules: new schedules (with new-to-old crosswalks and Frequently Asked Questions [FAQs]), old schedules annotated for supersession by new schedules, and an old-to-new crosswalk for the entire old GRS. Transmittal 27 includes only schedules newly issued or updated since the last transmittal (with new-to-old crosswalks and FAQs for each).

Users may find the entire set of GRS at *http://www.archives.gov/records-mgmt/grs.html,* both individually and in a single document containing just schedules (no crosswalks or FAQs). FAQs about the whole GRS and the GRS Update Project no longer appear in new Transmittals. You can still access them at *http://www.archives.gov/records-mgmt/grs.html.*

What changes does this transmittal make to the GRS?

GRS Transmittal 27 publishes five new schedules:

GRS 2.6 Employee Training Records (DAA–GRS–2016–0014)

GRS 5.3 Continuity and Emergency Planning Records (DAA–GRS–2016–0004)

GRS 5.4 Facility, Equipment, Vehicle, Property, and Supply Records (DAA–GRS–2016- 0011)

GRS 5.5 Mail, Printing, and Telecommunication Service Management Records (DAA–GRS 2016–0012)

GRS 6.4 Public Affairs Records (DAA–GRS–2016–0005)

It also publishes new or updated items in four schedules:

GRS 1.1 Financial Management and Reporting Records (see question 3)

GRS 2.5 Employee Separation Records (see question 4)

GRS 3.1 General Technology Management Records (see question 5)

GRS 4.2 Information Access and Protection Records (see question 6)

This transmittal also updates the general FAQs on Deviations, clarifying the definition of a deviation to the GRS, and how GRS deviations differ from GRS notifications.

How has GRS 1.1 changed? How might these changes affect my agency?

We added one new item (001) to cover financial management and reporting administrative records.

How has GRS 2.5 changed?

We added two news items (050 and 051) for records created by phased retirement programs.

How has GRS 3.1 changed?

We added one new item (001) to cover technology management administrative records.

How has GRS 4.2 changed?

We added two new items. Item 001 covers administrative records on FOIA, Privacy Act, and classified documents. Item 180 covers virtual public access library records. Also, we slightly altered titles of items 060, 061, 120, and 121 from what appeared in Transmittal 26 to match the titles under which they were approved in ERA. The new titles alter neither meaning nor coverage of the items.

What GRS items does GRS Transmittal 27 rescind?

Many old GRS items are superseded by new GRS items. A few old items, however, have outlived their usefulness and cannot be crosswalked to new items. The table below lists old items newly rescinded by GRS Transmittal 27.

GRS	Item	Title	Reason
10	11a	Recordkeeping copies of maintenance manuals for unique or customized aircraft.	Only a very few agencies create these records. They relate to agencies' missions and should therefore be scheduled on an agency-specific schedule.
12	3b	Copies of incoming and original copies of outgoing messages, including Standard Form (SF) 14, Telegraphic Message maintained by communications offices or centers, and EXCLUDING the copies maintained by originating program office.	Telegram service in the United States ceased January 27, 2006. The last telegram in the world was sent in India on July 14, 2013. The very short two-month retention of these records means that none should now exist. SF 14 has been discontinued.
14	3	Press Service files	These records appear to no longer exist.
18	29a	National Defense Executive Reserve (NDER) case files on reservists.	According to FEMA, the National Defense Executive Reserve program has been dormant for the past 5 years and no agency has open programs. For this reason, FEMA suggested that we rescind these items.
18	29b	National Defense Executive Reserve case files on individuals whose applications were rejected or withdrawn.	
27	6	CIO subject and office records	CIOs are considered high-level officials under Capstone email guidance. It is therefore not appropriate to schedule these records as universally temporary.
27	7	CIO schedules of daily activities.	

Rescinded items are shown in context of their schedules in the old-to-new crosswalk.

How do I cite new GRS items?

When you send records to an FRC for storage, you should cite the records' legal authority—the ''DAA'' number—in the ''Disposition Authority'' column of the table. For informational purposes, please include schedule and item number. For example, ''DAA–GRS–2013–0001–0004 (GRS 4.3, item 020).''

Do I have to take any action to implement these GRS changes?

NARA regulations (36 CFR 1226.12(a)) require agencies to disseminate GRS changes within six months of receipt.

Per 36 CFR 1227.12(a)(1), you must follow GRS dispositions that state they must be followed without exception.

Per 36 CFR 1227.12(a)(3), if you have an existing schedule that differs from a new GRS item that does *not* require being followed without exception, and you wish to continue using your agency-specific authority rather than the GRS authority, you must notify NARA within 120 days of the date of this transmittal.

If you do not have an already existing agency-specific authority but wish to apply a retention period that differs from that specified in the GRS, you must submit a records schedule to NARA for approval via the Electronic Records Archives.

How do I get copies of the new GRS?

You can download the complete current GRS, in PDF format, from NARA's Web site at *http://www.archives.gov/records-mgmt/grs.html.*

Whom do I contact for further information?

Writing and maintaining the GRS is the responsibility of the GRS Team. You may contact the team with general questions about the GRS at *GRS_Team@nara.gov.* This team is part of Records Management Services in the National Records Management Program of the Office of the Chief Records Officer at NARA.

Your agency's records officer may contact the NARA appraiser or records analyst with whom your agency normally works for support in carrying out this transmittal. A list of the appraisal and scheduling work group and regional contacts is on the NARA Web site at *http://www.archives.gov/records-mgmt/appraisal/index.html.*

Dated: January 3, 2017.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2017–00157 Filed 1–6–17; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of Government Information Services

[NARA–2017–014]

Freedom of Information Act (FOIA) Advisory Committee; Meeting

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (5 U.S.C. App) and the second United

States Open Government National Action Plan (NAP) released on December 5, 2013, NARA announces an upcoming Freedom of Information Act (FOIA) Advisory Committee meeting.

DATES: The meeting will be on January 26, 2017, from 10:00 a.m. to 1:00 p.m. EDT. You must register for the meeting by 5:00 p.m. EDT on January 23, 2017.

Location: National Archives and Records Administration (NARA); 700 Pennsylvania Avenue NW.; William G. McGowan Theater, Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Kate Russ, Designated Federal Officer for this committee, by mail at National Archives and Records Administration; Office of Government Information Services; 8601 Adelphi Road—OGIS; College Park, MD 20740–6001, by telephone at 202–741–5770, or by email at *foia-advisory-committee@nara.gov.*

SUPPLEMENTARY INFORMATION: *Agenda and meeting materials:* You may find all meeting materials at *https://ogis.archives.gov/foia-advisory-committee/2016-2018-term/Meetings.htm.* This will be the third meeting of the second committee term. The purpose of this meeting will be to review the work of the committee's three subcommittees. *https://ogis.archives.gov/foia-advisory-committee/2016-2018-term/Subcommittees.htm.*

Procedures: The meeting is open to the public. Due to access procedures, you must register in advance if you wish to attend the meeting. You will also go through security screening when you enter the building. Registration for the meeting will go live via Eventbrite on January 3, 2017, at 10:00 a.m. EDT. To register for the meeting, please do so at this Eventbrite link: *https://www.eventbrite.com/e/freedom-of-information-act-foia-advisory-committee-meeting-january-26-2017-registration-30222704924.*

This program will be live-streamed on the US National Archives' YouTube channel, *https://www.youtube.com/user/usnationalarchives/playlists.* The webcast will include a captioning option. To request additional accommodations (*e.g.,* a transcript), email *foia-advisory-committee@nara.gov* or call 202–741–5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Kate Russ at the phone number, mailing address, or email address listed above.

Dated: December 23, 2016.

Patrice Little Murray,

Committee Management Officer.

[FR Doc. 2017–00103 Filed 1–6–17; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0001]

Sunshine Act Meeting

DATE: January 9, 16, 23, 30, February 6, 13, 2017.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of January 9, 2017

Friday, January 13, 2017

9:00 a.m. Briefing on Operator Licensing Program (Public Meeting), (Contact: Nancy Salgado: 301–415–1324).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of January 16, 2017—Tentative

There are no meetings scheduled for the week of January 16, 2017.

Week of January 23, 2017—Tentative

Monday, January 23, 2017

10:00 a.m. Discussion of Management and Personnel Issues (Closed Ex. 2 & 6).

Week of January 30, 2017—Tentative

There are no meetings scheduled for the week of January 30, 2017.

Week of February 6, 2017—Tentative

There are no meetings scheduled for the week of February 6, 2017.

February 13, 2017—Tentative

Thursday, February 16, 2017

9:00 a.m. Briefing on Lessons Learned from the Fukushima Dai-ichi Accident (Public Meeting), (Contact: Andrew Proffitt: 301–415–1418).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Friday, February 17, 2017

9:30 a.m. Briefing on Project Aim (Public Meeting) (Contact: Tammy Bloomer: 301–415–1785).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0981 or via email at *Denise.McGovern@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: January 5, 2017.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2017–00327 Filed 1–5–17; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–9092; NRC–2013–0164]

Reno Creek *In Situ* Uranium Recovery Project in Campbell County, Wyoming

AGENCY: Nuclear Regulatory Commission.

ACTION: Final supplemental environmental impact statement; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing the Final Supplemental Environmental Impact Statement (SEIS) (NUREG–1910, Supplement 6) for the Reno Creek *In Situ* Uranium Recovery (ISR) Project. By letter dated October 3, 2012, AUC LLC submitted an application to the NRC for a new source materials license for the proposed Reno Creek ISR Project proposed to be located in Campbell County, Wyoming. The SEIS is

Supplement 6 to NUREG–1910, ''Generic Environmental Impact Statement for *In-Situ* Leach Uranium Milling Facilities.''

DATES: NUREG–1910, Supplement 6, is available December 16, 2016.

ADDRESSES: Please refer to Docket ID NRC–2013–0164 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0164. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The Final SEIS (NUREG–1910, Supplement 6) is available in ADAMS under Accession No. ML16342A973.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jill Caverly, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7674; email: *Jill.Caverly@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Under the NRC's environmental protection regulations in part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), which implement the National Environmental Policy Act of 1969 (NEPA), preparation of an Environmental Impact Statement (EIS) or supplement to an EIS (SEIS) is required for issuance of a license to possess and use source material for uranium milling (see 10 CFR 51.20(b)(8)).

In May 2009, the NRC staff issued NUREG–1910, ''Generic Environmental Impact Statement for *In-Situ* Leach Uranium Milling Facilities'' (herein referred to as the GEIS). In the GEIS, the NRC assessed the potential environmental impacts from construction, operation, aquifer restoration, and decommissioning of an in situ leach uranium milling facility (also known as an ISR facility) located in four specific geographic regions of the western United States. The proposed Reno Creek ISR Project is located within the Wyoming East Uranium Milling Region identified in the GEIS. The final SEIS supplements the GEIS and incorporates by reference relevant portions from the GEIS, and uses site-specific information from AUC LLC's license application and independent sources to fulfill the requirements in 10 CFR 51.20(b)(8).

The final SEIS was prepared in response to an application submitted by AUC LLC (the applicant) by letter dated October 3, 2012. The applicant proposes the construction, operation, aquifer restoration, and decommissioning of an in situ recovery facility to recover uranium.

The final SEIS was prepared by the NRC and its contractor, the Center for Nuclear Waste Regulatory Analyses, in compliance with NEPA (as amended, and the NRC's regulations for implementing NEPA (10 CFR part 51).

The proposed Reno Creek ISR Project will be located in Campbell County between the communities of Wright, Edgerton, and Gillette and would encompass approximately 2,451 hectares (6,057 acres).

The final SEIS is being issued as part of the NRC's process to decide whether to issue a license to AUC LLC pursuant to 10 CFR part 40. In this final SEIS, the NRC staff has assessed the potential environmental impacts from the construction, operation, aquifer restoration, and decommissioning of the proposed Reno Creek ISR Project. The NRC staff assessed the impacts of the proposed action and its alternative on land use; historical and cultural resources; visual and scenic resources; climatology, meteorology and air quality; geology, minerals, and soils; water resources; ecological resources; socioeconomics; environmental justice; noise; traffic and transportation; public and occupational health and safety; and waste management. Additionally, the final SEIS analyzes and compares the benefits and costs of the proposed action. In preparing this final SEIS, the NRC staff also considered, evaluated, and addressed the public comments received on the draft SEIS published on July 7, 2016 (81 FR 44333). Appendix D of final SEIS captures the public's comments and the NRCs responses.

In doing so, the NRC staff evaluated site-specific data and information from the Reno Creek ISR Project to determine if AUC LLC's proposed activities and the site characteristics were consistent with those evaluated in the GEIS. The NRC then determined which relevant sections of, and impact conclusions in, the GEIS could be incorporated by reference. The NRC staff also determined if additional data or analysis was needed to assess the potential environmental impacts for a specific environmental resource area. The NRC documented its assessments and conclusions in the final SEIS.

In addition to the action proposed by AUC LLC, the NRC staff addressed the no-action alternative which serves as a baseline for comparison of the potential environmental impacts of the proposed action.

After weighing the impacts of the proposed action and comparing the alternative, the NRC staff, in accordance with 10 CFR 51.71(f), sets forth its recommendation regarding the proposed action. Unless safety issues mandate otherwise, the NRC staff recommends that the proposed action be approved (*i.e.,* the NRC should issue a source material license for the proposed Reno Creek ISR Project).

The final SEIS for the proposed Reno Creek ISR Project may be accessed on the internet at *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/* by selecting ''NUREG–1910'' and then ''Supplement 6,'' or on the NRC's Reno Creek ISR Project Web page at *http://www.nrc.gov/materials/uranium-recovery/license-apps/reno-creek.html.* Additionally, a copy of the final SEIS will be available at the following public libraries: Campbell County Library, 2101 S 4–J Road, Gillette, Wyoming 82718; and Campbell County Library, Wright Branch, 105 Wright Boulevard, Wright, Wyoming 82732.

Dated at Rockville, Maryland, this 29th day of December, 2016.

For the U.S. Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2017–00171 Filed 1–6–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0276]

Category 3 Source Security and Accountability

AGENCY: Nuclear Regulatory Commission.

ACTION: Source protection; public meetings and request for comment.

SUMMARY: On October 18, 2016, the U.S. Nuclear Regulatory Commission (NRC) issued a Staff Requirements Memorandum (SRM) for COMJMB–16–0001 and directed NRC staff to take specific actions to evaluate whether it is necessary to revise NRC regulations or processes governing source protection and accountability. Specifically, the Commission asked the staff to conduct an evaluation of, among other things, the pros and cons of different methods of requiring transferors of Category 3 quantities of radioactive material to verify the validity of a transferee's license prior to transfer, the pros and cons of including Category 3 sources in the National Source Tracking System (NSTS), and the risks posed by aggregation of Category 3 sources into Category 2 quantities. As part of this evaluation, the NRC is seeking input from licensees, Agreement States, and the public to inform the staff's assessment of potential revisions to regulations or processes requiring Category 3 source protection and accountability.

DATES: Submit comments by March 10, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0276. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Irene Wu, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1951; email: *Irene.Wu@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0276 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0276.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0276 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In 2007, the Government Accountability Office (GAO) conducted an investigation (GAO–07–1038T) on NRC's licensing program and was able to obtain a radioactive materials license using a fictitious company and place orders that would have resulted, if actually obtained, in receipt of an aggregated Category 3 quantity of radioactive material. After the 2007 investigation, the NRC and the Agreement States made a number of important changes to strengthen the licensing and regulatory processes to prevent malevolent individuals from obtaining a radioactive material license. The NRC staff submitted an Action Plan (SECY–07–0147) (ADAMS Accession No. ML072360206) to the Commission to respond to recommendations for addressing security issues in the National Materials Program. The Commission approved the staff's Action Plan, which included a consideration of expanding the NSTS to include Category 3 sources plus a subset of ''high-end'' Category 4 sources (SRM–SECY–07–0147) (ADAMS Accession No. ML072620088). The proposed rule on Expansion of NSTS to include additional nationally tracked sources was published in the **Federal Register** in April 2008 (73 FR 19749).

In January 2009, licensees began reporting Category 1 and 2 source information to the NSTS. The NRC staff submitted a request to the Commission to defer further expansion of the NSTS to allow staff to monitor operation of the NSTS for one year and to apply insights gained for the decision on system expansion (SECY–09–0011) (ADAMS Accession No. ML083540566). This request for deferral was not approved, so in June 2009, the staff requested approval of the final rule amending parts 20 and 32 title 10 of the *Code of Federal Regulations* (10 CFR) to expand reporting to the NSTS to include Category 3 sources (SECY–09–0086) (ADAMS Accession No. ML091390202). In June 2009, the Commission did not reach a decision on the proposed rulemaking (2–2 split vote), and the final rule was not approved (SRM–SECY–09–0086) (ADAMS Accession No. ML091811125). Some of the Commission votes indicated that further expansion of the NSTS should be based upon a vulnerability assessment, built off an interagency risk study for sources, and that the original recommendation

lacked a risk-informed foundation for proposed regulatory action.

In 2014, the GAO initiated an audit of the materials licensing program to determine whether the licensing vulnerabilities identified in their 2007 investigation had been addressed by the regulatory framework and other improvements implemented by the NRC and the Agreement States. In 2015, as part of the audit, GAO conducted an investigation that attempted to obtain radioactive materials licenses from one NRC regional office and two separate Agreement States. The investigation sought approval of licenses authorizing the procurement of one Category 3 source using a fictitious company. The 2015 investigation went beyond the 2007 investigation in its sophistication and planning, such that GAO rented storefront/warehouse space to demonstrate their legitimacy during pre-licensing visits. Despite this level of effort, the GAO was unsuccessful in two of three attempts; however, the GAO was able to acquire a license for a Category 3 well logging source in one attempt. GAO successfully placed an order for one Category 3 source using the license, then altered it and used it to place an order for a second Category 3 source. The investigation demonstrated that GAO could have acquired an aggregated Category 2 quantity of material, although at no point in the investigation were radioactive materials actually shipped to the fictitious company. Once notified of the investigation by GAO in October 2015, the NRC and Agreement States took a number of actions, one of which included forming two NRC-Agreement State working groups to evaluate vulnerabilities identified as a result of the 2015 GAO investigation. Specifically, one working group considered enhancements to the pre-licensing guidance while the second working group evaluated the need for enhancements to existing requirements or guidance for license verification and source tracking beyond Category 1 and Category 2 thresholds.

On July 15, 2016, the GAO published its final report of the material licensing audit and investigation, GAO–16–330, entitled ''Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain.'' The report made three recommendations:

1. Take steps needed to include Category 3 sources in the NSTS and add Agreement State Category 3 licenses to the Web-based Licensing System as quickly as reasonably possible.

2. At least until such time that Category 3 licenses can be verified using the License Verification System, require that transferors of Category 3 quantities of radioactive materials confirm the validity of a would-be purchaser's radioactive materials license with the appropriate regulatory authority before transferring any Category 3 quantities of licensed materials.

3. As part of the ongoing efforts of NRC working groups meeting to develop enhancements to the pre-licensing requirements for Category 3 licenses, consider requiring that an on-site security review be conducted for all unknown applicants of Category 3 licenses to verify that each applicant is prepared to implement the required security measures before taking possession of licensed radioactive materials.

Given the NRC's operating experience with higher-risk sources and in response to the findings by GAO, the Commission directed the staff to take specific actions to evaluate whether it is necessary to revise NRC regulations or processes governing source protection and accountability. Specifically, on October 18, 2016, the Commission issued its SRM for COMJMB–16–0001, ''Proposed Staff Re-Evaluation of Category 3 Source Accountability'' (ADAMS Accession No. ML16292A812). The SRM required the staff to conduct the following tasks:

1. An evaluation of the pros and cons of different methods of requiring transferors of Category 3 sources to verify the validity of a transferee's license prior to transfer;

2. An evaluation of the pros and cons of including Category 3 sources in NSTS;

3. An assessment, based on these evaluations, of these and any additional options that the staff identifies for addressing the source accountability recommendations made by the GAO;

4. A vulnerability assessment which identifies changes in the threat environment between 2009 and today that argue in favor of or against expansion of the NSTS to include Category 3 sources;

5. A regulatory impact analysis of the accrued benefit and costs of the change, to include impacts to the NRC, Agreement States, non-Agreement States, and regulated entities;

6. A discussion of potential regulatory actions that would not require changes to our regulations that arose from or were considered by the staff working groups, to include changes to guidance, training, and other program improvements such as more closely monitoring the implementation of the staff recommendations using the Integrated Materials Performance Evaluation Program process; and

7. Any other factors arising from the staff's currently ongoing assessment that the staff concludes would bear on the Commission's deliberation on the proposed change.

The SRM also directed the staff to assess the risks posed by the aggregation of Category 3 sources into Category 2 quantities and to collaborate with its Agreement State partners, non-Agreement States, regulated entities, public interest groups, industry groups, and the reactor community.

Additionally, the SRM directed the staff to consider the results of the assessment of the security requirements in 10 CFR part 37, ''Physical Protection of Category 1 and 2 Quantities of Radioactive Material,'' as required by the Energy and Water Development and Related Agencies Appropriations Bills for Fiscal Year 2015, as a means to inform the staff's evaluation. This assessment, referred to as the ''program review'' of 10 CFR part 37, encompassed an evaluation of nine review areas related to implementation of the security requirements in the rule. These areas included the results of inspections conducted of NRC licensees in the first two years of rule implementation, as well as an evaluation of events reported under the provisions of the rule. The program review also included consideration of the definition of aggregation as it applies to well logging sources and an evaluation of enhanced tracking and accounting of radioactive sources. A report detailing the program review was provided to Congress on December 14, 2016 (ADAMS Accession No. ML16348A230).

In the interest of fully informing the public of the staff's evaluation of Category 3 source security and accountability, the staff is issuing this notice to request specific feedback from stakeholders. The information received from this request will help to fully assess the regulatory impact for any recommendations related to Category 3 source security and accountability and will be documented in a paper that will be provided to the Commission in August 2017.

III. Specific Considerations

The NRC has developed specific questions that are separated into sections based on the topics and applicability to relevant stakeholders. These include: general questions related to license verification, general questions related to the NSTS, specific questions for licensees related to license verification, specific questions for licensees related to the NSTS, specific questions for Agreement States related to license verification, specific

questions for Agreement States related to the NSTS, and other questions.

The NRC is requesting comments on license verification involving transfers of Category 3 quantities of radioactive material and the inclusion of Category 3 sources in the NSTS. Please note that Table 1 of Appendix A to 10 CFR part 37 provides the thresholds for Category 1 and Category 2 quantities of radioactive material and Appendix E of 10 CFR part 20 provides the thresholds for Category 1 and 2 sources included in NSTS. The list of radionuclides subject to physical security requirements in 10 CFR part 37 is different than the list of radionuclides included in NSTS. NRC regulations do not include a definition for Category 3 but the NRC has historically considered the Category 3 threshold to be greater than 1/10th of the Category 2 threshold but less than the Category 2 threshold.

Please be cautious in providing comments that contain specific examples and do not provide any specific official-use-only, safeguards, and/or classified information related to a specific facility.

General Questions Related to License Verification

1. Should the current methods for verification of licenses prior to transferring Category 3 quantities of radioactive material listed in 10 CFR 30.41(d)(1)–(5), 10 CFR 40.51(d)(1)–(5), and 10 CFR 70.42(d)(1)–(5) be changed such that only the methods prescribed in 10 CFR 37.71 are allowed?

2. Would there be an increase in safety and/or security if the regulations were changed to only allow license verification through the NRC's License Verification System (LVS) or the transferee's license issuing authority for transfers of Category 3 quantities of radioactive material? If so, how much of an increase would there be?

3. If the NRC changed the regulations to limit license verification only through the LVS or the transferee's license issuing authority for transfers of Category 3 quantities of radioactive material, should licensees transferring Category 3 quantities to manufacturers and distributors be excepted from the limitation?

4. Is there anything else we should consider when evaluating different methods of license verification prior to transferring Category 3 quantities of radioactive material?

General Questions Related to the NSTS

1. Should Category 3 sources be included in the NSTS? Please provide a rationale for your answer.

2. If Category 3 sources are included in the NSTS, should the NRC consider imposing the same reporting requirements currently required for Category 1 and 2 sources (10 CFR 20.2207(f))?

3. Should the NRC consider alternatives to the current NSTS reporting requirements for Category 1 and 2 sources to increase the immediacy of information availability, such as requiring the source transfers to be reported prior to, or on the same day as, the source shipment date?

4. Would there be an increase in safety and/or security if the regulations were changed to include Category 3 sources in the NSTS? If so, how much of an increase would there be?

5. Is there anything else we should consider as part of our evaluation of including Category 3 sources in the NSTS?

Specific Questions for Licensees Related to License Verification

1. It currently takes approximately one month to get credentialed to access the LVS. If you currently do not have online access to LVS, and NRC establishes new requirements for license verification involving Category 3 quantities of radioactive material, would you be inclined to sign up for online access, or would you use alternative methods for license verification such as emailing the NRC Form 748 ''Manual License Verification Report'' to the LVS Help Desk or calling the license-issuing regulatory authority directly?

2. Approximately how many transfers involving Category 3 quantities of radioactive material do you do monthly? What percentage involves transfers directly to/from a manufacturer?

3. Should license verification be required when transferring to an established manufacturer?

4. Do you have online access to LVS? If so, have you experienced any issues with the LVS? Do you have any recommendations on how to improve LVS?

Specific Questions for Licensees Related to the NSTS

1. It currently takes approximately one month to get credentialed to access the NSTS. If you currently do not have online access to the NSTS and NRC establishes new requirements for the tracking of Category 3 sources in the NSTS, would you be inclined to sign up for online access or would you use alternative methods for NSTS reporting such as emailing or faxing the NRC Form 748 ''National Source Tracking Transaction Report'' to the NSTS Help Desk?

2. Do you have online access to the NSTS? If so, have you experienced any issues with the NSTS? Do you have any recommendations on how to improve the NSTS?

Specific Questions for Agreement States Related to License Verification

1. Approximately how many licenses do you authorize for Category 1, 2, and 3 quantities of radioactive material?

2. If license verification through the LVS or the transferee's license issuing authority is required for transfers involving Category 3 quantities of radioactive material, would you encourage the use of LVS among your licensees, or plan for the additional burden imposed by the manual license verification process?

3. If license verification through the LVS or the transferee's license issuing authority is required for transfers involving Category 3 quantities of radioactive material, would you consider adopting the Web-Based Licensing System (WBL) to ensure that the most up-to-date licenses are available for license verification using the LVS or voluntarily provide your Category 3 licenses (similar to what some Agreement States do now for Category 1 and 2 licenses) to be included in WBL, or would you do neither and prefer licensees to use the manual license verification process?

4. What would the impact in time and resources be on your program to handle the additional regulatory oversight needed for Category 3 licensees if license verification through the LVS or the transferee's license issuing authority was required for transfers involving Category 3 quantities of radioactive material?

Specific Question for Agreement States Related to the NSTS

1. The NRC currently administers the annual inventory reconciliation process on behalf of the Agreement States. This process involves providing hard copy inventories to every licensee that possesses nationally tracked sources at the end of the year, processing corrections to inventories, and processing confirmations of completion of the reconciliation into the NSTS. The process involves a significant amount of staff time and resources from November to February. If the Agreement States were to adopt administration of the annual inventory reconciliation process and if Category 3 sources were included in the NSTS, what would the additional regulatory burden be on the Agreement States to perform the annual inventory reconciliation for Category 1, 2, and 3 sources?

Other Questions

1. Should physical security requirements for Category 1 and 2 quantities of radioactive material be expanded to include Category 3 quantities?

2. Some Category 3 sources are covered under a general license (10 CFR 31.5). Should the NRC consider establishing maximum quantities in general licensed devices, thereby reserving authorization to possess Category 1, 2, and 3 quantities of radioactive material to specific licensees?

IV. Public Comments Process

The NRC is committed to keeping the public informed and values public involvement in its assessment effort. Responses to this solicitation will be considered by NRC in preparing a report to the Committees on Appropriations of the House of Representatives and the Senate, pursuant to Public Law 113–235, Section 403 and will inform staff consideration of the regulatory impacts for any recommendations related to Category 3 source security and accountability, which will be documented in a paper to be provided to the Commission in August 2017. The NRC, however, does not intend to provide specific responses to comments or other information submitted in response to this request.

V. Public Meetings

The NRC plans to hold three public meetings and two webinars during the public comment period for this action. The first public meeting is scheduled for January 31, 2017, at NRC Headquarters. The two other public meetings will be held outside of the Washington DC area. The webinars are scheduled for February 21, 2017 and March 2, 2017. The public meetings and webinars will provide forums for the NRC staff to discuss the issues and questions with members of the public. The information received will be used by NRC to develop a report to the Commission. The NRC does not intend to provide any responses to comments submitted during the public meetings and webinars. Each public meeting and webinar will be noticed on the NRC's public meeting Web site at least 10 calendar days before the meeting. Members of the public should monitor the NRC's public meeting Web site for additional information about the public meetings at *http://www.nrc.gov/public-involve/public-meetings/index.cfm.* The NRC will post the notices for the public meetings and webinars and may post additional material related to this action to the Federal Rulemaking Web site at *www.regulations.gov* under Docket ID NRC–2016–0276. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2016–0276); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

Dated at Rockville, Maryland, this 30th day of December 2016.

For the Nuclear Regulatory Commission.

Pamela J. Henderson,

Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2017–00169 Filed 1–6–17; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[NRC–2012–0235]

Tribal Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing this Statement of Policy to set forth principles to be followed by the NRC staff to promote effective government-to-government interactions with American Indian and Alaska Native Tribes, and to encourage and facilitate Tribal involvement in the areas over which the Commission has jurisdiction. It provides agencywide guidelines that achieve consistency, but also encourage custom-tailored approaches to consultation and coordination that reflect the circumstances of each situation and the preference of each Tribal government. It is the NRC's expectation that all program and regional office consultation and coordination practices will be consistent with or adhere to the NRC Tribal Policy Statement.

DATES: This policy statement is effective on January 9, 2017.

ADDRESSES: Please refer to Docket ID NRC–2012–0235 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0235. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The Tribal Policy Statement, in its entirety, is in the attachment to this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Kevin O'Sullivan, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8112, email: *Tribal_Outreach.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion
III. Opportunity for Public Participation
IV. Procedural Requirements

I. Background

The purpose of the NRC Tribal Policy Statement is to establish policy principles to be followed by the NRC to promote effective government-to-government interactions with Indian Tribes, and to encourage and facilitate Tribal involvement in the areas over which the Commission has jurisdiction. The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, common defense and security, and the environment under the Atomic Energy Act of 1954, as amended (AEA) (42 U.S.C. 2011). Other statutory provisions such as the National Historic Preservation Act (NHPA) (54 U.S.C. 300101) can require Tribal consultation as part of the NRC's evaluation of agency activities during licensing actions, rulemaking, or policy development. The NRC complies with statutory provisions and NRC regulatory

provisions that require Tribal consultation and interacts with Tribal governments accordingly.

A. NRC Previous Interactions with Indian Tribes

Historically, the NRC has had limited, but significant, interactions with Indian Tribes. The Commission has upheld statutory obligations to consult with Tribes under Federal law and acted in a manner consistent with the spirit of certain Presidential initiatives pertaining to Tribal consultation and coordination. However, the NRC has not previously formalized an agencywide policy statement.

Many Federally recognized Tribes have an interest in public health and safety and environmental protection associated with NRC regulatory activities that include uranium recovery, commercial nuclear power, and nuclear waste transportation, disposal, and storage activities. The NRC has exercised its Trust Responsibility in the context of its authorizing statutes, including the AEA. The NRC Tribal Policy Statement formally reflects the NRC's recognition of the Federal Trust Responsibility and the NRC's commitment to a government-to-government relationship, which is distinct from interactions with members of the public, with Federally recognized Tribes. The NRC will make efforts to consult in good faith with Indian Tribes on agency actions that have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is required under Federal Statute. Under the NRC's policy, the NRC or Tribal governments can request consultation on regulatory activities that have Tribal implications. The NRC's policy is to consult on a government-to-government basis with Tribal governments as soon as practicable on NRC regulatory actions with Tribal implications.

On November 6, 2000, President Clinton issued Executive Order (EO) 13175, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249). Executive Order 13175 states, "'Policies that have Tribal implications' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.'' Executive Order 13175, established the following principles to guide agencies when forming and implementing policies with potential Tribal implications:

- The United States has a unique legal relationship with Indian Tribal governments as set forth in the Constitution of the United States, treaties, statutes, EOs, and court decisions. The Federal government recognizes Indian Tribes as domestic dependent nations under its protection and has enacted statutes and promulgated regulations that establish and define a trust relationship with Indian Tribes.
- The Federal government has recognized the right of Indian Tribes to self-government with inherent sovereign powers over their members and territory. The United States continues to work with Indian Tribes on a government-to-government basis to address issues concerning Tribal self-government, Tribal trust resources, and Indian Tribal treaty and other rights.
- The United States recognizes the right of Indian Tribes to self-government and supports Tribal sovereignty and self-determination.

As an independent regulatory agency, the NRC is exempt from the requirements of certain EOs, including EO 13175. However, on January 26, 2001, the Commission sent correspondence to the Office of Management and Budget stating that ''. . . in exercising its regulatory authority this agency [NRC] acts in a manner consistent with the fundamental precepts expressed in the Order [EO 13175]'' (ADAMS Accession No. ML010260297). To that end, the Commission has developed agency practices for Tribal consultation consistent with the principles articulated in EO 13175.

The NRC's past practice for government-to-government interaction with Federally recognized Tribes has reflected the spirit of the relevant EOs, without establishing a formal policy. The NRC has interacted with Tribal governments on a case-by-case basis, allowing the NRC and the Tribes to initiate communication and consultation. The NRC staff has also maintained working relationships with Tribal governments and Tribal organizations that have an interest in NRC regulated activities.

B. Development of the Draft Tribal Policy Statement

In SECY–96–187, ''Policy Issues Raised in Meeting with Prairie Island Dakota Indian Representatives'' (ADAMS Accession No. ML16293A128), the NRC staff provided to the Commission an analysis of Tribal issues. The paper centered on issues raised by representatives from the Prairie Island Dakota Indian Community including: (1) Entering into a Memorandum of Understanding with the NRC; 2) allowing Tribal representatives to observe inspections at the Prairie Island Nuclear Generating Plant; and 3) developing a formal policy on cooperation with Federally recognized Tribes. In the Staff Requirements Memorandum (SRM) dated November 13, 1996, the Commission approved the staff's recommendation not to develop a formal policy on cooperation with Federally recognized Tribal governments at that time, but to continue addressing Native American issues on a case-by-case basis and operating with Tribal governments on a government-to-government basis (ADAMS Accession No. ML16293A154).

On January 8, 2009, the Commission issued SRM–M081211, from the December 11, 2008, ''Briefing on Uranium Recovery,'' directing the NRC staff to develop and implement an internal protocol for interaction with Native American Tribal Governments that would allow for custom tailored approaches to address both the NRC and Tribal interests on a case-by-case basis (ADAMS Accession No. ML090080206). The Commission also directed the NRC staff to assess what policies other Federal agencies have for interactions with Native American Tribal Governments and to report those findings, which could determine the efficacy of an NRC Tribal Policy Statement, to the Commission. The NRC staff responded to this Commission direction in SECY–09–0180, ''U.S. Nuclear Regulatory Commission Interaction with Native American Tribes'' (ADAMS Accession No. ML092920384). The staff communicated the determination that the NRC's case-by-case approach to interaction was effective and met the needs of the Commission and the Tribes. The staff concluded that Tribal interactions would not benefit from a formal Tribal policy at that time. The NRC staff also developed NUREG–2173, ''NRC Tribal Protocol Manual: Guidance for NRC Employees,'' as an internal protocol for interacting with Tribal governments (ADAMS Accession No. ML092990559).

On May 22, 2012, the Commission issued the SRM for COMWDM–12–0001, ''Tribal Consultation Policy Statement and Protocol'' (ADAMS Accession No. ML121430233), directing the NRC staff to provide a proposed Policy Statement and protocol on consultation with Tribal governments. The Commission also directed the NRC staff to do the following when developing the proposed policy

statement: (1) Use the existing ''Tribal Protocol Manual: Guidance for NRC Employees,'' and the NRC staff's ongoing efforts outlined in SECY–09–0180 as a starting point and the basis for developing the proposed policy statement and protocol; (2) seek input from the Tribes and the public on how to improve the existing manual; (3) clearly articulate in the policy statement and protocol that the NRC's actions must be in accordance with its governing statutes and regulations; (4) respect and reflect in the policy statement and protocol sensitivity to the distinction made in executive orders and statutes between Indian Tribes who are Federally recognized and those who are not; (5) indicate in the policy statement and protocol that the NRC will conduct outreach to State-recognized Tribes on a case-by-case basis; (6) explore additional opportunities within our current regulatory processes for information sharing and outreach to State-recognized Tribes; and (7) make the protocol prominently publicly available on the NRC's public Web site. The Commission also specified that the proposed policy statement should serve as a high-level foundation for the protocol and should echo the language and spirit of the relevant Presidential Memoranda and EOs.

The NRC staff formed an agency working group to develop a proposed NRC Tribal Policy Statement and to revise the NRC Tribal Protocol Manual. On October 12, 2012 (77 FR 62269), the NRC requested public comment on the NRC Tribal Protocol Manual and requested suggestions for the development of a proposed NRC Tribal Policy Statement to establish policy principles to be followed by the NRC to promote effective government-to-government interactions with Indian Tribes, and to encourage and facilitate involvement by Indian Tribes in the areas over which the Commission has jurisdiction. The public comment period was open for 180 days, and the NRC received a total of six comment letters from two Tribal governments, two mining associations, one inter-Tribal organization, and a Tribal college.

Informed by internal working group representatives, external outreach, and review of similar policies at other Federal agencies, the NRC developed the proposed NRC Tribal Policy Statement. The NRC engaged with Tribal governments and other interested parties by: (1) Collaborating with the National Congress of American Indians to conduct mass mailings to Federally recognized Tribes; and (2) participating in Tribal meetings hosted by Tribal organizations and other Federal agencies (these meetings included attendees from Federally recognized and State-recognized Tribes). Additionally, the NRC staff reviewed Tribal policy statements of executive departments, their related agencies, and other independent agencies and provided their findings to the Commission.

The proposed NRC Tribal Policy Statement was consistent with the language of EO 13175 and was intended to cover a broad range of Tribal consultations, outreach, and interactions conducted by NRC staff. The proposed NRC Tribal Policy Statement applied to Federally recognized Indian Tribes as defined by the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 479a). It also encouraged participation by State-recognized Tribes in the NRC's regulatory process. On December 1, 2014, the NRC published the proposed NRC Tribal Policy Statement in the **Federal Register** for public comment (79 FR 71136). (See Section III, ''Opportunity for Public Participation,'' of this document for additional information.)

C. Development of the Final NRC Tribal Policy Statement

After the December 2014 publication of the proposed NRC Tribal Policy Statement in the **Federal Register**, the NRC staff engaged in internal and external collaboration and outreach to inform the final NRC Tribal Policy Statement. The NRC staff also sought comments on the final NRC Tribal Policy Statement through participation in external conferences and presentations, periodic telephone calls, teleconferences, and webinars. The NRC staff continued to participate in standing Tribal meetings hosted by Federal partners and Tribal organizations and initiated additional outreach to Tribal leadership through various regional or affiliated Tribal leadership councils. A list of all outreach efforts can be found in NRC Tribal Liaison Annual Report Fiscal Year 2015 (ADAMS Accession No. ML15247A011).

The final NRC Tribal Policy Statement reflects responses to both internal and external comments. The final NRC Tribal Policy Statement applies to all NRC staff and activities within the NRC's regulatory jurisdiction. The NRC Tribal Policy Statement is written at a high level to cover a wide variety of interactions, consultation, and outreach to Indian Tribes, including Federally recognized American Indian and Alaska Native Tribes.

II. Discussion

Within the context of this discussion, the following definitions will apply unless otherwise indicated:

Consultation means efforts to conduct meaningful and timely discussions between the NRC and Tribal governments on the NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes and those regulatory actions for which Tribal consultation is required under Federal statute. The NRC's Tribal consultation allows Indian Tribes the opportunity to provide input on regulatory actions with Tribal implications and those where Tribal consultation is required, and is different from the outreach and public comment periods. The consultation process may include, but is not limited to, providing for mutually-agreed protocols, timely communication, coordination, cooperation, and collaboration. The consultation process provides opportunities for appropriate Tribal officials or representatives to meet with NRC management or staff to achieve a mutual understanding between the NRC and the Tribes of their respective interests and perspectives.

Indian Tribe means any American Indian or Alaska Native Tribe, Band, Nation, Pueblo, or other organized group or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 479a).

Interaction means reciprocal actions involving the NRC and Indian Tribes, and may include, but is not limited to, outreach, consultation, coordination, training, and information exchanges. Interactions may be oral or written and can take place remotely (through electronic media) or in face-to-face meetings.

Outreach means NRC staff efforts to inform Indian Tribes about the agency's actions and plans. Outreach includes sharing information and encouraging Tribal governments to communicate their concerns and interests to NRC staff.

Regulatory Actions with Tribal Implications refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Tribal Official means an elected, appointed, or designated official or

employee of an Indian Tribe or authorized intertribal organization.

Trust Responsibility means a fiduciary duty, on the part of the United States, to protect Tribal treaty rights, lands, assets, and resources, as well as a duty to carry out the mandates of Federal law with respect to Indian Tribes. The NRC exercises its Trust Responsibility in the context of its authorizing statutes, which include the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets, or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities.

III. Opportunity for Public Comment

On December 1, 2014 (79 FR 71136), the NRC published a **Federal Register** notice requesting public comments on the proposed NRC Tribal Policy Statement. The original 120-day comment period was extended to 180 days (ending on May 31, 2015) through an additional **Federal Register** notice that was published on February 5, 2015 (80 FR 6553).

A. Overview of Public Comments

The NRC received nine comment submissions, including comments from two representatives from Federally recognized Tribes, two representatives from inter-Tribal organizations, a Federal agency, an electric utility company, and three individuals who did not provide an organizational affiliation.

Comments and responses related to the proposed NRC Tribal Policy Statement are listed in this section, and comments are quoted directly from comment submissions. The NRC Tribal Protocol Manual was published concurrently with the proposed Policy Statement in the **Federal Register** for public comment; comments and related responses will be published separately, with the exception of overlapping comments that cover both the NRC Tribal Policy Statement and the NRC Tribal Protocol Manual.

The following table lists the commenter's name and affiliation, ADAMS accession number for the comment submission, and the document related to each comment.

Commenter Name	Affiliation	Comment Submission ADAMS Accession No.	Document
Charlene Dwin Vaughn	Advisory Council on Historic Preservation (ACHP).	ML15154A842	Proposed Tribal Policy Statement
R. Budd Haemer	Indiana Michigan Power	ML15155A564	Proposed Tribal Policy Statement and Tribal Protocol Manual
Richard Arnold	National Transportation Stakeholders Forum Tribal Caucus.	ML15175A161	Proposed Tribal Policy Statement
Bill Thompson	National Tribal Air Association	ML15124A013	Proposed Tribal Policy Statement
Philip R. Mahowald	Prairie Island Indian Community	ML15159A181	Proposed Tribal Policy Statement and Tribal Protocol Manual
Heather Westra	Prairie Island Indian Community	ML15065A219	Proposed Tribal Policy Statement
Cassandra Bloedel	Private Citizen	ML15159A179	Proposed Tribal Policy Statement
Doreen Dupont	Private Citizen	ML15159A180	Proposed Tribal Policy Statement
Savannah Halleaux	Private Citizen	ML14345A750	Proposed Tribal Policy Statement

B. Public Comment Analysis

The NRC has reviewed every comment submission and has identified 42 unique comments requiring NRC consideration and response. Comments and the NRC responses are presented in this section. The comments generally fell within the following categories: NRC's Trust Responsibility as a Federal agency; suggested changes to the language of the NRC Tribal Policy Statement; NRC's Tribal outreach and consultation; and NRC's government-to-government relationship with Tribes. Commenters provided additional comments that did not fall within those categories as well as comments that were out of scope of the NRC Tribal Policy Statement; these comments have been included at the end of this section, along with NRC responses.

1. NRC's Trust Responsibility as a Federal Agency

Multiple commenters provided input related to the NRC's Trust Responsibility to Federally recognized Tribes as a Federal agency.

Comment 1.1. ''Politics should not come into play in the Trust Relationship. The Trust Relationship requires more in terms of interactions access, and voice.''

Response 1.1. The NRC agrees with this comment. The NRC upholds its Trust Relationship with Federally recognized Tribes without consideration of politics. In achieving its mission, the NRC adheres to the principles of good regulation—independence, openness, efficiency, clarity, and reliability. The NRC seeks to use the highest possible standards of ethical performance and professionalism with regard to regulatory activities. Tribal governments and others are encouraged to participate in the regulatory process to provide relevant facts and opinions pertaining to an action. The NRC considers many, and possibly conflicting public interests, when making decisions that are based on objective, unbiased assessments of all information, and must be documented with reasons explicitly stated.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 1.2. ''It is inconsistent to say that the Trust Responsibility is met simply by meeting standards for the general public. Need to recognize the uniqueness of Tribes and the Trust Relationship. Trust relationship requires more than simply meeting what is required.''

Response 1.2. The NRC agrees with this comment. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility under its authorizing statutes including the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy

Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities. The NRC Tribal Policy Statement formally reflects the NRC's recognition of the Federal Trust Responsibility and the NRC's commitment to a government-to-government relationship with Federally recognized Tribes that is distinct from interactions with members of the public. The NRC will consult in good faith with Indian Tribes on agency actions that have substantial direct effects on one or more Indian Tribes as well as those agency actions for which Tribal consultation is required under Federal Statute.

The NRC Tribal Policy Statement has been revised to reflect the comment, in part.

Comment 1.3. ''NRC has not historically met its Trust Responsibilities. Tribal Advance Notification Rule and the requirement for tribes to 'opt-in' is inconsistent with the Tribal Policy Statement. States do not have to opt-in, while Tribes have to. Tribes should be given the opportunity to 'opt-out.'''

Response 1.3. The NRC disagrees with the comment that the NRC has not historically met its Trust Responsibility. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal Government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility under its authorizing statutes including the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities. The NRC Tribal Policy Statement formally reflects the NRC's recognition of the Federal Trust Responsibility and the NRC's commitment to a government-to-government relationship with Federally recognized Tribes that is distinct from interactions with members of the public. In addition to affording Tribal members protections under its implementing regulations, the NRC will consult in good faith with Indian Tribes on agency actions that have substantial direct effects on one or more Indian Tribes as well as those agency actions for which Tribal consultation is required under Federal statute.

While the comment related to the Tribal Advance Notification Rule is out of scope of the NRC Tribal Policy Statement, the NRC believes the Tribal Advance Notification Rule is consistent with the NRC Tribal Policy Statement because it requires Tribal governments to opt-in to participate in the advanced notification program. The Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste (Tribal Advance Notification Rule) amends NRC rules to require licensees to provide advance notification to participating Federally recognized Tribal governments regarding shipments of irradiated reactor fuel and certain types of nuclear waste for any shipment that passes within or across their reservations (77 FR 34194). After reviewing public comments received during the development of the Tribal Advance Notification Rule, the NRC staff concluded that Tribes should have the option of whether to opt into the program because the program requires training, certain equipment, and has civil and criminal penalties for non-compliance.

The NRC Tribal Policy Statement has been revised to reflect the comment, in part.

Comment 1.4. ''The ACHP [Advisory Council on Historic Preservation] recommends expanding the discussion on trust responsibility [related to policy principle 2 on Trust Responsibility] and including an acknowledgement of trust responsibility. For more information about trust responsibility, please reference the Bureau of Indian Affairs [BIA] definition of trust responsibility (*http://www.bia.gov/FAQs/*).''

Response 1.4. The NRC agrees with this comment. In comparison with the BIA, the NRC is an independent regulatory agency and does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal Government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility in the context of its authorizing statutes including the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities. The NRC Tribal Policy Statement formally recognizes the unique relationship between the Federal Government and Indian Tribes and describes NRC's continuing commitment to a government-to-government relationship with Tribal governments that is distinct from the interactions that the agency has with members of the public. The discussion section of Policy Principle 1 has been revised to provide further clarification and acknowledgment of the NRC's Trust Responsibility.

The NRC Tribal Policy Statement has been revised to reflect the comment.

Comment 1.5. ''To Indian tribes, upholding a Trust relationship with Indian tribes means more to Indian tribes than just ensuring the tribal members receive the same protections that are available to other persons (*i.e.,* the general public). In our view, the NRC is required to do more, not less.

''The 'trust responsibility' that the federal government owes to Indian tribes imposes both substantive and procedural duties on the federal government.''

Response 1.5. The NRC agrees with the comment. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal Government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility under its authorizing statutes including the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy

Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities. The NRC Tribal Policy Statement formally reflects the NRC's recognition of the Federal Trust Responsibility and the NRC's commitment to a government-to-government relationship with Federally recognized Tribes that is distinct from interactions with members of the public.

Other procedural components for carrying out interactions with Tribal governments are articulated in the Tribal Protocol Manual and specific agency regulations and guidance documents.

The NRC Tribal Policy Statement has been revised to reflect the comment.

Comment 1.6. ''PIIC [Prairie Island Indian Community] believes that the trust responsibility must mean more than solely complying with existing statutes and regulations. Compliance of this type is no different than what is owed to the general public. In order for the trust responsibility to have any vitality, Federal agencies must exercise a higher responsibility when taking action that may affect a tribe. This is especially true when the issues concern lands held in trust by the United States for a tribe and the tribal cultural and historic resources and a tribe's ancestral homeland.''

Response 1.6. The NRC agrees with this comment. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal Government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility under its authorizing statutes including the AEA, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities. The NRC Tribal Policy Statement formally reflects the NRC's recognition of the NRC's commitment to a government-to-government relationship with Federally recognized Tribes with respect to agency actions that have a substantial direct effect on one or more Indian Tribes that is distinct from interactions with members of the public. The NRC also upholds the statutory obligation to consult with Federally recognized Tribes under Section 106 of the NHPA, which is intended to protect historic properties that may be affected by a Federal undertaking. The NHPA requirement to engage in Tribal consultation applies regardless of the location of the historic property and can include Tribal ancestral lands that are not part of the Tribe's current reservation or trust lands.

The NRC Tribal Policy Statement has been revised to reflect the comment.

2. Suggested changes to the language of the NRC Tribal Policy Statement

Multiple commenters proposed changes to the language of the NRC Tribal Policy Statement or to the discussion section that defines terms utilized throughout the NRC Tribal Policy Statement.

Comment 2.1. ''While the 6 principles [of the NRC Tribal Policy Statement] originally proposed serve as foundation of which to build upon, the [U.S. Department of Energy] DOE National Transportation Stakeholders Forum Tribal Caucus believes the proposed principles should be expanded to include an additional Principle Policy Statement #7. Specifically, it is recommended that the existing policy statement include:

PRINCIPLE POLICY STATEMENT #7

7. *NRC is committed to collaborating with tribes in regulatory activities that may have the potential of affecting tribal interests.*''

Response 2.1. The NRC disagrees with this comment. The NRC Tribal Policy Statement is consistent with EO 13175, which states ''Policies that have tribal implications refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.'' The suggested language could be interpreted to require the NRC to seek consultation and collaboration on all of NRC's activities because they have the potential to impact Tribal members even if the activity has no greater potential effect on Tribal members than the general public. For example, health and safety regulations relating to well-logging or medical use of byproduct material could fall under this definition. Therefore, the NRC limited the obligation for the NRC to specifically seek Tribal consultation to activities defined in EO 13175 and those for which Tribal consultation is required under Federal statute. However, Tribes can always request consultation with the NRC regarding ''regulatory activities that may have the potential of affecting Tribal interests.'' The NRC would evaluate such requests on a case-by-case basis.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 2.2. [The commenter suggested including the underlined text in the discussion of policy principle 1.] ''The NRC shall respect Indian Tribal self-government and sovereignty, will honor Tribal *treaty and other* rights, and meet responsibilities that arise from the unique relationship between the Federal government and Indian Tribal governments. *Further, the NRC shall encourage states to recognize the Federal government's trust relationship with Tribes and incorporate this recognition in their own practices.*''

Response 2.2. The NRC disagrees with this comment. Our understanding of the phrase ''Tribal rights'' would also cover ''tribal treaty and other rights,'' so the change is unnecessary.

Section 274b. of the AEA authorizes the NRC to enter into agreements with States so that the NRC relinquishes, and the State assumes, regulatory authority over the radioactive material and activities specified in the agreement. The NRC approves the agreement if the NRC finds the State program adequate to protect public health and safety and compatible with the NRC's regulatory program. The NRC periodically reviews the State's program, but the NRC does not mandate to the State how they should interact with Tribal governments when implementing these regulatory requirements and the States apply their own laws to implement their radiation control program for the specified AEA radioactive materials covered in the Agreement.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 2.3. [The commenter suggested including the underlined text in the discussion of policy principle 2, ''The NRC Recognizes and Is Committed to a Government-to-Government Relationship With Indian Tribes.''] ''The NRC recognizes the right of each Indian Tribe to self-governance and supports Tribal sovereignty and self-determination. The NRC recognizes Tribal governments as dependent domestic sovereign nations, independent from State governments, with separate and distinct authorities *with inherent sovereign powers over their members and territory.*''

Response 2.3. The NRC agrees with this comment. The second sentence of the discussion related to Policy Principle 2 now reads, ''The NRC recognizes Tribal governments as dependent domestic sovereign nations, independent from State governments, with separate and distinct authorities with inherent sovereign powers over their members and territory, consistent with applicable statutes and authorities.''

The NRC Tribal Policy Statement has been revised to reflect the comment.

Comment 2.4. [The Commenter suggested including the underlined text in the discussion of policy principle 4, ''The NRC Will Engage in Timely Consultation.''] ''The NRC will provide timely notice to, and consult with, Tribal governments on NRC's regulatory *and non-regulatory* actions that have substantial direct effects on one or more Indian Tribes. Tribal officials may request that the NRC engage in government-to-government consultation with them on matters that have not been identified by the NRC to have substantial direct effects on one or more Indian Tribes. The NRC will make efforts to honor such requests, taking into consideration the nature of the activity at issue, past consultation efforts, available resources, timing issues, and other relevant factors. The NRC will establish early communication and begin consultation at the earliest permissible stage, as appropriate. The NRC will consult in good faith throughout the agency decisionmaking process and develop and maintain *regular and meaningful* effective communication, coordination, and cooperation with Indian Tribes. The NRC representatives for consultations with Tribal officials or representatives will be of an appropriate rank of NRC representatives and level of interaction commensurate with the circumstances *and who shall have decision-making power.* The appropriate level of interaction will be determined by past and current practices, continuing dialogue between NRC and Tribal governments, and program office consultation procedures.''

Response 2.4. The NRC agrees in part and disagrees in part with this comment. The term ''regulatory action'' is used to reflect the scope of the NRC's mission as a regulatory agency, and no change has been made to the existing text. ''Effective communication'' already reflects that communication should be ongoing during the consultation process. The text has been revised to reflect that ''The NRC representatives for consultations with Tribal officials or representatives will be of an appropriate rank and the level of interaction will be commensurate with the circumstances. The appropriate level of interaction will be determined by a discussion between the NRC and Tribal governments, and program office consultation procedures and guidance. Participating Tribal and NRC representatives will serve as respective decisionmakers, based on the established agenda and to the extent possible.''

The NRC Tribal Policy Statement has been revised to reflect the comment.

Comment 2.5. [The commenter suggested including the underlined text in the discussion of Policy Principle 5, ''The NRC Will Coordinate with Other Federal Agencies.''] ''The NRC Will Coordinate With Other Federal Agencies *and States.* When the Commission's action involves other Federal agencies *and States,* the NRC will perform its Tribal consultation jointly with other Federal agencies *and States,* as appropriate.''

Response 2.5. The NRC agrees in part and disagrees in part with this comment. The NRC coordinates with other Federal agencies and with States, as appropriate, during consultations. For example, when following the regulatory procedures related to the NHPA and National Environmental Policy Act (NEPA) the NRC coordinates with the State by communicating with the State Historic Preservation Officer, who is included as a consulting party under the NHPA, or the State agency regarding State listed species of concern for environmental impact determinations on specific resource areas. The NRC disagrees that Policy Principle 5 should be revised to include States since the Principle is limited to Federal coordination.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 2.6. ''The ACHP recommends defining *interactions* and using *interactions* consistently throughout the document. In certain cases, *interactions* could be confused with more formal government to government consultations.''

Response 2.6. The NRC agrees with this comment. The definition of interaction has been included in the discussion section of the policy statement to identify activities covered by the term ''interaction.''

The discussion section related to the NRC Tribal Policy Statement has been revised as a result of the comment.

Comment 2.7. ''The ACHP recommends defining *substantial direct effects* in order to provide clarity to the NRC's practices addressing Executive Order 13175.''

Response 2.7. The NRC disagrees with this comment. The use of ''substantial direct effects'' is consistent with the language used in EO 13175, which also does not define the term. Since the Tribal Policy Statement covers a vast range of regulatory activities, the NRC has not defined ''substantial direct effects'' in the NRC Tribal Policy Statement. The NRC will consider including criteria in future guidance documents to determine whether an activity has a ''substantial direct effect'' on one or more Indian Tribes.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 2.8. ''The ACHP recommends specifying *outreach* should be done in addition to formal government to government consultation with Native Americans tribes and/or Native Hawaiian Organizations. Also, the NRC should include a definition for *outreach.* Outreach and consultation should be discussed as two separate activities conducted by the NRC.''

Response 2.8. The NRC agrees in part and disagrees in part with this comment. The NRC agrees that outreach is distinct from government-to-government consultation. The NRC Tribal Policy Statement reflects the distinction between outreach and consultation by putting forth two separate and distinct policy principles related to outreach and consultation. In an effort to provide clarification regarding the distinction between outreach and consultation, Policy Principle 3 has been revised.

The NRC agrees that a definition of *outreach* should be included in the Discussion Section in an effort to provide further clarification The purpose of NRC's Tribal outreach can be broad, ranging from participation in standing Tribal meetings hosted by Federal partners and Tribal organizations, to conducting informational meetings related to a licensing project or rulemaking, to an informational webinar. The NRC Tribal

liaison team continues to seek new opportunities to engage Tribal representatives.

The NRC disagrees that the NRC Tribal Policy Statement's discussion of outreach should include Native Hawaiian Organizations. The Tribal Policy Statement pertains to consultation with Tribal Governments recognized by the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a. (See response to Comment 4.1 for additional information regarding the Native Hawaiian Organizations.)

The NRC Tribal Policy Statement has been revised as a result of the comment.

Comment 2.9. ''The ACHP recommends stating [in the discussion of policy principle 4, ''The NRC Will Engage in Timely Consultation''] that it is the federal agency's responsibility to engage in consultation. It is not the tribe's responsibility to request engagement in consultation.''

Response 2.9. The NRC agrees in part and disagrees in part with this comment. The NRC agrees that it is its responsibility to initiate consultation when Tribal consultation is required under Federal statute. The discussion of Policy Principle 4 has been revised to clarify that the NRC also engages in consultation when required under Federal statute. However, the NRC disagrees with the suggestion to state specifically in Policy Principle 4 that ''it is the federal agency's responsibility to engage in consultation'' or that ''it is not the tribe's responsibility to request engagement in consultation.'' As stated in Policy Principle 4 the NRC will provide timely notice and consult in good faith with Tribal Governments on NRC regulatory actions that have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is required under Federal statute. In some circumstances, Federally recognized Tribes may request to engage in consultation on matters that have not been identified by the NRC as having substantial direct effects on one or more Indian Tribes or for which Tribal consultation is not required under Federal statute. The NRC can make a good faith effort to invite Tribes to consult, but cannot mandate their participation in the process.

The NRC Tribal Policy Statement has been revised to address this comment, in part.

Comment 2.10. ''The Policy and Manual generally reflect the differences between outreach and consultation. However, there are several specific spots, discussed below, where the language is unclear or the terms are used interchangeably. Confusion as to whether the NRC is engaged in outreach or consultation or the scope of consultation can result in confusion and delay. The Tribes may even get the impression that the NRC is only pretending to consult; see, for example, the eighth bullet on page 6 of the letter from the Seneca Nation of Indians, dated April 1, 2013, in this docket.

''Principles 3 and 4 of the Policy are potentially confusing as they use the terms 'consult' and 'outreach' interchangeably. In addition, these Principles state that they apply to 'regulatory actions' without clarifying whether what is meant are policy setting, rulemaking, issuing guidance, or a licensing action. As reflected in Section 1.D and associated note 25 of the Manual, as a regulatory agency, the NRC fulfills the fiduciary obligation to Tribes by ensuring uniform treatment action in providing protection under its implementing regulations. On the other hand, where the NRC is engaged in setting policy, issuing rules, or providing guidance that directly impact Tribes, consultation on subjects within the scope of the impact may be appropriate where the impact is significant. To minimize confusing ambiguity, the following clarifications are suggested:

A. The Policy

(1) In Principle 3, replace 'consult' with 'inform' in the first sentence and replace 'NRC regulatory actions that have substantial direct impacts on one or more Indian Tribe' with 'NRC regulatory actions, including licensing actions, in which one or more Indian Tribes have an interest.' This clarification ensures that outreach to Indian Tribes will include any regulatory action of interest to a Tribe.''

Response 2.10. The NRC disagrees in part and agrees in part with this comment. The NRC recognizes that consultation and outreach are distinct terms that should not be used interchangeably. The NRC disagrees with the proposed changes to Policy Principle 3, but agrees that Policy Principle 3 should be revised to provide greater clarity. ''Consult'' has been removed from the first sentence, but ''regulatory actions that have substantial direct impacts on one or more Indian Tribe'' remains. The NRC Tribal Policy Statement reflects the distinction between outreach and consultation by setting forth two separate and distinct policy principles related to outreach and consultation. In an effort to provide clarification regarding the distinction between outreach and consultation, Policy Principle 3 has been revised. The purpose of NRC's Tribal outreach can be broad, ranging from participation in standing Tribal meetings hosted by Federal partners and Tribal organizations to conducting informational meetings related to a licensing project or rulemaking to an informational webinar. The NRC Tribal liaison team continues to seek new opportunities to engage Tribal representatives.

The NRC Tribal Policy Statement has been revised as a result of the comment.

Comment 2.11. ''In Principle 4, replace 'on NRC's regulatory actions' with 'prior to the NRC issuing policies, rules, or guidance' in the first sentence. This clarification reflects that consultation on NRC licensing actions would generally not be consistent with the NRC's statutory authority. This clarification also harmonizes the Policy with the Presidential directive for agencies to consult on policies with tribal implications, E.O. [Executive Order] 13175, § I(a), Nov. 6, 2000.''

Response 2.11. The NRC agrees in part and disagrees in part with this comment. The focus of E.O. 13175 is specifically related to consultation on ''policies that have Tribal implications'' (*i.e.,* ''regulations, legislative comments on proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes''). The revised text proposed by the commenter would harmonize the Policy Statement with the E.O. by replacing the term ''NRC's regulatory actions'' with a specific set of activities that are consistent with the activities covered in the E.O. However, the NRC Tribal Policy Statement covers a broader set of activities than those covered in the EO. Not all NRC Tribal consultation is related to ''policies, rules, or guidance'' as noted in the comment. The NRC licensing actions may also trigger Tribal consultation under other Federal statutes. Therefore, the discussion of Policy Principle 4 has been revised to clarify the broader set of activities covered by the Policy Statement.

The NRC Tribal Policy Statement has been revised to address the comment, in part.

Comment 2.12. ''Consistent with the practices of other agencies, the Policy designates an official to facilitate meaningful and timely consultations with Indian Tribes. See generally, E.O. [Executive Order] 13175, § 5(a), Nov. 6, 2000. The designated official is to work with other NRC personnel to ensure Tribal implications have been considered. The conclusions from these intra-agency considerations should be documented in the papers provided to the Commission (SECY papers), much

the way the conclusions of the Chief Financial Officer or legal office are reflected now. Such documentation would serve to provide timely feedback to the Commission, to be mindful with the resource implications associated with formal Tribal consultations, and to show respect for the solemnity of conducting Tribal consultations on a Government-to-Government basis. Also, the second sentence of the first paragraph under 'Designated Official and Tribal Liaisons' is an ambiguous, run-on sentence that does not clarify that where the NRC is engaged in setting policy, issuing rules, or providing guidance that directly impact Tribes, consultation on subjects within the scope of the impact may be appropriate where the impact is significant as reflected in Comment 2, above. It is suggested that sentence be split into four sentences that read:

The designated Official shall ensure that agency program personnel have considered the Tribal implications related to their responsibilities within the NRC's scope of jurisdiction. Where programs, policies, rulemaking or guidance are proposed to the Commission, the conclusions from review of these considerations shall be briefly discussed; specifically whether or not there potentially are direct effects on one or more Indian Tribes. The designated official shall facilitate meaningful and timely consultation concerning the development, administration, and enforcement of NRC's policy, rulemaking, or guidance actions that have a substantial direct effect on one or more Indian Tribes, including obtaining Commission approval to initiate formal consultation with one or more Indian Tribes on subjects within the scope of such substantial direct effects. Prior Commission approval to initiate consultation is not required where consultation is required by a Federal statute.''

Response 2.12. The NRC agrees in part and disagrees in part with this comment. The NRC agrees that the ''designated official'' should be involved in regulatory actions that have Tribal implications, but disagrees with the commenter's suggested edits and related implications. Some of the commenter's proposed language would introduce procedures that are not appropriate for a high-level policy statement. The NRC would consider developing specific procedures in a future guidance document. Regulatory actions involving Tribal consultation, would be reviewed by the Office of the Executive Director for Operations, including the designated official, before being sent to the Commission. The NRC Tribal Policy Statement identifies the Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration, and Human Capital Programs as the ''designated official'' for purposes of the NRC Tribal Policy Statement, and not pursuant to E.O. 13175, as noted by the commenter. The NRC agrees that the second sentence of the section titled, ''Designated Officials and Tribal Liaisons,'' referenced by the commenter should be restructured and has divided it into two sentences.

The NRC Tribal Policy Statement has been revised to reflect part of the comment.

3. Outreach and Consultation

Multiple commenters provided input related to the use of the terms ''outreach'' and ''consultation'' in the policy principles of the NRC Tribal Policy Statement.

Comment 3.1. ''The NTAA [National Tribal Air Association] supports Principle No. 3 which provides:

The NRC Will Conduct Outreach to Indian Tribes.

The NRC will consult and coordinate with Indian Tribes, as appropriate, related to its regulatory actions with Tribal implications and will seek additional opportunities for general outreach. The NRC will participate in national and regional Tribal conferences and summits hosted by Federal agencies and Tribal organizations, and will seek Tribal representation in NRC meetings and advisory committees concerning NRC regulatory actions that have substantial direct effects on one or more Indian Tribes.

While the NTAA supports Principle No. 3, it does not find that current NRC outreach to Indian Tribes is being done or happening in a timely manner. For example, apart from some local efforts, the NTAA is unaware of any venue where Tribes are being brought together to discuss radiation issues and air quality impacts from the nuclear program. The NTAA finds that NRC must be more diligent in conducting outreach on all issues as they are brought to the attention of the NRC by Tribes, the NTAA, or other Tribal organizations.''

Response 3.1. The NRC agrees in part and disagrees in part with this comment. The NRC agrees with the commenter's support of the NRC Tribal Policy Principle 3. The NRC disagrees that the NRC has not conducted outreach to Indian Tribes in a timely manner. While the NRC has not hosted particular meetings to bring Tribes together to discuss radiation issues and air quality impacts from the nuclear program, the NRC has participated in national and regional Tribal conferences and summits hosted by Federal agencies and Tribal organizations. Additionally, the NRC has provided instructor-led training sessions at multiple Tribal Colleges and Universities to inform Tribes regarding NRC's mission, basic health physics, radiation safety, and environmental review. The NRC will continue to provide training, as needed, to Tribes who are affected by regulated activities and will seek outreach opportunities.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 3.2. ''Principle No. 4: Development of a Consultation Plan. The NTAA recommends that Principle No. 4 require the NRC to also develop a comprehensive Tribal consultation plan for NRC regulatory and non-regulatory actions having potentially substantial direct effects on one or more Indian Tribes. Although Tribes consider consultation to be very important, Tribes have limited resources and time to expend on it. The NRC must be sensitive to this fact and make every effort to provide Tribes with any additional resources and assistance that they might require to engage in effective consultation. Some recommendations to help the NRC to conduct effective consultation with Tribes include:

1. Develop guidance on how the NRC intends to assure that consultation meetings result in meaningful dialogue rather than simply pro forma consultation;

2. Assign a Tribal liaison to the specific NRC action who has extensively worked with Tribes on similar issues; and

3. Provide adequate time to Tribes to review and provide comments concerning proposed NRC actions well beyond the 30- to 60-day periods provided to the public to make its comments.''

Response 3.2. The NRC disagrees in part and agrees in part with this comment. The NRC staff has developed an implementation plan that will be revised to reflect the final NRC Tribal Policy Statement. The NRC disagrees that Policy Principle 4 should state specifically that the NRC has to develop a comprehensive Tribal consultation plan for NRC regulatory and non-regulatory actions having potentially substantial direct effects on one or more Indian Tribes. The NRC agrees that the NRC should consider development of consultation plans for actions that have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is required under Federal statute, in an effort to promote more effective consultations. The NRC Tribal liaison staff will continue to work in conjunction with program office staff

during licensing and other regulatory actions, and may be assigned to specific sites or actions, as resources and staffing permit. The NRC strives to establish an effective consultation process and will consider time allowed for Tribal engagement, including Tribal review and comment of relevant documents, on a case by case basis, as appropriate, during the regulatory process.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 3.3. ''Further, the NRC must engage in government-to-government consultation with individual Tribes and not groups of Tribes which might occur as part of an outreach session at a conference or other similar gathering. Such a consultation approach is necessary for a number of reasons. First, it provides for more candid conversations between the individual Tribe and NRC than would occur otherwise during a group meeting. Second, each Tribe's circumstances are unique and must be treated as such by the NRC. A group meeting of Tribes would only give short shrift to these circumstances. Third, most cultural resources information is protected from release under statutory exemptions to the Freedom of Information Act. Discussion of such information by an individual Tribe as part a group meeting of Tribes risks its release to the general public and potentially endangers Tribal cultural sites and practices. Finally, the subject matter may be so unique that government-to-government consultation between the individual Tribe and NRC provides the best opportunity for a resolution to the situation versus a group meeting of Tribes where any number of Tribal issues could be discussed in a finite period of time.''

Response 3.3. The NRC agrees with this comment. The NRC does not consider outreach during a conference to be consultation. The NRC will make an effort to engage Tribes on a government-to-government basis, and will consider whether it is more appropriate to consult individually or simultaneously with multiple Tribes, on a case-by-case basis, taking into consideration site-specific facts, resource limitations, and preference of consulting Tribes.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 3.4. ''The NRC will consult and coordinate with Indian Tribes, as appropriate, related to its regulatory actions with Tribal implications and will seek additional opportunities for general outreach. The NRC will participate in national and regional Tribal conferences and summits hosted by Federal agencies and Tribal organizations, and will seek Tribal representation in NRC meetings and advisory committees concerning NRC regulatory actions that have substantial direct effects on one or more Indian Tribes.

''Attending major tribal conferences and meetings is an excellent way of interacting with Indian tribes. As well, NRC staff should endeavor to attend meetings of other federal agencies that attract tribal representatives.

''. . . [I]t is important to recognize that while there might not be delineated reservation or Trust lands in a given area that does not necessarily mean that there are no tribes interested in or impacted by NRC regulatory actions. Many tribes were forcibly removed from their ancestral lands or ceded vast tracts of land to the federal government through treaties and have retained or reserved rights (fishing, hunting, gathering) for these lands or these lands contain archaeological, cultural or historical resources, including important sacred sites.''

Response 3.4. The NRC agrees with this comment. The NRC agrees that attending conferences and meetings is an effective way of engaging Tribes and that the NRC staff should attend meetings held by other Federal agencies that attract Tribal representatives. The NRC staff participates in Tribal meetings hosted by other Federal agencies, including conferences hosted by the U.S. Environmental Protection Agency, the U.S. Department of Energy, and the U.S. Department of Transportation, along with meetings hosted by inter-Tribal organizations, including the National Congress of American Indians. The NRC also agrees that Tribes may have an interest in areas that do not have current reservation or trust lands. The current location and geographic proximity to NRC regulated sites is not the sole consideration of the NRC when engaging in outreach with Tribes. The NRC also considers whether there are Tribes that have historic and cultural ties to the land in question.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 3.5. [The Commenter provided input specific to policy principle 4, ''The NRC Will Engage in Timely Consultation.''] ''Early and frequent consultation must be the cornerstone of the government-to-government relationship. Publishing a notice in the **Federal Register** is not consultation. It should be noted that sometime the consultative process can take time.''

Response 3.5. The NRC agrees with this comment. The definition of ''consultation'' and Policy Principle 4 have been revised to provide further clarification. The revisions clarify that consultation is a process and may include, but is not limited to, providing for mutually-agreed protocols, timely communication, coordination, cooperation, and collaboration and provides opportunities for appropriate Tribal officials or representatives to meet with NRC management or staff to achieve a mutual understanding between the NRC and the Tribes of their respective interests and perspectives.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

4. NRC's Government-to-Government Relationship With Tribes

Comment 4.1. ''The ACHP recommends including Alaska Natives and Native Hawaiians in the NRC Tribal Policy Statement and the Tribal Protocol Manual. The NRC is responsible for licensing materials in Alaska and Hawaii. Additionally, the NRC should avoid homogenizing Native American tribes and reference Native American communities [in the Tribal Protocol Manual], not the Native American community.''

Response 4.1. The NRC disagrees in part and agrees in part with this comment. The NRC disagrees that the NRC Tribal Policy Statement should include Native Hawaiian Organizations. The NRC Tribal Policy Statement and Tribal Protocol Manual pertain to consultation with Tribal governments recognized by the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a. The definition of Indian Tribe includes Alaska Native Tribes. The United States has recognized and implemented a special political and Trust Responsibility with the Native Hawaiian community through programs and services that are, in many respects, analogous to, but separate from the programs and services enacted for Federally recognized Indian Tribes. However, Native Hawaiian Organizations are not governmental entities. As a result, Native Hawaiian Organizations are not covered by the NRC Tribal Policy Statement. The NRC does comply with statutory obligations to consult with Native Hawaiian Organizations. For example, the NRC consults with Native Hawaiian Organizations, as appropriate, under Section 106 of the NHPA.

The NRC agrees with the comment, ''the NRC should avoid homogenizing Native American Tribes'' and recognizes distinctions between Federally

recognized Tribes, as noted in the Tribal Protocol Manual. The Tribal Protocol Manual has been revised to reflect the suggested change from ''community'' to ''communities.''

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 4.2. ''Taken together, both the Tribal Protocol Manual and the NRC Tribal Policy Statement (and their respective **Federal Register** notices) provide important historical information, such as various treaties, Congressional Acts affecting Indian tribes and rights, and a discussion of the Federal Trust Responsibility. This information provides the proper historical context critical to understanding the unique relationship federally recognized Indian Tribes have with the Federal Government. This point is underscored in the Tribal Protocol Manual, which notes that Indian tribes are not the public or special interest groups, but are, in fact, governments. This point is important in understanding why tribes desire to have a government-to-government relationship with the NRC and do not wish to be considered 'stakeholders'.''

Response 4.2. The NRC agrees with this comment. The NRC Tribal Policy Statement and Tribal Protocol Manual underscore the NRC's commitment to a government-to-government relationship with Indian Tribes. The NRC Tribal Policy Statement formalizes the NRC's commitment to engaging Indian Tribes on a government-to-government basis, providing opportunities for participation in the NRC's regulatory process beyond those available to members of the general public or interested stakeholders, consistent with the principles articulated in E.O. 13175.

No changes were made to the NRC Tribal Policy Statement or Tribal Protocol Manual as a result of the comment.

Comment 4.3. [The commenter provided input on policy principle 2, ''The NRC Recognizes and Is Committed to a Government-to-Government Relationship with Indian Tribes.'']

''It should be noted that there are differences among tribes and that there is no 'one size, fits all' approach when it comes to interacting with and understanding Indian tribes. Each tribe is unique and should be treated as such. There should not be a 'standard process' as recommended by some commenters.''

Response 4.3. The NRC agrees with this comment. The NRC recognizes distinctions between Federally recognized Tribes, as noted in the Tribal Protocol Manual. The NRC Tribal Policy Statement does not prescribe a ''standard process'' for interacting with Tribes. Instead, it identifies policy principles that guide the NRC's interactions with Indian Tribes.

No changes were made to the NRC Tribal Policy Statement as a result of the comment.

5. Additional Comments

Comment 5.1. ''The Nuclear Regulatory Commission should look to the policies and practices of the Environmental Protection Agency [EPA] in developing its relationship with tribal governments. In particular, the EPA identified certain tribal governments to be granted with the same treatment as states, allowing the tribes to have primacy in civil jurisdiction with regards to enforcement of EPA regulations on tribal lands. The NRC should consider implementing a similar policy with some or all tribal governments.''

Response 5.1. The NRC disagrees with this comment. Unlike States, the AEA does not authorize Tribal governments to assume regulatory authority over AEA radioactive material. However, the NRC has treated Federally recognized Tribes in a similar manner to States in some instances. For example, Tribal governments can participate in a program to receive advance notification of shipments of certain types of radioactive material and spent nuclear fuel under the Tribal Advance Notification Rule.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.2. ''NRC needs to be committed to the Tribal Policy Statement. If not, policies can be easily side-stepped. NRC needs to implement these policies.''

Response 5.2. The NRC agrees with this comment. The Commission approved a Tribal Policy Statement Implementation Plan in March 2015 (ADAMS Accession No. ML15078A039), which aligns the agency's Tribal activities with policy principles in the NRC Tribal Policy Statement. The NRC staff will utilize the plan to implement the NRC Tribal Policy Statement, and will update it, as appropriate.

No change has been made to the NRC Tribal Policy Statement as a result of this comment.

Comment 5.3. ''The NRC should encourage tribal participation on working groups.''

Response 5.3. The NRC agrees with this comment. The NRC will consider inviting Tribes to participate on working groups related to regulatory actions that have substantial direct effects on one or more Indian Tribes, as appropriate.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.4. ''As subject-matter experts, the NRC will invite tribal representatives to participate on working groups developed for those activities that have the potential of impacting tribal interests, including but not limited to: Integrated Performance Evaluation Program [(IMPEP)] Reviews, Rule-making and other related activities impacting our tribal governments.''

Response 5.4. The NRC disagrees in part and agrees in part with this comment. The NRC disagrees with the threshold for Tribal working group participation set by the commenter's language, ''for those activities that have the potential of impacting Tribal interests.'' The NRC agrees that it may invite Tribal representatives to participate on working groups on matters that have substantial direct effects on one or more Indian Tribes, as appropriate. This is consistent with Policy Principle 3 on the NRC outreach to Indian Tribes, which states ''The NRC will encourage Tribal governments to communicate their preferences to NRC staff during outreach activities and will seek to provide information about opportunities for Tribal participation in NRC meetings and advisory committees concerning NRC regulatory actions that have substantial direct effects on one or more Indian Tribes, as appropriate.'' Because the NRC does not have statutory authority to enter into agreements with Tribes like it does with States, Tribal government employees cannot participate in IMPEP Reviews as a review team member in the same manner as an Agreement State government employee. However, IMPEP reports are publically available and meetings are open to the public.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.5. ''Further, the NRC will present a yearly report to tribal organizations describing all agency undertakings involving or relating to Indian Tribes.''

Response 5.5. The NRC disagrees with this comment. The NRC has no current plans to present an annual report describing ''all agency undertakings involving or relating to Indian Tribes.'' As part of the NRC Tribal Policy implementation Plan, the NRC staff prepares an annual report of the agency's implementation of the NRC Tribal Policy Statement, including some of the agency's Tribal-related interactions. While the report is intended for internal use, it will be available on the NRC's public Web site.

It will also be available in hardcopy, upon request.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.6. ''Yes, extend the comment period.''

Response 5.6. The NRC agrees with this comment. The comment period was extended for the NRC Tribal Policy Statement from 120 days to 180 days. The NRC considers comments received after the end of the comment period if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before the comment period closes.

No changes were made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.7. ''We believe that the key to effectively implementing the Tribal Policy Statement is via actions that will protect Indian people, lands, and resources. Toward that end, an evaluation of existing staff guidance is a strong start. This evaluation should not be limited to the Tribal Protocol Manual, but all NRC staff guidance.''

Response 5.7. The NRC agrees with this comment. The NRC staff has reviewed numerous agency and office-level guidance documents to determine if changes were necessary before the Commission approves the final NRC Tribal Policy Statement, ensuring that the guidance documents are consistent with policy principles in the NRC Tribal Policy Statement. The NRC will revise guidance, as needed, to reflect the policy principles of the final NRC Tribal Policy Statement.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 5.8. ''We suggest that the NRC work with a number of tribes, representing a cross-section of NRC regulatory activities, as well as the Bureau of Indian Affairs (BIA) to gain a better understanding of Indian land tenure and the potential consequences of contamination to Indian lands.

''We understand that the NRC may possibly be developing a guidance document pertaining to the National Historic Preservation Act (NHPA) Section 106 consultation. We applaud this effort. We recommend that the NRC work with tribes, the Advisory Council on Historic Preservation (ACHP), industry (limited participation), and possibly other federal agencies to develop this guidance document.

''Finalizing and fully implementing the Tribal Protocol Manual will also help NRC staff to be informed on tribal issues. Training, awareness, and continuity of staff are also key elements of an effective tribal program.''

Response 5.8. The first part of this comment related to Indian land tenure is out of scope of the NRC Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. NRC disagrees in part and agrees in part with the remainder of the comment. The NRC is in the process of finalizing NHPA Section 106 guidance for uranium recovery licensing. The NRC sought input from NRC Staff, ACHP, Tribal governments, industry representatives, and members of the public. The NRC published the draft Interim Staff Guidance, FSME–ISG–02, ''Guidance for Conducting the Section 106 Process of the National Historic Preservation Act for Uranium Recovery Licensing Actions,'' for public review and comment on June 18, 2014 (79 FR 34792). On September 3, 2014, the NRC extended the comment period (79 FR 52374). The NRC staff is in the process of developing the final program specific guidance. The NRC staff has reviewed staff guidance documents and concluded that no guidance documents directly contradict the NRC Tribal Policy Statement. The NRC staff review identified documents that will need to be revised to be consistent with the final NRC Tribal Policy Statement. Guidance will be updated as scheduled, and will incorporate the final NRC Tribal Policy Statement, as appropriate. The NRC staff has also developed and implemented a Tribal cultural sensitivity training that is available agencywide.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

6. Out of Scope Comments

Comment 6.1. ''We have reviewed the comment letters submitted in 2013 by other entities on the Tribal Protocol Manual (most notably those representing the uranium mining industry) and found the comments to be self-serving, ill-informed and insensitive [to] tribal history, culture and tradition. These commenters complained that the Section 106 process was 'too cumbersome, time consuming, and costly for the uranium recovery industry' and that the pace of the consultation should be accelerated and standardized. Moreover, the commenters suggested that the NRC should not be making an exhaustive effort to identify all potentially impacted Indian tribes. In other words, hurry up and get it done!

The NRC has an obligation under the NHPA to ensure that its actions do not have adverse impacts. The NRC also has an obligation to federally recognized Indian tribes.

With regard to tribes delaying the process or lacking incentive to work with the NRC, it should be noted that it can be a burden (financially and technically) to effectively participate in NRC proceedings.''

Response 6.1. This comment is out of scope of the NRC Tribal Policy Statement because the comment centers on specific statutory requirements to consult with Tribes under NHPA. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. It does not prescribe procedural requirements for fulfilling NHPA consultation requirements. The NRC upholds all statutory obligations to consult with Federally recognized Tribes, including consultation responsibilities under the NHPA and NEPA.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.2. ''The NEPA process (for either [an] EA [environmental assessment] or EIS [environmental impact statement]) does not ensure that environmental issues and concerns identified by the impacted tribes will be addressed adequately, as EA's or EIS's are disclosure tools that do not and cannot offer remedies or mitigation. It is through the NRC's Atomic Safety and Licensing Board (ASLB) adjudicatory process that identified issues can be addressed (if the Board admits the affected tribe as an intervener because the tribe has articulated a deficiency with an application before the NRC). Achieving intervener status is a difficult and costly undertaking, given the high legal and regulatory standards to be met. Nevertheless, this is a huge barrier that many tribes cannot overcome and this should be recognized a severe limitation to effective participation by any tribes impacted by NRC licensing actions.''

Response 6.2. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agency-wide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. It does not prescribe procedural requirements for fulfilling NEPA Tribal consultations. The process for achieving intervenor status before an NRC Atomic Safety and Licensing Board (or other NRC adjudicator) is outside the scope of the NRC Tribal Policy Statement. Under the

NRC Tribal Policy Statement, the NRC will provide timely notice and consult in good faith with Tribal governments on NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes. In addition, Tribes will have the opportunity to raise environmental, historic, and cultural issues during the NEPA environmental review and NHPA process. This process provides an additional opportunity to address the Tribe's concerns with a proposed licensing action. Good faith efforts to consult with Indian Tribes under the NRC Tribal Policy Statement or during the NEPA and NHPA review process may also have the potential to resolve issues outside the hearing process.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.3. ''In 2013, the NRC finalized its advance notification rule (10 CFR 71.97) that allows Indian tribes to receive advance notification of shipments of irradiated reactor fuel through reservation land (not Trust lands). To participate, interested tribes must 'opt in' and complete safeguards training. Although the NRC was very flexible with some of the prerequisites, the fact that no tribe is currently participating in this pre-notification program should cause the NRC to pause and ask why. It could be that it is just too cumbersome for the tribes to participate, due to a lack of resources (staff, financial, etc.) or competing priorities for resources.''

Response 6.3. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. The Tribal Advance Notification Rule amended NRC regulations to require licensees to provide advance notification to participating Federally recognized Tribal governments regarding shipments of irradiated reactor fuel and certain types of nuclear waste for any shipment that passes within or across their reservations (77 FR 34194). After reviewing public comments received during the development of the Tribal Advance Notification Rule, the NRC staff concluded that Tribes should have the option of whether to opt into the program because the program requires training, certain equipment, and has civil and criminal penalties for non-compliance. As of July of 2016, one Indian Tribe completed the process of enrolling in the Tribal Advance Notification Program. A list of participating Tribes is maintained on the NRC Web site at *http://www.nrc.gov/about-nrc/state-tribal/tribal-advance-notification.html#tribes.*

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.4. ''Principle No. 4: An Example of Lack of Implementation. In 2012, the NRC proposed an Advance Notification Rule, by which Indian Tribes would receive advance notification of shipments of irradiated reactor fuel and other nuclear wastes transported across their reservations. (''Tribal Advance Notification'' at *http://www.nrc.gov/about-nrc/state-tribal/tribal-advance-notification.html#def* (last visited on April 12, 2015).)

''Yet, the NRC claims that 'there are no tribes that have the prerequisite required to receive advance notifications.' (''Tribal Advance Notification'' at *http://www.nrc.gov/about-nrc/state-tribal/tribal-advance-notification.html#def__* (last visited on April 12, 2015).)

''Nuclear waste is being transported through a number of reservations weekly by unmarked trucks (*e.g.,* missing placards) and Indian Tribes of these reservations have not been made privy to the transportation schedules for the waste. Knowing the schedule would enable Tribes to protect their reservation environments by having emergency response teams in place in case of any accidental waste releases. Regardless of whether Tribes meet the aforementioned prerequisite, the NRC should still be actively consulting with Tribes on shipments across their reservations and other NRC actions having potentially substantial air quality and other direct effects on one or more Tribes.

''The NTAA has also seen several inconsistencies in the reporting of the number of regulated facilities in Indian Country. The NTAA finds that, an update of NRC's maps or inventories of regulated facilities, would help the NRC to more effectively contact and identify Tribes about NRC regulatory and non-regulatory actions having substantial air quality and other direct effects on one or more Tribes.''

Response 6.4. This comment is out of scope of the NRC Tribal Policy Statement in part. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. The Tribal Advance Notification Rule amended NRC regulations to require licensees to provide advance notification to participating Federally recognized Tribal governments regarding shipments of irradiated reactor fuel and certain types of nuclear waste for any shipment that passes within or across their reservations (77 FR 34194). After reviewing public comments received during the development of the Tribal Advance Notification Rule, the NRC staff concluded that Tribes should have the option of whether to opt into the program because the program requires training, certain equipment, and has civil and criminal penalties for non-compliance. As of July of 2016, one Indian Tribe completed the process of enrolling in the Tribal Advance Notification Program. A list of participating Tribes is maintained on the NRC Web site at: *http://www.nrc.gov/about-nrc/state-tribal/tribal-advance-notification.html#tribes.* The NRC continues to update maps of Tribal reservation and trust lands within a 50-mile radius of NRC-regulated nuclear power plants. The NRC staff is developing tools that they may utilize to identify Tribal lands near other NRC-regulated facilities.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.5. ''Hire natives to be liaisons with our own people. Create trust, transparency and rapport. These people have been deceived and betrayed since the white man stepped foot on this land. It's very important to really reach the native people and it's high time they got many seats at the round table. Thank you for your work and hope it can improve to genuinely include First Nation's peoples.''

Response 6.5. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. However, the NRC does seek to foster a diverse workplace. The Office of the Chief Human Capital Officer participates in extensive recruitment, including the American Indian Science and Engineering Society's annual conference. Additionally, the NRC's Office of Small Business and Civil Rights promotes diversity by sponsoring Equal Employment Opportunity Advisory Committees, including the Native American Advisory Committee (NAAC). The NAAC recommends initiatives and approaches to attract qualified Native Americans and Alaskan Natives to the NRC and to support and retain the Native American and Alaskan Native employees of the NRC. The Committee has also forged a working relationship with the American Indian Science and Engineering Society through a memorandum of understanding. For clarification, the

listed activities do not cover the ''First Nations [of Canada]'' referenced by the commenter.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.6. ''Lastly, the NRC will ensure there are mechanisms in place to prevent an unfunded mandate upon any tribe, including but not limited to requirements of acquiring GSA safe or other supplies or materials as stipulated in the in the advance notification rule.''

Response 6.6. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. The Tribal Advance Notification Rule amended NRC regulations to require licensees to provide advance notification to participating Federally recognized Tribal governments regarding shipments of irradiated reactor fuel and certain types of nuclear waste for any shipment that passes within or across their reservations (June 11, 2012; 77 FR 34194). After reviewing public comments received during the development of the Tribal Advance Notification Rule, the NRC staff concluded that Tribes should have the option of whether to opt into the program because the program requires training, certain equipment, and has civil and criminal penalties for non-compliance. The NRC is committed to ensuring that Tribal Nations are informed of the requirements for receiving Safeguards Information and sensitive information. It is the responsibility of all Tribal governments that volunteer to participate in the Tribal Advance Notification program to ensure that the information is secure and used in a manner that will provide for the protection of the public health and the environment.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.7. ''It is important to note, even though NRC has expanded educational tools for Radiation Workshops as open communication protocol, there is a need for Native speakers to provide the information. Non-English speakers attend the workshops and do not comprehend the contents. More workshops related to DOE Radiation site locations throughout Indian Country is strongly urged that NRC has oversight. Many of these sites are under DOE–LM [DOE Office of Legacy Management] and not necessarily under DOE–EM [DOE Office of Environmental Management] as it seems there is a communication barrier, and updated cleanups by site is missing, especially with transport of radioactive sludge from holding/evaporation ponds.

''Many transport routes go through Native communities, and are not part of the DOE–EM START [Stakeholder Tool for Assessing Radioactive Transportation] programming. It may be missing out of other regulatory components as 108(c) under DOE for transport. Consideration for links for the public with RECA [Radiation Exposure Compensation Act] benefits and DownWinder Web sites under NRC is important as many suffer the health devastation of cancer due to radiation.''

Response 6.7. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. Previously the NRC staff received similar feedback on the inclusion of non-English speakers in the NRC's Tribal Training Program. The NRC will consider the inclusion of Native speakers when arranging future training sessions for Tribes. DOE–EM START programming is not administered by the NRC, and therefore is not covered by the NRC Tribal Policy Statement. The RECA benefits are administered by the Department of Justice's program for claims relating to atmospheric nuclear testing and claims relating to uranium industry employment. The NRC does not oversee the program, make related determinations, or administer payment of claims. The Downwinder Web sites are maintained by the U.S. Department of Health and Human Services and do not fall under the NRC's jurisdiction.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

Comment 6.8. [The commenter quoted policy principle 5, ''The NRC Will Coordinate with Other Federal Agencies,'' stating ''When the Commission's action involves other Federal agencies, the NRC will perform its Tribal consultation jointly with other Federal agencies, as appropriate.''] ''This will be especially important if/when shipments of spent nuclear fuel to a federal repository or an interim storage facility commence. Shipments of spent nuclear fuel will involve the NRC, the US Department of Energy (DOE) and the US Department of Transportation (DOT). Equally important is the engagement of federal agencies involved in the uranium mining regulation (*i.e.,* the Bureau of Indian Affairs or the Bureau of Land Management).''

Response 6.8. This comment is out of scope of the NRC Tribal Policy Statement. The NRC Tribal Policy Statement is an agencywide, high-level document that encompasses a broad range of NRC Tribal interactions, consultation, and outreach. The NRC currently coordinates with other Federal agencies, as appropriate, on issues within its regulatory jurisdiction, including the shipment of spent nuclear fuel and licensing and regulation of uranium recovery facilities. Currently, there is neither a Federal repository for spent nuclear fuel nor an interim storage facility but the NRC will follow the Tribal Policy Statement and appropriate regulations when processing any applications for these facilities. The NRC does have regulations that govern the transport of spent nuclear fuel and implements them in coordination with relevant Federal agencies, including the DOE and the DOT. The NRC does not have regulatory authority over uranium mining facilities. However, the NRC does have regulatory authority over uranium recovery and uranium milling facilities and coordinates with other Federal agencies, as appropriate, including the Bureau of Land Management and EPA, during the consultation process.

No change has been made to the NRC Tribal Policy Statement as a result of the comment.

V. Procedural Requirements

Congressional Review Act Statement

This final NRC Tribal Policy Statement is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

Paperwork Reduction Act Statement

This Policy Statement does not contain new or amended information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated at Rockville, Maryland, this 3rd day of January, 2017.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Tribal Policy Statement

The purpose of this Tribal Policy Statement is to set forth principles to be followed by the U.S. Nuclear Regulatory Commission (NRC) to promote effective government-to-government interactions with Federally recognized American Indian and Alaska Native Tribes, and to

encourage and facilitate Tribal involvement in the areas that the NRC has jurisdiction. It seeks to provide agencywide principles to achieve consistency but also encourage custom-tailored approaches to consultation and coordination that reflect the circumstances of each situation and the preference of each Tribal government. It is the NRC's expectation that all program and regional office consultation and coordination practices will be consistent with or adhere to the NRC Tribal Policy Statement. This NRC Tribal Policy Statement is based on the United States Constitution, treaties, statutes, Executive Orders, judicial decisions, and the unique relationship between Indian Tribes and the Federal government.[1]

The following principles will guide the NRC's interaction with Indian Tribes:

1. The NRC Recognizes the Federal Trust Relationship With and Will Uphold Its Trust Responsibility to Indian Tribes

The NRC shares the Federal government's unique Trust Relationship with, and Trust Responsibility to, Indian Tribes. Under the Federal Trust Doctrine, the United States—and the individual agencies of the Federal government—owe a fiduciary duty to Indian Tribes. The nature of that duty depends on the underlying substantive laws (*i.e.,* treaties, statutes, agreements) creating the duty. The NRC exercises its Trust Responsibility in the context of its authorizing statutes including the Atomic Energy Act, the Energy Reorganization Act of 1974, the Nuclear Waste Policy Act of 1982, the Low-Level Radioactive Waste Policy Act of 1985, and the Uranium Mill Tailings Radiation Control Act of 1978, as amended. As an independent regulatory agency that does not hold in trust Tribal lands or assets or provide services to Federally recognized Tribes, the NRC fulfills its Trust Responsibility through implementation of the principles of the Tribal Policy Statement, by providing protections under its implementing regulations, and through recognition of additional obligations consistent with other applicable treaties and statutory authorities.

2. The NRC Recognizes and Is Committed to a Government-to-Government Relationship With Indian Tribes

The NRC recognizes the right of each Indian Tribe to self-governance and supports Tribal sovereignty and self-determination. The NRC recognizes Tribal governments as dependent domestic sovereign nations, independent from State governments, with separate and distinct authorities with inherent sovereign powers over their members and territory, consistent with applicable statutes and authorities.

3. The NRC Will Conduct Outreach to Indian Tribes

The NRC will conduct outreach to keep Indian Tribes informed about the agency's actions and plans, as appropriate, related to its regulatory actions that have substantial direct effects on one or more Indian Tribes. The NRC will participate in national and regional Tribal conferences and summits hosted by Federal agencies, Tribal governments, and Tribal organizations, as appropriate. The NRC will encourage Tribal governments to communicate their preferences to NRC staff during outreach activities and will seek to provide information about opportunities for Tribal participation in NRC meetings and advisory committees concerning NRC regulatory actions that have substantial direct effects on one or more Indian Tribes, as appropriate.

4. The NRC Will Engage in Timely Consultation

The NRC will provide timely notice and consult in good faith with Tribal governments on NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is required under Federal statute.

Tribal officials may also request that the NRC engage in consultation with them on matters that have not been identified by the NRC to have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is not required under Federal statute. The NRC will make efforts to grant such requests, taking into consideration the nature of the activity at issue, past consultation efforts, available resources, timing issues, and other relevant factors.

The NRC will establish early communications and begin consultation as soon as practicable. The NRC will consult in good faith throughout the agency decisionmaking process and develop and maintain effective communication, coordination, and cooperation with Indian Tribes. The NRC representatives for consultations with Tribal officials or representatives will be of an appropriate rank and the level of interaction will be commensurate with the circumstances. The appropriate level of interaction will be determined by a discussion between the NRC and Tribal governments, and program office consultation procedures and guidance. Participating Tribal and NRC representatives will serve as respective decisionmakers, based on the established agenda and to the extent possible.

5. The NRC Will Coordinate With Other Federal Agencies

When the Commission's action involves other Federal agencies, the NRC will perform its Tribal consultation jointly with other Federal agencies, as appropriate and to the extent possible.

6. The NRC Will Encourage Participation by State-Recognized Tribes

The NRC recognizes the distinction between Indian Tribes who are Federally recognized and those who are not. The NRC will reach out to States to identify the appropriate State-recognized Tribes to invite to participate in its regulatory process, including opportunities related to rulemaking, licensing and decommissioning.

Designated Official and Tribal Liaisons

The Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration, and Human Capital Programs serves as the NRC's designated official for Tribal consultations. The designated official will ensure that the agency program personnel have considered the Tribal implications related to their responsibilities within the NRC's jurisdiction. The designated official will also make efforts to facilitate meaningful and timely consultation and coordination regarding NRC's regulatory actions that have substantial direct effects on one or more Indian Tribes as well as those regulatory actions for which Tribal consultation is required under Federal statute.

The designated official will be supported by staff who have functional responsibility to serve as intergovernmental liaisons to Indian Tribes. These NRC Tribal liaisons will facilitate government-to-government consultation by serving as the agency's primary points of contact for Indian Tribes, coordinating with the appropriate office or personnel

[1] This Tribal Policy Statement is not intended to, and does not, grant, expand, create, or diminish any rights, benefits, or trust responsibilities, substantive or procedural, enforceable at law or in equity in any cause of action by any party against the United States, the Commission, or any person. This Tribal Policy Statement does not alter, amend, repeal, interpret, or modify Tribal sovereignty, any treaty rights of any Indian Tribes, or preempt, modify, or limit the exercise of such rights. Nothing herein shall be interpreted as amending or changing the Commission's regulations.

regarding programmatic inquiries, and will facilitate the appropriate level of communication and exchange of information between Tribal officials and the NRC staff. The Tribal liaisons will also educate the NRC staff about Tribal issues including cultural sensitivity and the Federal Trust Responsibility. The designated official will have the authority to delegate tasks to the NRC Tribal liaisons as he/she deems fit.

[FR Doc. 2017–00091 Filed 1–6–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79719; File No. SR–NYSEArca–2016–143]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Introducing NYSE OptX

January 3, 2017.

I. Introduction

On November 3, 2016, NYSE Arca, Inc. (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce NYSE OptX, an order entry platform that will allow for the submission of Qualified Contingent Cross orders (''QCC Orders'') by OTP Holders and OTP Firms. On November 15, 2016, the Exchange filed Amendment No. 1 to the proposal.[3] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on November 22, 2016.[4] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change

The Exchange proposes to introduce NYSE OptX, an order entry platform that will allow OTP Holders [5] and OTP Firms [6] (collectively, ''OTPs'') to submit QCC Orders to the Exchange. According to the Exchange, OTPs currently send QCC Orders to the Exchange through the use of third-party front end order management systems or by calling Floor Brokers and relaying their orders by telephone.[7]

According to the Exchange, NYSE OptX is an order entry platform that will utilize a combination of Instant Messaging (''IM'') and browser-based technology to allow OTPs to submit QCC Orders for execution on the Exchange's trading system.[8] To execute a QCC Order through NYSE OptX, an OTP will send the order in plain text to NYSE OptX,[9] which will then translate the message into a pre-populated order ticket with details of the order and return the order ticket to the OTP in a browser-based URL. The OTP will then confirm the order ticket and submit the order to the Exchange for execution, or send the order to a Floor Broker for execution. After an order is executed on the Exchange, NYSE OptX will remit details of the execution back to the OTP.

According to the Exchange, NYSE OptX is designed as an alternative to front end order management systems and the use of telephones for the sending of QCC Orders to the Exchange.[10] The Exchange notes that NYSE OptX will not provide OTPs with the capability to send any other type of orders or the capability to send QCC Orders for execution to other options markets.[11] Further, OTPs will continue to be able to submit QCC Orders through the use of a third-party front end order management system, or by telephone, as they currently do.[12] The Exchange notes that use of OptX to send QCC Orders to the Exchange is optional and voluntary.[13]

The Exchange stated that it will announce the effective date of NYSE OptX in a Trader Update to be published no later than 90 days following approval of this proposal, and that such effective date will be no later than 270 days following publication of the Trader Update.[14]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [15] and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Commission notes that, according to the Exchange, NYSE OptX will provide OTPs an alternative to third-party front end order management systems and the use of telephones to send QCC Orders to the Exchange.[18] Such an alternative may help protect the interests of investors by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange clarified that QCC Orders sent through NYSE OptX to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange, which are set forth in Exchange Rule 6.67.

[4] *See* Securities Exchange Act Release No. 79327 (November 16, 2016), 81 FR 83890 (''Notice'').

[5] The term ''OTP Holder'' refers to a natural person, in good standing, who has been issued an OTP, or has been named as a Nominee. An OTP Holder must be a registered broker or dealer pursuant to Section 15 of the Act, or a nominee or an associated person of a registered broker or dealer that has been approved by the Exchange to conduct business on the Exchange's Trading Facilities. *See* Exchange Rule 1.1(q).

[6] The term ''OTP Firm'' refers to a sole proprietorship, partnership, corporation, limited liability company, or other organization in good standing that holds an OTP or upon which an individual OTP Holder has conferred trading privileges on the Exchange's Trading Facilities pursuant to and in compliance with Exchange Rules. An OTP Firm must be a registered broker or dealer pursuant to Section 15 of the Act. *See* Exchange Rule 1.1(r).

[7] *See* Notice, *supra* note 4, at 83891.

[8] *See id.* The Exchange represents that NYSE OptX will not require any changes to the Exchange's communication or surveillance rules. *Id.* at 83891, n.9.

[9] The Exchange states that OTPs will be required to provide all the essential information regarding the QCC Order when sending it to NYSE OptX, including the price of the option and the stock, the size and side of the order, and delta. The Exchange further represents that QCC Orders sent to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange. *See* Notice, *supra* note 4, at 83891, n.11. *See also* Exchange Rule 6.67—Order Format and System Entry Requirements.

[10] *See* Notice, *supra* note 4, at 83891.

[11] *See id.*

[12] *See id.*

[13] *See id.*

[14] *See id.*

[15] 15 U.S.C. 78f.

[16] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Notice, *supra* note 4, at 83891. As stated above, the Exchange represented that OTPs will be required to provide all the essential information regarding the QCC Order when sending the order to NYSE OptX and QCC Orders sent to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange. *Id.* at 83891, n.11.

offering OTPs an additional way to send QCC Orders to the Exchange for execution. The Commission notes that the use of OptX will be entirely voluntary and OTPs will still be able to submit QCC Orders as they do today, either through the use of third-party front end order management systems or by telephone. For these reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–NYSEArca–2016–143), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00097 Filed 1–6–17; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79724; File No. SR–Phlx–2016–105]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Rules 501, 507, 508, 510, and 511

January 3, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 21, 2016, NASDAQ PHLX LLC (''Phlx'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 501 (Specialist Appointment), Rule 507 (Application for Approval as an SQT, RSQT, or RSQTO and Assignment in Options), Rule 508 (Transfer Application), Rule 510 (SQT and RSQT Performance Evaluation), and Rule 511 (Specialist Allocation and Performance Evaluation).[3] The proposed amendments are described further below.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend: (1) Rule 501 to delete a reference to a back-up specialist; (2) Rule 507 to: Update the reference to ''Board'' to permit the Board to appoint a panel; update the composition of the review committee; and update the reference to Rule 510; (3) Rule 508 to delete the reference to ''lease'' and the cross-reference to Rule 511; (4) Rule 510 to re-entitle the rule ''Good Standing for Specialist, SQT, and RSQT,''[4] and add relevant good standing language, and appeal rights; and (5) Rule 511 to delete the rule.

Rules 501, 507, 508, 510, and 511 are part of the 500 series of rules in the Rules of the Exchange (the ''Series 500 Rules''), which are entitled ''Allocation, SQT, RSQT, and Evaluation Rules (Rule 500–599).''[5] Many Series 500 Rules were established more than three decades ago with the advent of options trading on the Exchange,[6] at which time Exchange options trading was strictly on-floor open outcry through specialists. Exchange options trading has, since that time, developed into a robust hybrid system that is currently largely electronic and off-floor[7] but continues to have an on-floor specialist[8] and an open outcry trading floor. The Exchange is now updating and modernizing the Series 500 Rules as discussed below.[9]

Updating Rule 501

The Exchange proposes in Rule 501 to delete the reference to a back-up specialist.

Currently, Rule 501 states that initial application(s) to become a specialist unit shall include information regarding the specialist, back-up specialist unit and a substitute specialist unit. With the development of liquidity-enhancing electronic market makers on the Exchange such as RSQTs, which make markets in the same options issues as specialists, and the diminution of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] References to rules are to Phlx rules unless otherwise noted. The terms SQT, RSQT, RSQTO, and Specialist are discussed below.

[4] ''Specialist'' is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a). ''Remote Specialist'' is a specialist that does not have a physical presence on the floor of the Exchange. Streaming quote trader (''SQT'') and remote streaming quote trader (''RSQT'') are electronic traders on the Exchange pursuant to Rule 1014(b)(ii)(A) and Rule 1014(b)(ii)(B), respectively.

[5] These Series 500 Rules apply to Exchange members that trade options. The Exchange continues to have a hybrid options floor, but no longer has an equities floor or a commodities floor.

[6] For example, Rules 501, 505, and 506, were adopted on a pilot basis in 1982. *See* Securities Exchange Act Release No. 18975 (August 17, 1982), 47 FR 37019 (August 24, 1982) (approval order regarding pilot in respect of Rules 501–506 and authorizing the Phlx Allocation, Evaluation and Securities Committee, which no longer exists). *See also* Securities Exchange Act Release No. 18975 (August 17, 1982), 47 FR 37019 (August 24, 1982) (SR–Phlx–81–1) (approval order regarding Rules 100, 201, 203 and 214 in combination with Rules 500 through 505). Rules 500, 501, 505, 506, 508, 511, 515, 520, 522, 523, 525, and 526 (of which Rules 500, 515, 516, 520, 522, 523, 525, and 526 no longer exist) were permanently approved in 1991. *See* Securities Exchange Act Release No. 29369 (June 26, 1991), 56 FR 30604 (July 3, 1991) (SR–Phlx–87–42) (order granting permanent approval). Rule 507 was adopted in 2004. *See* Securities Exchange Act Release No. 50100 (July 27, 2004), 69 FR 46612 (August 3, 2004) (SR–Phlx–2003–59) (order granting approval). Rule 510 was adopted in 2007. *See* Securities Exchange Act Release No. 55080 (January 10, 2007), 72 FR 2324 (January 18, 2007) (SR–Phlx–2006–51) (order granting approval). The Exchange has filed a separate proposal regarding two of the rules in the Series 500 Rules, namely Rules 505 and 506. *See* Securities Exchange Act Release No. 77121 (February 11, 2016), 81 FR 8308 (February 18, 2016) (SR–Phlx–2016–22) (notice of filing and immediate effectiveness to delete Rule 505 and update Rule 506).

[7] Electronic traders include Registered Options Traders or ''ROTs,'' that are Streaming Quote Traders or ''SQTs'', Remote Streaming Quote Traders or ''RSQTs,'' as well as off-floor specialists (Remote Specialists) (collectively ''market makers''). *See* Rules 1014(b)(ii)(A), 1014(b)(ii)(B), and 1020.

[8] Unlike specialists, Remote Specialists do not have a physical presence on the floor of the Exchange. Rule 1020.

[9] While the vast majority of options-related rules are found in Rule 1000 and higher (with option index rules found in Rule 1000A and higher), some of the older options-related rules are, as discussed, in the Series 500 Rules.

role that the specialist plays in managing the order book on the Exchange, both a back-up specialist and substitute specialist are no longer needed.[10] Therefore, obsolete language in Rule 501 in respect of back-up specialists, which includes Commentary .01 to Rule 501, is proposed to be deleted from Rule 501. All of the other initial application requirements of Rule 501, which include the following information, remain unchanged: The identity of the individual who will act as head specialist and as assistant specialist(s) in the unit; the identity of the unit's staff positions and who will occupy those positions; the identity of a substitute specialist unit not associated with the specialist unit, which shall serve as a substitute specialist unit in the event that the specialist unit is unable to perform the duties of a specialist; the unit's clearing arrangements; and the unit's capital structure, including any lines of credit.[11]

Updating Rule 507

The Exchange proposes in Rule 507 to update the reference to ''Board,'' update the composition of the review committee, and update the reference to Rule 510.

First, Rule 507(a) currently states that the Board has the ability to perform functions such as deferring or limiting approval of SQTs or RSQTs. The Exchange proposes to replace the role of the Board with Exchange staff. The Exchange may therefore defer, for a period to be determined in the Exchange's discretion, approval of qualifying applications for SQT or RSQT status pending any action required to address the issue of concern to the Exchange. The Exchange's Membership department[12] may not defer a determination of the approval of the application of any SQT or RSQT applicant or place any limitation(s) on access to the Exchange's electronic quoting and trading system on any SQT or RSQT applicant unless the basis for such limitation(s) or deferral have been objectively determined by the Exchange, subject to Securities and Exchange Commission approval or effectiveness pursuant to a rule change filing under Section 19(b) of the Securities Exchange Act of 1934, as amended. The Exchange shall provide written notification to any SQT or RSQT applicant whose application is the subject of such limitation(s) or deferral, describing the objective basis for such limitation(s) or deferral. The Exchange believes that this change will help with the administration and application of Rule 507. Also, there is an appeal to the Board from any action of Exchange staff within Rule 507(e).

Second, Rule 507(e) currently states that an appeal to the Board from a decision of the Exchange regarding an SQT, RSQT, or RSQTO[13] application may be requested by a member or member organization; and that such appeal shall be heard by a special committee of the Board composed of three (3) Directors, at least one of whom will be Independent. In light of and commensurate with the first proposed Rule 507 change regarding the Board, the Exchange proposes to state that any appeal from a decision pursuant to Rule 507 may be heard by the Board or a panel appointed by the Board (''Board Panel'') composed of three (3) members not materially involved in the Exchange decision appealed from;[14] and that, as now, there shall be no appeal to the Board from a decision of the Board Panel. If a Board Panel is appointed by the Board, three persons shall be selected to serve on the Board Panel and in making such selections the Board shall choose individuals whose background, experience and training qualify them to consider and make determinations regarding the subject matter to be presented to the Board Panel. The Exchange notes that references to ''special committee'' will now refer to ''Board'' or ''Board Panel'' with this proposal. The Board Panel shall consist of two members of the Exchange, or general partners or officers of member organizations and one other person that would qualify as a public member as defined in Article I of the By-Laws, whom the Board considers to be qualified.

Third, Rule 507(b) currently states that, when making a decision concerning an application for assignment in an option, the Exchange shall consider the applicant's prior performance as a specialist, SQT, or RSQT based on evaluations conducted pursuant to Exchange Rule 510.[15] The Exchange is, as discussed below, proposing to update Rule 510 so that in lieu of the current formulaic language in the rule, there is new language that accentuates the good standing of members. In light of this, the Exchange proposes to update the 507(b) reference to state that the Exchange can consider the applicant's prior performance as a specialist, SQT or RSQT based on ''good standing pursuant to Rule 510.'' The Exchange is not proposing any other change to Rule 507. The Exchange notes that the other aspects of Rule 507, such as, for example, RSQTO eligibility

[10] The function of a back-up specialist unit not associated with the specialist unit, as in current Rule 501(b), is for one specialist unit on the floor to provide staffing when needed to another specialist unit on the floor. Because multiple specialist units are no longer present on the floor, the back-up function is no longer feasible. Moreover, as discussed below, the specialist unit must clearly indicate its staffing to the Exchange, and the substitute specialist requirement continues unchanged.

[11] Rule 501(a) and (b).

[12] Applications for SQTs and RSQTs would be reviewed by the Membership department. Today, the Exchange's Membership Department review applications for membership to Phlx for both equities and options members.

[13] ''RSQTO'' is a Remote Streaming Quote Trader Organization with up to five affiliated RSQTs. Rule 507(a).

[14] The language stating that one of the Board members shall be an Independent is proposed to be deleted. The Exchange believes that this is proper as the ''Independent'' label is now a distinction with little, if any, effect. Whereas the vast majority of Phlx Board members were not Independent when Rule 507 was put into place and the Exchange was a membership corporation, and application of the Independent label may have made sense under those circumstances, the composition of the Phlx Board has radically changed since Phlx became a subsidiary of a public company, Nasdaq, Inc., in 2008. The By-Laws of the Exchange now provide that the Exchange may have Public Directors, Non-Industry Directors, and Industry Directors; and that Industry Directors may include no more than two officers of the Exchange, selected at the sole discretion of the Board, which may serve in the role of Staff Director (not Independent). Phlx By-Laws Article I. *See also* Securities Exchange Act Release No. 77165 (February 17, 2016), 81 FR 9041 (February 23, 2016) (SR–BSECC–2015–002; SR–SCCP–2015–02; SR–BX–2015–085; SR–NASDAQ–2015–160; SR–Phlx–2015–113) (order granting approval). Now, all but one of the twelve members on the Phlx Board are Independent (the only exception being one Staff Board member who is an officer of the Exchange). Thus, in light of the composition of the Phlx Board, which has one Staff Board member, only one of the three Directors on the special committee discussed in current Rule 507 could even possibly be not Independent; and, by Phlx By-Laws no more than two Directors could ever be not Independent. The Exchange believes that, distinct from the Independent criteria, the ability of the Board to appoint a panel as proposed will serve to enhance the ability to quickly assemble a panel in case of potential appeal, if one occurs. The Exchange notes that a special committee per Rule 507 has not been instituted since, let alone before, Phlx became a subsidiary of Nasdaq, Inc. The Exchange also notes that the compositional requirements for the Boards that oversee the three options markets under the umbrella of Nasdaq, Inc. (Phlx, The NASDAQ Options Market LLC (''NOM''), and NASDAQ BX, Inc. (''BX Options'')) are similar. While there is no requirement in this proposal for an Independent panel member to be appointed to the Board Panel, the Exchange notes that the public member has some independent aspect. *See* Phlx By-Laws at Article I (hh), ''The term 'public member' means a member of any committee appointed by the Board of Directors who has no material business relationship with a broker or dealer, the Exchange, or its affiliates.''

[15] Other factors for consideration include: (A) The financial and technical resources available to the applicant; and (B) the applicant's experience and expertise in market making or options trading. Rule 507(b).

criteria,[16] SQT and RSQT eligibility criteria,[17] and technological ability for RSQTOs, SQTs, or RSQTs,[18] remain in place.[19]

Updating Rule 508

The Exchange proposes in Rule 508 to delete the reference to ''lease'' and to Rule 511.

First, Rule 508 currently refers to ''lease.'' Leasing is no longer practiced on the Exchange, and for this reason the Exchange is proposing to delete this obsolete term from Rule 508. This is similar to a recent proposal wherein the Exchange noted that leasing is an obsolete term that should be deleted.[20]

Second, Rule 508 currently refers to Rule 511, regarding specialists. The Exchange proposes to delete the Rule 508 reference to Rule 511. This is because, as discussed below, Rule 511 is proposed to be deleted as the language of Rule 510 is proposed to be modified to include specialists.[21]

Updating Rule 510

The Exchange proposes to entitle Rule 510 ''Good Standing for Specialist, SQT, and RSQT'' and to add relevant good standing language.

First, Rule 510 currently applies only to SQTs and RSQTs. The Exchange proposes to change the language of Rule 510 to indicate that this rule will also be applicable to specialists. Thus, the Exchange proposes to entitle Rule 510 as ''Good Standing for Specialist, SQT, and RSQT.'' The good standing requirement, which is discussed below, is a continuous requirement rather than a periodic evaluation requirement as in current Rules 510 and 511.[22] The requirements to remain in good standing are discussed in the new language in Rule 510(a). These obligations will be continuous and not periodic. The Exchange will provide written notice to a specialist (including Remote Specialist), SQT, or RSQT of a contemplated action regarding good standing pursuant to Rule 510, as noted below. A specialist (including Remote Specialist), SQT, or RSQT may request and the Exchange may hold an informal meeting to discuss the alleged failure to remain in good standing and to explore possible appropriate remedies. Written notice of the date and time of the meeting will be given to the specialist (including Remote Specialist), SQT, or RSQT and no verbatim record will be kept. If the Exchange believes there are no mitigating circumstances that would demonstrate substantial improvement of or reasonable justification for the failure to meet the good standing requirements of this Rule 510, the Exchange may take appropriate action pursuant to subsection (b) of this Rule 510. This process is described in further detail below. Exchange staff will evaluate good standing which entails continuous compliance with, among other things, Exchange options rules and procedures as well as market making requirements (market making requirements are found in Rule 1014).

Second, Rule 510 currently is written in terms of doing performance evaluations for SQTs and RSQTs. Currently, Rule 507 has a very detailed process for applying for and approving SQTs and RSQTs, and for assigning options to SQTs and RSQTs. In addition, today Rule 501 defines the application and approval process for specialists.[23] To more closely align the Exchange with another options exchange, namely BX Options, the Exchange is adopting language similar to BX Options Rule at Chapter VII, Section 4 (the ''BX Options rule'').[24] Similar to Phlx, BX Options has market makers (''BX Options Market Makers'', which are also known as lead market makers (''LMMs'')). All BX Options Market Makers are designated as specialists on BX for all purposes under the Act or rules thereunder.[25] The Exchange is adopting the BX Options rule and proposing, in lieu of the current formulaic language in Rule 510, to insert new language indicating how a member of the Exchange can remain in good standing on the Exchange. The Exchange believes that this new proposal will obligate market participants that conduct market making activities with continuous requirements to remain in good standing as compared to periodic requirements. The continuous requirements will serve to accentuate the good standing of members who have remained in compliance. The Exchange believes that it is important for market structure for these participants to have continuous

[16] These RSQTO criteria include: (A) Significant market-making and/or specialist experience in a broad array of securities; (B) Superior resources, including capital, technology and personnel; (C) Demonstrated history of stability, superior electronic capacity, and superior operational capacity; (D) Proven ability to interact with order flow in all types of markets; (E) Existence of order flow commitments; (F) Willingness to accept allocations as an RSQT in options overlying 400 or more securities; and (G) Willingness and ability to make competitive markets on the Exchange and otherwise to promote the Exchange in a manner that is likely to enhance the ability of the Exchange to compete successfully for order flow in the options it trades. Rule 507(a)(i).

[17] These SQT and RSQT criteria include: (A) Significant market-making and/or specialist experience in a broad array of securities; (B) Superior resources, including capital, technology and personnel; (C) Demonstrated history of stability, superior electronic capacity, and superior operational capacity; (D) Proven ability to interact with order flow in all types of markets; (E) Willingness and ability to make competitive markets on the Exchange and otherwise to promote the Exchange in a manner that is likely to enhance the ability of the Exchange to compete successfully for order flow in the options it trades; (F) A current affiliation with an Exchange-approved RSQTO (RSQT applicants only). Rule 507(a)(ii).

[18] No application for initial assignment in an option shall be approved without verification that (A) the RSQTO, SQT or RSQT applicant has sufficient technological ability to support his/her continuous quoting requirements as set forth in Rule 1014(b)(ii), and (B) the RSQTO, SQT or RSQT applicant has successfully completed, or is scheduled to complete, testing of its quoting system with the Exchange. Rule 507(b)(ii).

[19] Specialist (and Remote Specialist) eligibility and qualification requirements are discussed in Rules 501, 506, 1014, and 1020.

[20] *See* Securities Exchange Act Release No. 77121 (February 11, 2016), 81 FR 8308 (February 18, 2016) (SR–Phlx–2016–22) (notice of filing and immediate effectiveness to delete Rule 505 and update Rule 506).

[21] Rule 508 will continue to indicate, without reference to Rule 511, that failure to provide the Exchange prior notice of a transfer in accordance with Rule 508, or failure to obtain Exchange approval of a transfer, permits the Exchange to recover the allocated securities and reallocate them pursuant to Rule 506.

[22] Proposed Rule 510, which applies to specialists (including Remote Specialists), SQTs, and RSQTs, discusses that good standing on the Exchange means continuous compliance with, among other things, Exchange options rules and procedures as well as market making requirements (market making requirements are found in Rule 1014). In light of the proposed continuous and extensive good standing requirements per Rule 510 as well as other rule requirements, the old evaluations applicable to SQTs, RSQTs, and specialists are not needed.

[23] Rules 506, 508, and 513 discuss other aspects of the process.

[24] *See* Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (order approving establishment of BX Options and marketplace rules) (SR–BX–2012–030).

[25] *See* BX Options Chapter VII, Section 2.

For obligations of BX Options Market Makers, *see* BX Options Chapter VII, Section 5, entitled ''Obligations of Market Makers.'' This section indicates that BX Options Markets Maker obligations include, but are not limited to: Maintain a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market in transactions where acting in a market making capacity; not make bids or offers or enter into transactions that are inconsistent with such course of dealings; maintain a two-sided market, during trading hours, in those options in which the Market Maker is registered to trade, in a manner that enhances the depth, liquidity and competitiveness of the market; compete with other Market Makers in all options in which the Market Maker is registered to trade; update quotations in response to changed market conditions in all options in which the Market Maker is registered to trade; and maintain active markets in all options in which the Market Maker is registered.

The BX Options Market Maker obligations are similar in nature to those of Phlx specialists, which can be found in Phlx Rule 1014, entitled ''Obligations and Restrictions Applicable to Specialists and Registered Options Traders,'' and include: Maintain a fair and orderly market; not enter into transactions or make bids or offers that are inconsistent with such a course of dealings; quote a two-sided market; and maintain a two-sided market.

requirements to remain in good standing rather than only periodic evaluations.

The proposed new language is similar, in all material respects,[26] to BX Options rule at Chapter VII, Section 4. Specifically, the Exchange proposes to adopt new language in Rule 510(a) to state that to remain in good standing as a specialist (including Remote Specialist), SQT, or RSQT, the specialist, SQT, or RSQT must:

(i) Continue to meet the requirements established in SEC Rule 15c3–1(a)(6)(i),[27] and the requirements set forth in the Series 500 Rules in the Rules of the Exchange;

(ii) continue to satisfy the specialist, SQT or RSQT qualification and market making requirements specified by the Exchange, as amended from time to time;

(iii) comply with the Rules of the Exchange and the Options Rules [28] as well as the rules of The Options Clearing Corporation (''OCC'') and the rules of the Federal Reserve Board [sic] ''FRB''); and

(iv) pay on a timely basis such member, transaction and other fees as the Exchange shall prescribe.[29]

These proposed requirements to remain in good standing on the Exchange are not periodic, as are the evaluation and performance concepts in current Rules 510 and 511, but rather are continuous in nature.

Third, the Exchange notes that with the proposed new good standing requirements, specialist and other market maker (*e.g.,* RSQT) obligations, such as market making, will continue to apply.[30] For specialists (and RSQTs functioning as Remote Specialists) the Rule 1014 market making obligations are applicable throughout the trading day. Thus, a specialist (or Remote Specialist) shall continue to be responsible to quote two-sided markets in the lesser of 99% of the series or 100% of the series minus one call-put pair in each option in which such specialist is assigned. To satisfy this requirement with respect to quoting a series, the specialist must quote such series 90% of the trading day (as a percentage of the total number of minutes in such trading day) or such higher percentage as the Exchange may announce in advance. These obligations will apply collectively to all appointed issues of the specialist, rather than on an issue-by-issue basis. Compliance with this obligation will be determined on a monthly basis. However, determining compliance with the continuous quoting requirement on a monthly basis does not relieve the specialist (including the Remote Specialist) of the obligation to provide continuous two-sided quotes on a daily basis, nor will it prohibit the Exchange from taking disciplinary action against the specialist (including the Remote Specialist) for failing to meet the continuous quoting obligation each trading day.[31]

Fourth, the proposed new language in Rule 510(b) states that the good standing of a specialist (including Remote Specialist), SQT, or RSQT may be suspended, terminated or otherwise withdrawn, as provided in the Exchange's rules, if any of these conditions for approval cease to be maintained or the specialist, SQT, or RSQT violates any of its agreements with the Exchange or any of the provisions of the Rules of the Exchange or of the Options Rules. The Exchange is proposing to add an Informal Meeting process and appeal rights, which do not exist in Rule 510 for specialists at this time.

The Informal Meeting process proposed in Rule 510 is based on the Informal Meeting process in current Rules 510 (for SQTs and RSQTs) and 511 (for specialists), which is in respect of performance evaluations. The Informal Meeting process proposed in Rule 510 is, however, in respect of good standing. Specifically, the Exchange proposes to amend Rule 510 to adopt the following language in Rule 510(b)(i): The Exchange will provide written notice to a specialist (including Remote Specialist), SQT, or RSQT of a contemplated action regarding good standing pursuant to this Rule 510. A specialist (including Remote Specialist), SQT, or RSQT may request and the Exchange may hold an informal meeting to discuss the alleged failure to remain in good standing and to explore possible appropriate remedies. Written notice of the date and time of the meeting will be given to the specialist (including Remote Specialist), SQT, or RSQT and no verbatim record will be kept. If the Exchange believes there are no mitigating circumstances that would demonstrate substantial improvement of or reasonable justification for the failure to meet the good standing requirements of this Rule 510, the Exchange may take appropriate action pursuant to subsection (b) of this Rule 510. Nothing in this Informal Meeting process limits the Exchange from enforcing the rules of the Exchange, which may include a disciplinary action pursuant to such rules. The Regulatory staff may, for example, initiate a disciplinary action pursuant to Rule 960.3 against a member for failure to meet continuous quoting obligations in Rule 1014.[32] The proposed appeal rights in Rule 510(c) are taken from current Rule 511, but expanded to cover specialists (including Remote Specialists), SQTs, and RSQTs.[33] Specifically, the Exchange proposes to amend Rule 510 to adopt the following language in Rule 510(c): An appeal by a specialist (including Remote Specialist), SQT, or RSQT to the Board of Directors from a decision of the Exchange may be requested by a member or member organization interested therein by filing with the Secretary of the Exchange written notice of appeal within ten (10) days after the decision has been rendered. Any appeal from a decision pursuant to Rule 510 may be heard by the Board or a Board Panel composed of three (3) members not materially involved in the Exchange decision appealed from.[34] If a Board

[26] As with virtually all rules text copied from another exchange, changes are made to the proposed rule text to better fit the structure of the existing rules of the Exchange.

[27] SEC Rule 15c–3, 240 CFR 15c3–1, is the net capital requirement for brokers or dealers.

[28] As discussed, while the vast majority of options-related rules are found in Rule 1000 and higher (with option index rules in Rule 1000A and higher), some of the older options-related rules are found in rules below 1000, such as, for example, the Series 500 Rules.

[29] Member assessments are generally reflected in the Phlx Pricing Schedule.

[30] Other obligations include, for example: Order exposure, order handling, and best execution.

[31] *See* Rule 1014(b)(ii)(D)(2).

For the market making obligations of SQTs and RSQTs (including Directed SQT or DRSQTs [sic], and Directed RSQTs or DRSQTs), which remain unchanged, *see* Rule 1014(b)(ii)(D)(1). This rule states that, like for specialists, compliance for SQTs and RSQTs will be determined on a monthly basis. However, determining compliance with the continuous quoting requirement on a monthly basis does not relieve an SQT, RSQT, DSQT, or DRSQT of the obligation to provide continuous two-sided quotes on a daily basis, nor will it prohibit the Exchange from taking disciplinary action against an SQT, RSQT, DSQT, or DRSQT for failing to meet the continuous quoting obligation each trading day. Rule 1014(b)(ii)(D)(1).

[32] Specifically, the Exchange may pursue disciplinary process against a member that commits an egregious market making violation evidenced by a pattern of repeated failure to make a two-sided market in assigned options.

[33] The SQT and RSQT appeal rights to the Board currently in Rule 510 are limited to apply only in respect of performance evaluations. The Exchange believes that the appeal rights afforded SQTs and RSQTs in proposed Rule 510, which will be to the Board or a Board Panel, are appropriate in that they are expanded to cover any decision of the Exchange regarding Rule 510; and, an informal meeting process is also afforded prior to appeal. The Board or a Board Panel would serve as a secondary appeal to a group of individuals that were not involved in the primary decision making. The Exchange is seeking to afford its members due process when seeking an appeal.

[34] Rule 511(f) now states, in relevant part, that any appeal from a decision pursuant to Rule 511 regarding evaluation or review shall be heard by a special committee of the Board of Directors

Continued

Panel is appointed by the Board, three persons shall be selected to serve on the Board Panel and in making such selections the Board shall, to the extent practicable, choose individuals whose background, experience and training qualify them to consider and make determinations regarding the subject matter to be presented to the Board Panel. The Board Panel shall consist of two members of the Exchange, or general partners or officers of member organizations and one other person who would qualify as a public member as defined in Article I of the By-Laws, whom the Board considers to be qualified. The person requesting review shall be permitted to submit a written statement to and/or appear before the Board or Board Panel. The Secretary of the Exchange shall certify the record of the proceeding, if any, and the written decision, and shall submit these documents to the Board or Board Panel. The Board's or Board Panel's review of the action shall be based solely on the record, the written decision and any statement submitted by the person requesting the review. The Board or Board Panel shall prepare and deliver to such person a written decision and reasons therefore. If the Board or Board Panel affirms the action, the action shall become effective ten (10) days from the date of the Board Panel's decision. There shall be no appeal to the Board from any decision of the Board Panel.[35]

The memorialization of appeal rights in proposed Rule 510(c) is done to ensure that if the good standing of a specialist, SQT, or RSQT is suspended, terminated or otherwise withdrawn then they have a clear way to initiate and prosecute an appeal regarding such decision. The proposed due process methodology is similar to other rules of the Exchange. By proposing new language in Rule 510(a) and (b) regarding specialists, SQTs, and RSQTs regarding good standing, which is similar to that of BX Options, the continuous good standing rules of the Exchange and BX Options will be more aligned and easier to apply. Proposed Rule 510 describes an Informal Meeting process and appeal rights applicable to specialists (including Remote Specialists), SQTs, and RSQTs. The Exchange is replacing the current *periodic* evaluation or performance requirements in Rule 510 (*e.g.,* monthly for SQTs and RSQTs), as also in Rule 511 (*e.g.,* annually for specialists) as discussed, with the proposed Rule 510 *continuous* requirements for specialists (including Remote Specialists), SQTs, and RSQTs to meet Exchange, Commission, OCC and FRB rules and requirements to remain in good standing. Compliance with good standing requirements is monitored across the Exchange.[36]

Deleting Rule 511

The Exchange has concluded that, with the placement of the good standing concepts into proposed Rule 510 in such a way that they include specialist (and Remote Specialist), Rule 511 is no longer needed. In Rule 510, as discussed, in lieu of the current language, the Exchange is proposing to adopt new language indicating how a member of the Exchange can remain in good standing.

The proposed new language in Rule 510 is, in all material respects, similar to the BX Options rule at Chapter VII, Section 4. Because of this proposed new language in Rule 510, which addresses specialists (as also Remote Specialists, RSQTs, and SQTs), the Exchange proposes to delete Rule 511 in its entirety. The Exchange believes that, within the effort to update and consolidate the Series 500 Rules as discussed, it is reasonable and proper to delete Rule 511. This rule was established decades ago for the purpose of dealing with the extensive on-floor open outcry specialist system, with multiple competing specialist units. Since the implementation of Rule 511, the open outcry options floor has evolved into a robust and competitive principally electronic system, and the remaining hybrid options floor does not have numerous competing specialists as was the case when Rule 511 was instituted.

The Exchange believes that under the circumstances, and because specialists are proposed to be covered in Rule 510 in terms of good standing, and continue to be covered in the Series 500 Rules and other rules of the Exchange,[37] deletion of Rule 511 is proper.

As discussed, the Exchange is deleting the performance evaluation structure of Rule 511 and is proposing to relocate the concept within Rule 510 with the proposed good standing requirement and appeal rights applicable to specialists, SQTs, and RSQTs. The Exchange believes that the proposed good standing approach, which is applicable to specialists, SQTs, and RSQTs, enhances the current rule because unlike the periodic nature of the performance evaluation structure the proposed good standing approach would have continuous requirements that must be maintained in order to remain in good standing on the Exchange (*e.g.,* compliance with the equity and options rules of the Exchange, OCC, and FRB).

As discussed, options trading on the Exchange has developed into a robust hybrid system that is currently largely electronic and off-floor. The Exchange continues to have an open outcry trading floor, however, rather than a proliferation of competitive specialists on the options floor as was the case when Rule 511 was instituted: There is currently one specialist unit on the options floor and therefore Rule 511 is not needed. In the past, when so many specialists conducted business on the options floor, Rule 511 served a purpose. Today, Rule 511, with its specialist evaluation process and allocation process constructed for multiple competitive specialists on the floor, is no longer needed with one specialist unit on the floor.[38] As such, in light of the current realities of the options floor Rule 511 is obsolete, particularly in light of numerous rules

composed of three (3) Directors, of whom at least one (1) shall be an Independent. The Exchange believes that, as discussed, the old independence requirement is no longer needed when Rule 510 is restructured. Commensurate with other proposed changes discussed herein, Rule 510 appeals can be heard by the Board or a Board Panel.

[35] The appeal process in proposed Rule 507(e) is amended to reflect an appeal to the Board or a Board Panel.

[36] Thus, in Rule 510 the Exchange is proposing an Informal Meeting process and appeal rights applicable to specialists (including Remote Specialists), SQTs, and RSQTs. And, the Exchange is replacing the current *periodic* evaluation or performance requirements in Rule 510 (*e.g.,* monthly for SQTs and RSQTs), as also in Rule 511 (*e.g.,* annually for specialists) as discussed, with the proposed Rule 510 *continuous* requirements for specialists (including Remote Specialists), SQTs, and RSQTs to meet Exchange, Commission, OCC and FRB rules and requirements to remain in good standing. Compliance with good standing requirements is monitored across the Exchange. Thus, for example, units that monitor the application, allocation, and fees requirements and processes include membership, listing, and finance groups. And the surveillance group will continue to use its current processes to monitor compliance with Exchange rules and where appropriate will pursue disciplinary action against members for rule violations(s) (*e.g.,* failure to make two-sided market(s) per Phlx Rule 1014). Moreover, while proposed Rule 510 is being changed the market making and other obligations for specialists, SQTs, and RSQTs continue as discussed.

[37] *See, e.g.,* Rule 501 (Specialist Appointment); Rule 506 (Allocation Application, Allocation, Reallocation, and Transfer); Rule 508 (Transfer Application); and Rule 513 (Voluntary Resignation of Options Privileges). *See also, e.g.,* Rule 1022 (Securities Accounts and Orders of Specialists and Registered Options Traders; and Rule 1020 (Registration and Functions of Options Specialists), which discusses on-floor options specialists and electronic Remote Specialists.

[38] The Exchange believes that even if additional floor specialists begin to conduct business on the options floor, Rule 511 was designed for a very different competitive floor environment and is not needed, particularly in light of proposed Rule 510 and the numerous other Exchange rules applicable to options specialists.

in the Phlx rulebook that apply to specialists.

The many rules that continue to apply to specialists discuss topics such as application, approval, allocation, re-allocation, market making, and obligations of specialists. For example, Rule 501 as proposed discusses the specialist allocation process and specialist approval process. To be an approved specialist unit and retain the privilege of such status, for example, a specialist unit must maintain the approved clearing arrangements and capital structure stated on their application and changes regarding certain requirements must be submitted and approved by the Exchange. In addition, each unit must consist of at least one head specialist and one assistant specialist that must be associated with the specialist unit; the Exchange, in its discretion, may require a unit to obtain additional staff depending upon the number of assigned options classes and associated order flow. Rule 506 discusses allocation application, reallocation of a previously allocated options, and transfer of allocated options.[39] Rule 506 also discusses that, in addition to a minimum allocation period of one year, the Exchange may establish an ''alternate specialist period'' period of less than one year to act as a specialist in an options class. Rule 508 as proposed discusses the Exchange approval process if there is agreement between or among specialist units to transfer one or more options classes already allocated to a specified specialist unit. Rule 513, which is not proposed to be amended with this filing, discusses the process if an option specialist unit voluntarily resigns from allocation in a particular option and there is a future allocation regarding such option.[40] In addition, Rule 1014 discusses the obligations and restrictions applicable to specialists and registered options traders during each trading day; these obligations and restrictions include, as discussed above, very specific market making requirements. Finally, Rule 1022 discusses securities accounts and orders of specialists and registered options traders and proper identification of accounts, reporting of options, and orders of underlyings.[41]

The Exchange believes that the changes to the noted rules in the Series 500 Rules will make remaining Rules 501, 507, 508, and 510 easier to apply, clearer and better.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[42] in general, and furthers the objectives of Section 6(b)(5) of the Act,[43] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest by proposing to make changes to five rules in the Series 500 Rules as discussed. The proposed rule change is designed to promote just and equitable principles of trade by updating and modernizing the Series 500 Rules and making them clearer and easier to use while continuing to protect investors and the public interest.

In particular, the Exchange is proposing to change Rule 501 to delete reference to a back-up specialist. With the development of liquidity-enhancing electronic market makers on the Exchange such as RSQTs, which make markets in the same options issues as specialists, and the diminution of the role that the specialist plays in managing the order book on the Exchange, both a back-up specialist and substitute specialist are no longer needed. The Exchange believes that this proposal amendment is consistent with the Act because the advent of streaming quote traders on the Exchange served to perfect the mechanism of a free and open market because of the liquidity that such participants brought to Phlx. These participants are obligated to continuously quote in the market and have filled a role which was previously reliant on a back-up specialist and a substitute specialist.

Obsolete language in Rule 501 in respect of back-up specialists, which includes Commentary .01 to Rule 501, is proposed to be deleted from Rule 501. Similarly, the Exchange is proposing to change Rule 508 to delete the cross reference to Rule 511 and references to ''lease.'' As discussed, with the change in Rule 510 to the good standing standard that applies to specialists as well as SQTs and RSQTs, Rule 511 is proposed to be deleted and therefore the reference is no longer needed. Moreover, leasing is no longer permitted on the Exchange, and for this reason the Exchange is proposing to delete this obsolete term from Rule 508. The Exchange believes it is consistent with the Act to delete obsolete references which serve to confuse members within the Rulebook.

The Exchange is proposing to amend Rule 507(a) to permit the Exchange, instead of the Board to defer approval of qualifying applications for SQT or RSQT status pending any action required to address the issue of concern to the Exchange. The applicant would have a right of appeal to the Board or a Board Panel of any action of Exchange staff pursuant to Rule 507(e). The Exchange believes that the application process should be handled by staff initially with appellate rights to the Board or a Board Panel. Currently Rule 507 states that the Board has the ability to perform functions such as deferring or limiting approval of SQTs or RSQTs. The Exchange believes that this amendment is consistent with the Act because it will change [sic] will promote just and equitable principles of trade by serving the administration and application of Rule 507 and permitting a right of appeal as provided in Rule 507(e).

With respect to Rule 507(e), the Exchange proposes to expand the appeal to either the Board or a Board Panel. Currently, Rule 507(e) states that an appeal shall be heard by a special committee of the Directors composed of three Directors, of whom at least one (1) shall be an Independent. The Exchange proposes to state that the appeal may be heard by a panel appointed by the Board composed of three (3) members not materially involved in the Exchange decision appealed from. If a panel is appointed by the Board, three persons shall be selected to serve on the panel and in making such selections the Board shall, to the extent practicable, choose individuals whose background, experience and training qualify them to consider and make determinations regarding the subject matter to be presented to the panel. The panel shall consist of two members of the Exchange, or general partners or officers of member organizations and one other person who would qualify as a public member as defined in Article I of the By-Laws, whom the Board considers to be qualified. The Exchange believes that this amendment is consistent with the Act because the Board or a Board Panel

[39] *See* Securities Exchange Act Release No. 77121 (February 11, 2016), 81 FR 8308 (February 18, 2016) (SR–Phlx–2016–22) (notice of filing and immediate effectiveness to delete Rule 505 and update Rule 506).

[40] One rule in the Series 500 Rules does not specifically deal with specialists. This is Rule 507, which was discussed above. This rule deals with the application and approval process for SQTs, RSQTs, or RSQTOs, and the assignment of options.

[41] The Exchange has previously discussed that the allocation and evaluation process in Rule 511 proposed to be deleted made sense when the rule was established with multiple competitive specialists on the floor, but is no longer needed in light of the current composition of the floor.

[42] 15 U.S.C. 78f(b).

[43] 15 U.S.C. 78f(b)(5).

would allow a path of impartial appeal for the applicant.

Also, currently Rule 507(b) states that when making a decision concerning an application for assignment in an option the Exchange shall consider the applicant's prior performance as a specialist, SQT or RSQT based on evaluations conducted pursuant to Exchange Rule 510. The Exchange proposes to update Rule 510 so that in lieu of the current formulaic language in the rule, there is new language that accentuates the good standing of members. In light of this, the Exchange proposes to update the 507(b) reference to state that the Exchange can consider the applicant's prior performance as a specialist, SQT or RSQT based on ''good standing pursuant to Rule 510.'' The Exchange believes that this amendment is consistent with the Act because it will consider a more holistic approach in evaluating members that engage in market making activities. The Exchange believes that this approach is broader and will take new factors into account which would serve to promote just and equitable principles of trade in evaluating market participants that engage in market making activities by considering their obligations and past performance.

The Exchange is proposing to update Rule 510 to give it a new title, ''Good Standing for Specialist, SQT, and RSQT,'' to add relevant good standing language, and appeal rights. The Exchange proposes to amend the language of Rule 510 to indicate that, with the deletion of Rule 511, Rule 510 will also be applicable to specialists. The Exchange proposes to change the language of Rule 510 to more closely align the Exchange with BX Options by adopting language from the BX Options rule at Chapter VII, Section 4. BX Options Market Makers are held to good standing standards per the BX Options rule. Specialists on Phlx are another type of market maker. The Exchange believes that these amendments are consistent with the Act because these changes serve to add clarity and transparency to the rule text.

The Exchange is adopting language from BX Options at Chapter VII, Section 4. Specifically, the Exchange proposes new language in Rule 510(a) to state that to remain in good standing on the Exchange as a specialist (including Remote Specialist), SQT, or RSQT, the specialist, SQT, or RSQT must meet specific requirements set forth in the rule.[44] As discussed, the proposed new good standing language in Rule 510 will be, in all material respects, similar to BX Options rules at Chapter VII, Section 4. This makes particular sense because all BX Options Market Makers are designated as specialists on BX for all purposes under the Act or rules thereunder and, like Phlx specialists, have market making obligations.[45] The Exchange believes that the good standing rule text is consistent with the Act because as described above the Exchange believes that this approach is broader and will take new factors into account which would serve to promote just and equitable principles of trade in evaluating market participants that engage in market making activities by considering their obligations and past performance.

The Exchange is proposing to add an Informal Meeting process and appeal rights, which do not exist in Rule 510 for specialists; as discussed, the appeal rights now in Rule 510 are regarding SQTs and RSQTs only in respect of performance evaluations. These proposed appeal rights for a specialist (including Remote Specialist), SQT, or RSQT, which are set forth in Rule 510(c) for, are adopted from Rule 511. The memorialization in Rule 510 of Informal Meeting process and appeal rights is done to affirm that if the good standing of a specialist, SQT, or RSQT is suspended, terminated or otherwise withdrawn then they have a clear way to meet with the Exchange to discuss the issue and initiate and prosecute an appeal regarding such decision. The Exchange's proposal to expand the role of the Board to permit an appeal to be heard by a Board Panel appointed by the Board composed of three (3) members not materially involved in the Exchange decision appealed from is consistent with the Act because the Board or a Board Panel would allow a path of impartial appeal for the applicant.[46]

The Exchange has concluded that, with the placement of the good standing concepts into proposed Rule 510 in such a way that they include a specialist (and Remote Specialist), Rule 511 is no longer needed and is therefore proposed to be deleted in its entirety (with transfer of specialist appeal rights from Rule 511 to Rule 510).

The Exchange is proposing to delete Rule 511. This rule was established decades ago for the purpose of dealing with the extensive on-floor open outcry specialist system, with multiple competing specialist units. Since the implementation of Rule 511, the open outcry options floor has evolved into a robust and competitive system that is principally electronic, and the remaining hybrid options floor does not have numerous competing specialists as was the case when Rule 511 was instituted. The Exchange believes that because of the extensive changes on the option floor (from having numerous competitive specialist units on the old options floor to having a specialist unit on the current options floor), and because specialists are proposed to be covered in Rule 510 in terms of good standing and continue to be covered in the Series 500 Rules and other rules of the Exchange, it is consistent with the Act and promotes just and equitable principles of trade to delete Rule 511.

Furthermore, numerous rules in the Phlx Rulebook continue to apply to specialists (as well as to other registered options traders). For example, Rule 501 as proposed discusses the specialist allocation process and specialist approval process. Rule 506 discusses allocation application, reallocation of previously allocated options, and transfer of allocated options. Rule 508 as proposed discusses the Exchange approval process if there is agreement between or among specialist units to transfer one or more options classes already allocated to a specified specialist unit. Rule 513, which is not proposed to be amended with this filing, discusses the process if an option specialist unit voluntarily resigns from allocation in a particular option and there is a future allocation regarding that option. Rule 1014 discusses the obligations and restrictions, including specific market making requirements, that are applicable to specialists each trading day. Finally, Rule 1022 discusses proper identification of accounts, reporting of options, and orders of underlyings in respect of securities accounts and orders of specialists and ROTs.

[44] The specific good standing requirements are: (i) Continue to meet the requirements established in SEC Rule 15c3–1(a)(6)(i), and the requirements set forth in the Series 500 Rules in the Rules of the Exchange; (ii) continue to satisfy the specialist, SQT or RSQT qualification requirements specified by the Exchange, as amended from time to time; (iii) comply with the Rules of the Exchange and the Options Rules as well as the rules of the Options Clearing Corporation and the rules of the Federal Reserve Board; and (iv) pay on a timely basis such member, transaction and other fees as the Exchange shall prescribe. Proposed Rule 510(a).

[45] *See, e.g., supra* note 24 [sic] and accompanying discussion.

[46] If a Board Panel is appointed by the Board, three persons shall be selected to serve on the Board Panel and in making such selections the Board shall, to the extent practicable, choose individuals whose background, experience and training qualify them to consider and make determinations regarding the subject matter to be presented to the Board Panel. The Board panel shall consist of two members of the Exchange, or general partners or officers of member organizations and one other person that would qualify as a public member as defined in Article I of the By-Laws, whom the Board considers to be qualified.

The Exchange believes that the changes to the noted rules in the Series 500 Rules will make remaining Rules 501, 507, 508, and 510 easier to apply, clearer and more transparent. Such proposed changes are in consistent with the Act, the public interest, and continue to serve to protect investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. While the Exchange does not believe that the proposed change is a burden on competition, or is competitive in nature, the Exchange believes that clearer, updated, modernized, and better-conforming rules that do not refer to obsolete concepts are always beneficial to market participants, are in the public interest, and serve to protect investors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–105. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–105, and should be submitted on or before January 30, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00100 Filed 1–6–17; 8:45 am]

BILLING CODE 8011–01–P

[47] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79725; File No. SR–BatsBZX–2016–30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, to List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust

January 4, 2017.

On June 30, 2016, Bats BZX Exchange, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade Winklevoss Bitcoin Shares issued by the Winklevoss Bitcoin Trust under BZX Rule 14.11(e)(4). The proposed rule change was published for comment in the **Federal Register** on July 14, 2016.[3]

On August 23, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On October 12, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7] On October 20, 2016, the Exchange filed Amendment No. 1 to the proposed rule change, and Amendment No. 1 was published for comment in the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78262 (Jul. 8, 2016), 81 FR 45554.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78653, 81 FR 59256 (Aug. 29, 2016). The Commission designated October 12, 2016, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 79084, 81 FR 71778 (Oct. 18, 2016). Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' *See id.,* 81 FR at 71781.

Federal Register on November 3, 2016.[8] The Commission has received 30 comment letters on the proposed rule change.[9]

Section 19(b)(2) of the Act[10] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on July 14, 2016. January 10, 2017 is 180 days from that date, and March 11, 2017 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[11] designates March 11, 2017 as the date by which the Commission should either approve or disapprove the proposed rule change (File No. SR–BatsBZX–2016–30), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00101 Filed 1–6–17; 8:45 am]

BILLING CODE 8011–01–P

[8] *See* Securities Exchange Act Release No. 79183 (Oct. 28, 2016), 81 FR 76650 (Nov. 3, 2016).

[9] *See* Letters from Robert D. Miller, VP Technical Services, RKL eSolutions (July 11, 2016); Jorge Stolfi, Full Professor, Institute of Computing UNICAMP (July 13, 2016); Guillaume Lethuillier (July 26, 2016); Michael B. Casey (July 31, 2016); Erik A. Aronesty, Sr. Software Engineer, Bloomberg LP (Aug. 2, 2016); Dan Anderson (Aug. 27, 2016); Robert Miller (Oct. 12, 2016); Lysle Shaw-McMinn, O.D. (Oct. 13, 2016); Nils Neidhardt (Oct. 13, 2016); Dana K. Barish (2 letters; Oct. 13, 2016); Xin Lu (Oct. 13, 2016); Rodger Delehanty CFA (Oct. 14, 2016); Dylan (Oct. 14, 2016); Dana K. Barish (Oct. 14, 2016); Dana K. Barish (2 letters; Oct. 15, 2016); Jorge Stolfi, Full Professor, Institute of Computing UNICAMP (Nov. 1, 2016); Michael B. Casey (Nov. 5, 2016); Anonymous (Nov. 8, 2016); Chris Burniske, Blockchain Products Lead, ARK Investment Management LLC (Nov. 8, 2016); Colin Keeler (Nov. 14, 2016); Robert S. Tull, (Nov. 14, 2016); Mark T. Williams (Nov. 15, 2016); Anonymous (Nov. 21, 2016); XBT OPPS Team (Nov. 21, 2016); Anonymous (Nov. 22, 2016); Ken Maher (Nov. 22, 2016); Kyle Murray, Assistant General Counsel, Bats Global Markets, Inc. (Nov. 25, 2016); and Colin Baird (Nov. 26, 2016). All comments on the proposed rule change are available on the Commission's Web site at: *https://www.sec.gov/comments/sr-batsbzx-2016-30/batsbzx201630.shtml.*

[10] 15 U.S.C. 78s(b)(2).

[11] *Id.*

[12] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79726; File No. SR–NYSEArca–2016–101]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change Relating to the Listing and Trading of Shares of SolidX Bitcoin Trust Under NYSE Arca Equities Rule 8.201

January 3, 2017.

On July 13, 2016, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the SolidX Bitcoin Trust under NYSE Arca Equities Rule 8.201. The proposed rule change was published for comment in the **Federal Register** on August 2, 2016.[3]

On September 6, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On October 27, 2016, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[6] The Commission has received seven comments on the proposed rule change.[7]

Section 19(b)(2) of the Act[8] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on August 2, 2016. January 29, 2017 is 180 days from that date, and March 30, 2017 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[9] designates March 30, 2017 as the date by which the Commission should either approve or disapprove the proposed rule change (File No. SR–NYSEArca–2016–101).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00102 Filed 1–6–17; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78426 (Jul. 27, 2016), 81 FR 50763 (Aug. 2, 2016).

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78770, 81 FR 62780 (Sept. 12, 2016).

[6] *See* Securities Exchange Act Release No. 79171, 81 FR 76400 (Nov. 2, 2016). Specifically, the Commission instituted proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' *See id.* at 76401.

[7] *See* Letters from Daniel H. Gallancy, CFA, SolidX Management LLP (Nov. 23, 2016); Thaya B. Knight, Associate Director, Financial Regulation Studies, The Cato Institute (Dec. 1, 2016); Jerry Brito, Executive Director, Coin Center (Dec. 7, 2016); Joseph Colangelo, President, Consumers' Research (Dec. 7, 2016); Denise Krisko, CFA, President and Co-Founder, Vident Investment Advisory, LLC (Dec. 7, 2016); Balaji Srinivasan, Chief Executive Officer & Cofounder, 21, *et al.* (Dec. 7, 2016); and Ken I. Maher (Dec. 8, 2016). All comments on the proposed rule change are available on the Commission's Web site at: *https://www.sec.gov/comments/sr-nysearca-2016-101/nysearca2016101.shtml.*

[8] 15 U.S.C. 78s(b)(2).

[9] *Id.*

[10] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79720; File No. SR–NYSEMKT–2016–102]

Self-Regulatory Organizations; NYSE MKT LLC; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Introducing NYSE OptX

January 3, 2017.

I. Introduction

On November 3, 2016, NYSE MKT LLC, on behalf of NYSE Amex Options (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce NYSE OptX, an order entry platform that will allow for the submission of Qualified Contingent Cross (''QCC'') Orders and orders executed in the Exchange's Customer Best Execution (''CUBE'') Auction by ATP Holders. On November 15, 2016, the Exchange filed Amendment No. 1 to the proposal.[3] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on November 22, 2016.[4] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change

The Exchange proposes to introduce NYSE OptX, an order entry platform that will allow ATP Holders to submit QCC Orders and CUBE Orders (collectively, ''paired orders'') to the Exchange.[5] According to the Exchange, ATP Holders currently send paired orders to the Exchange through the use of third-party front end order management systems or by calling Floor Brokers and relaying their orders by telephone.[6]

According to the Exchange, NYSE OptX is an order entry platform that will utilize a combination of Instant Messaging (''IM'') and browser-based technology to allow ATP Holders to submit paired orders for execution on the Exchange's trading system.[7] To execute a paired order through NYSE OptX, an ATP Holder will send the order in plain text to NYSE OptX,[8] which will then translate the message into a pre-populated order ticket with details of the order and return the order ticket to the ATP Holder in a browser-based URL. The ATP Holder will then confirm the order ticket and submit the order to the Exchange for execution, or send the order to a Floor Broker for execution. After an order is executed on the Exchange, NYSE OptX will remit details of the execution back to the ATP Holder.

According to the Exchange, NYSE OptX is designed as an alternative to front end order management systems and the use of telephones for the sending of paired orders to the Exchange.[9] The Exchange notes that NYSE OptX will not provide ATP Holders with the capability to send any other type of orders or the capability to send paired orders for execution to other options markets.[10] Further, ATP Holders will continue to be able to submit paired orders through the use of a third-party front end order management system, or by telephone, as they currently do.[11] The Exchange notes that use of OptX to send paired orders is optional and voluntary.[12]

The Exchange stated that it will announce the effective date of NYSE OptX in a Trader Update to be published no later than 90 days following approval of this proposal, and that such effective date will be no later than 270 days following publication of the Trader Update.[13]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [14] and the rules and regulations thereunder applicable to a national securities exchange.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[16] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Commission notes that, according to the Exchange, NYSE OptX will provide ATP Holders an alternative to third-party front end order management systems and the use of telephones to send paired orders to the Exchange.[17] Such an alternative may help protect the interests of investors by offering ATP Holders an additional way to send paired orders to the Exchange for execution. The Commission notes that the use of OptX will be entirely voluntary and ATP Holders will still be able to submit paired orders as they do today, either through the use of third-party front end order management systems or by telephone. For these reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act and the rules

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange clarified that QCC Orders sent through NYSE OptX to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange, which are set forth in Exchange Rule 955NY.

[4] *See* Securities Exchange Act Release No. 79328 (November 16, 2016), 81 FR 83888 (''Notice'').

[5] The term ''ATP Holder'' refers to a natural person, sole proprietorship, partnership, corporation, limited liability company, or other organization, in good standing, that has been issued an ATP. An ATP Holder must be a registered broker or dealer pursuant to Section 15 of the Act. *See* Exchange Rule 900.2NY.(5).

[6] *See* Notice, *supra* note 4, at 83889.

[7] *See id.* The Exchange represents that NYSE OptX will not require any changes to the Exchange's communication or surveillance rules. *Id.* at 83889, n.8.

[8] The Exchange states that ATP Holders will be required to provide all the essential information regarding the paired order when sending the order to NYSE OptX, including the price of the option and the stock, the size and side of the order, and delta. The Exchange further represents that QCC Orders sent to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange. *See* Notice, *supra* note 4, at 83889, n.10. *See also* Exchange Rule 955NY—Order Format and System Entry Requirements.

[9] *See* Notice, *supra* note 4, at 83889.

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See id.*

[14] 15 U.S.C. 78f.

[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] *See* Notice, *supra* note 4, at 83889. As stated above, the Exchange represented that ATP Holders will be required to provide all the essential information regarding the paired order when sending the order to NYSE OptX and QCC Orders sent to the Exchange for execution will comply with the order format and EOC entry requirements established by the Exchange. *Id.* at 83889, n.10.

and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[18] that the proposed rule change (SR–NYSEMKT–2016–102), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00098 Filed 1–6–17; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79718; File No. SR–BatsEDGX–2016–41]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Related to the Exchange's Equity Options Platform To Adopt a Price Improvement Auction, the Bats Auction Mechanism

January 3, 2017.

I. Introduction

On September 16, 2016, Bats EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change for the Exchange's equity options platform (''EDGX Options'') to adopt a price improvement auction, the Bats Auction Mechanism. The proposed rule change was published for comment in the **Federal Register** on October 5, 2016.[3] The Commission received no comments regarding the proposal. On November 17, 2016, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[4] On December 15, 2016, EDGX filed Amendment No. 1 to the proposal.[5] The Commission is publishing this notice to solicit comment on Amendment No. 1 from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis, with certain provisions subject to a pilot period scheduled to expire on January 18, 2017.

II. Description of the Proposal, as Amended

EDGX proposes to establish a price-improvement auction, the Bats Auction Mechanism (''BAM,'' ''BAM Auction,'' or ''Auction'') on the Exchange's equity options platform, in which an Exchange Member (an ''Initiating Member'') may electronically submit for execution a two-sided paired order, where one side is an order it represents as agent on behalf of a Priority Customer,[6] broker-dealer, or any other person or entity (''Agency Order'') and the other side is principal interest or any other order it represents as agent (an ''Initiating Order'') provided that the Member first exposes the Agency Order in the BAM Auction pursuant to the proposed Rule.

A. Auction Eligibility Requirements

All options traded on the Exchange are eligible for BAM.[7] To initiate a BAM Auction, an Initiating Member first must ''stop'' the Agency Order such that: (A) If the Agency Order is for less than 50 option contracts and the difference between the National Best Bid and Offer (''NBBO'') is $0.01, the Initiating Member must stop the entire Agency Order at one minimum price improvement increment better than the NBBO; or (B) for any other Agency Order, the Initiating Member must stop the entire Agency Order at the better of the NBBO or the Agency Order's limit price. In addition, if the EDGX BBO on the same side of the market as the Agency Order represents a Priority Customer order on the book, the stop price must be at least $0.01 better than the booked order's limit price. If the EDGX BBO on the same side of the market as the Agency Order represents a quote or order that is not a Priority Customer order on the book, the stop price must be at least $0.01 better than the booked order's limit price unless the Agency Order is a Priority Customer order and the Customer Overlay set forth in Rule 21.8(d)(1) is in effect.[8] In addition, Auctions in the same series of Agency Orders for less than 50 contracts may not queue or overlap in any manner; however, Auctions of Agency Orders for 50 contracts or more will be allowed to occur at the same time as other Auctions (of any size Agency Order) in the same series.[9] Finally, an

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78988 (September 29, 2016), 81 FR 69172.

[4] *See* Securities Exchange Act Release No. 79339, 81 FR 84625 (November 23, 2016).

[5] In Amendment No. 1, EDGX provided additional details to its proposal and made certain changes to original aspects of the proposal. Specifically, the proposal as revised would: (i) Restrict an Auction from commencing with a stop price equal to a same side resting order unless the resting order is not a Priority Customer order, the Exchange's ''Customer Overlay'' is in effect, and the incoming Agency Order is a Priority Customer order; (ii) prohibit an Initiating Order from being a solicited order for the account of an Options Market Maker assigned in the affected series on the Exchange; (iii) describe a survey conducted by the Exchange regarding the ability of participants to respond to an Auction lasting no less than one hundred milliseconds and no more than one second; (iv) provide additional explanation and justification of certain aspects of the proposal, including additional examples describing Auction processing and order allocation in various scenarios and details regarding the handling of overlapping Auctions for 50 contracts or more; and (v) make other minor structural, technical, and clarifying amendments to the proposal and the proposed rule text that EDGX believes does not result in any material differences over its original proposal. Amendment No. 1 amends and replaces the original filing in its entirety. To promote transparency of its proposed amendment, when EDGX filed Amendment No. 1 with the Commission, it also submitted a comment letter to the file with a brief description of Amendment No. 1, which the Commission posted on its Web site and placed in the public comment file for SR–BatsEDGX–2016–41. The Exchange also posted a copy of its Amendment No. 1 on its Web site when it filed the amendment with the Commission.

[6] A ''Priority Customer'' means any person or entity that is not: (A) A broker or dealer in securities; or (B) a Professional. The term ''Priority Customer Order'' means an order for the account of a Priority Customer. *See* EDGX Rule 16.1(a)(45). A ''Professional'' is any person or entity that: (A) Is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members. *See* EDGX Rule 16.1(a)(46).

[7] *See* proposed EDGX Rule 21.19(a).

[8] According to the Exchange, this condition is consistent with the operation of the Exchange generally, where Priority Customer orders receive a priority advantage over all other orders. *See* Amendment No. 1, *supra* note 5. *See also* EDGX Rule 21.8(d)(1), which specifies that when the Customer Overlay is in effect, Priority Customer Orders shall have priority over orders on behalf of all other types of participants (''non-Customers'') at the same price. The Exchange noted that the Customer Overlay is currently in effect with respect to all options traded on the Exchange. *See* Amendment No. 1, *supra* note 5.

[9] In its proposal, the Exchange notes that although it is possible for one or more Auctions for 50 contracts or more to overlap, each Auction will be started in a sequence and will have a distinct conclusion at which time the Auction will be allocated. Therefore, when the first Auction concludes, unrelated orders that then exist will be considered for participation in that Auction. If there is remaining unrelated order interest after the first Auction has been allocated, then such unrelated order interest will be considered for allocation when the subsequent Auction is processed. If there are multiple Auctions underway that are each terminated early pursuant to proposed EDGX Rule 21.19(b)(2)(B) or (C), the Auctions will be processed sequentially based on the order in which they commenced. *See* Notice, *supra* note 3, at 69178–79 and Amendment No. 1, *supra* note 5. *See also*

Agency Order may not be a solicited order for the account of any Options Market Maker assigned in the affected series.[10] Agency Orders that do not comply with the aforementioned auction eligibility requirements will be rejected. In addition, Agency Orders submitted at or before the opening of trading or when the NBBO is crossed are not eligible to initiate an Auction and will be rejected.

B. Auction Process

To initiate the Auction, the Initiating Member must mark the Agency Order for Auction processing, and specify either: (A) A single price at which it seeks to execute the Agency Order (a ''single-price submission''); (B) that it is willing to automatically match as principal or as agent on behalf of an Initiating Order the price and size of all BAM Auction Notification responses (''BAM responses'') and other trading interest (''auto-match'') as follows: (i) Stopping the entire order at a single stop price and auto-matching BAM responses and other trading interest at all prices that improve the stop price to a specified price; or (ii) stopping the entire order at a single stop price and auto-matching all BAM responses and other trading interest at all prices that improve the stop price. Once the Initiating Member has submitted an Agency Order for exposure in the Auction, such Agency Order may not be modified or cancelled.

Under no circumstances will the Initiating Member receive an allocation percentage, at the final price point, of more than 50% of the initial Agency Order in the event there is one competing quote, order, or BAM response or 40% of the initial Agency Order in the event there are multiple competing quotes, orders, or BAM responses.[11] However, when starting an Auction, the Initiating Member may submit the Agency Order with a designation of ''last priority'' to other BAM participants (''Last Priority''), which will result in the Initiating Member forfeiting priority and trade allocation privileges. If Last Priority is specified, the Initiating Order would trade only if there were not enough interest available to fully execute the Agency Order at prices which are equal to or improve upon the stop price.[12] Last Priority information would not be available to other market participants and may not be modified after the order is submitted to the Auction.

When the Exchange receives an Agency Order for Auction processing, an auction notification message detailing the side, size, price, and options series of the Agency Order would be sent over the Exchange's Multicast PITCH Feed and Auction Feed. BAM Auctions would be for a specified duration of no less than one hundred milliseconds and no more than one second, as determined by the Exchange and announced on the Exchange's Web site.[13] Any person or entity other than the Initiating Member may submit a response to the Auction, provided such response is properly marked specifying price, size, side of the market, and information identifying the Auction to which the response is targeted. BAM responses would not be visible to Auction participants, and would not be disseminated to OPRA. The minimum price increment for BAM responses and for an Initiating Member's submission would be $0.01, regardless if the class trades in another increment.[14]

A BAM response with a size greater than the size of the Agency Order will be capped at the size of the Agency Order (*i.e.,* the excess size will be ignored when processing the Auction). BAM responses may be modified or cancelled during the Auction. BAM responses on the same side of the market as the Agency Order or with a Time in Force of IOC or FOK are considered invalid and will be immediately cancelled.[15] Finally, multiple BAM responses from the same User may be submitted during the Auction. However, multiple orders at a particular price point submitted by a User in response to an Auction or resting on the EDGX Options Book will be aggregated together and will be capped at the size of the Agency Order (*i.e.,* the excess size will be ignored when processing the Auction).[16] BAM responses cannot cross the price of the Initial NBBO but will be executed, if possible, at the most aggressive permissible price within such Initial NBBO.

C. Conclusion of an Auction and Order Allocation

The BAM Auction would conclude at the earlier of: (i) The end of the Auction period; (ii) upon receipt by the Exchange of a Priority Customer order on the same side of the market and at the stop price of the Agency Order that is to be posted to the EDGX Options Book; (iii) upon receipt by the Exchange of an unrelated order or quote that is not a Priority Customer order that is on the same side of the market as the Agency Order that would cause the Agency Order's stop price to be outside of the EDGX BBO; (iv) at the close of trading; or (v) any time there is a trading halt on the Exchange in the affected series.[17]

If the BAM Auction concludes earlier than the end of the prescribed Auction period for any of the reasons described

proposed EDGX Rule 21.19(b)(3) and proposed Interpretation and Policy .04 to EDGX Rule 21.19. In addition, each BAM response must specifically identify the Auction for which it is targeted and will only be considered in the specified Auction. *See* Notice, *supra* note 3, at 69179 and Amendment No. 1, *supra* note 5. *See also* proposed EDGX Rule 21.19(b)(1)(E).

[10] *See* proposed EDGX Rule 21.19(a)(6). The Exchange stated that this prohibition is based on a prohibition contained in other options exchanges' auction mechanisms. *See* Amendment No. 1, *supra* note 5. *See also* Chapter VI, Section 9(i)(F) of the NASDAQ BX, Inc. (''BX'') Rules.

[11] *See* proposed EDGX Rule 21.19(b)(1)(A).

[12] Last Priority will not be permitted if both the Initiating Order and Agency Order are Priority Customer Orders. *See* proposed EDGX Rule 21.19(b)(1)(B)(ii). In addition, Last Priority is only compatible with single-price submissions and cannot be designated on an Agency Order specified as auto-match. *See* proposed EDGX Rule 21.19(b)(1)(B)(iii).

[13] The Exchange states that, in September 2016, it conducted a survey of active EDGX market maker firms and other active liquidity providers inquiring as to the timeframe within which these market participants can respond to an auction with a duration time ranging from less than fifty (50) milliseconds to more than one (1) second. Of the ten (10) active EDGX market maker firms that were surveyed, eight (8) responded to the survey. In addition, the Exchange included six (6) additional liquidity providers that are not active EDGX market makers but are active participants on EDGX Options. Of the survey respondents, 93% indicated that that their firm could respond to auctions with a duration time of at least 50 milliseconds, and 100% indicated that that their firm could respond to auctions with a duration time of at least 100 milliseconds. Based on the results of the survey, the Exchange believes that allowing for an auction period of no less than one hundred (100) milliseconds and no more than one (1) second would provide a meaningful opportunity for Members to respond to the BAM Auction while at the same time facilitating the prompt execution of orders. The Exchange believes that 100 milliseconds will continue to provide all market participants with sufficient time to respond, compete, and provide price improvement for orders and will provide investors and other market participants with more timely executions, thereby reducing their market risk. *See* Amendment No. 1, *supra* note 5.

[14] *See* proposed EDGX Rule 21.19(b)(1)(G). *See also* Amendment No. 1, *supra* note 5.

[15] *See* proposed EDGX Rule 21.19(b)(1)(K). *See also* Amendment No. 1, *supra* note 5.

[16] *See* proposed EDGX Rule 21.19(b)(1)(I).

[17] *See* proposed EDGX Rule 21.19(b)(2). In Amendment No. 1, the Exchange stated that the proposed difference between scenario (ii), where an unrelated, same-side Priority Customer order will cause early termination of an Auction when it arrives on the Exchange *at* the stop price, and scenario (iii), where an unrelated, same-side order or quote from a non-Priority Customer will cause early termination of an Auction only when it would be *better than* the stop price, is consistent with the Exchange's belief that a Priority Customer order received and placed on the Exchange's order book should have certainty that it will be the first order executed at that price in response to contra-side liquidity. *See* Amendment No. 1, *supra* note 5.

above other than a trading halt, the Auction will be processed pursuant to the order allocation process set forth in proposed EDGX Rule 21.19(b)(4).[18] In the event of a trading halt on the Exchange in the affected series, the Auction will be cancelled without execution.[19]

Any unexecuted BAM responses will be cancelled.[20] An unrelated market or marketable limit order (against the EDGX BBO) on the opposite side of the market from the Agency Order received during the Auction will not cause the Auction to end early and will execute against interest outside of the Auction.[21] If contracts remain from such unrelated order at the time the auction ends, they will be considered for participation in the order allocation process. All unrelated orders submitted to the Exchange with contracts remaining at the time the Auction ends, including orders marked as Post Only Orders pursuant to EDGX Rule 21.1(d)(8),[22] will be considered for participation in the order allocation process. If an Auction is initiated for an Agency Order designated as an ''Intermarket Sweep Order'' or ''ISO'' Order,[23] responses and executions will be permitted at a price inferior to the Initial NBBO.[24]

At the conclusion of the Auction, the Agency Order will be allocated at the best price(s), pursuant to the priority set forth in proposed EDGX Rule 21.19(b)(4).[25] First, Priority Customer orders would have time priority at each price level. Next, the Initiating Member would receive an allocation after Priority Customer orders.[26]

If the Initiating Member selected the *single-price submission option,* BAM executions will occur first at prices that improve the stop price, and then at the stop price with up to 40% of the remaining contracts after Priority Customer interest is satisfied being allocated to the Initiating Member at the stop price. However, if only one other quote, order, or BAM response matches the stop price, the Initiating Member may be allocated up to 50% of the contracts executed at such price.

If the Initiating Member selected the *auto-match option,* the Initiating Member would be allocated a number of contracts equal to the aggregate size of all other quotes, orders, and BAM responses at each price point until a price point is reached where the balance of the order can be fully executed, except that the Initiating Member would be entitled to receive up to 40% (if there are multiple competing quotes, orders, or BAM responses) or 50% (if there is only one competing quote, order, or BAM response) of the initial Agency Order at the final price point (including situations where the stop price is the final price), after Priority Customer interest has been satisfied but before remaining interest receives an allocation.

After Public Customers and the Initiating Participant receive their allocations, and for classes designated by the Exchange as eligible for ''Priority Order'' status, Users with resting quotes and orders that were at a price that is equal to the Initial NBBO on the opposite side of the market from the Agency Order (''Priority Orders'') would have priority up to their size in the Initial NBBO at each price level at or better than such Initial NBBO. Priority Orders and BAM responses submitted by Users with Priority Order Status will be allocated pursuant to the algorithm set forth in EDGX Rule 21.8(c).[27]

Finally, after Priority Customers, the Initiating Member, and Users with Priority Orders, if applicable, have received allocations, all other interest will be allocated pursuant to Rule 21.8(c).[28] Any remaining contracts will be allocated to the Initiating Member.

D. Crossing Agency Orders

The Exchange also proposes, in lieu of the BAM Auction procedures set forth in proposed paragraphs (a)–(b) to EDGX Rule 21.19, to allow an Initiating Member to enter an Agency Order for the account of a Priority Customer paired with an order for the account of another Priority Customer, and such paired orders will be automatically executed without an Auction. In its proposal, the Exchange notes that it would be a violation of EDGX Rule 22.12 for an Options Member to circumvent EDGX Rule 22.12 by providing an opportunity for (i) a Priority Customer affiliated with the Options Member, or (ii) a Priority Customer with whom the Options Member has an arrangement that allows the Options Member to realize similar economic benefits from the transaction as the Options Member would achieve by executing agency orders as principal, to regularly execute against agency orders handled by the firm immediately upon their entry as BAM Priority Customer-to-Priority Customer immediate crosses.[29]

E. Pilot Program Information to the Commission

Subject to a pilot program expiring January 18, 2017,[30] there will be no minimum size requirement for orders to be eligible for the Auction. During this pilot period, the Exchange represents that it periodically will submit certain data, as requested by the Commission staff, to provide supporting evidence that, among other things, there is meaningful competition in BAM Auctions for all size orders and that there is an active and liquid market functioning on the Exchange outside of the Auction mechanism.[31] The Exchange further noted that it would seek to request confidential treatment for any raw data that it submits to the Commission.[32]

The Exchange represented that it will provide the following additional information on a monthly basis:

(i) The number of contracts (of orders of 50 contracts or greater) entered into BAM Auctions;

(ii) The number of contracts (of orders of fewer than 50 contracts) entered into BAM Auctions;

[18] *See* proposed EDGX Rule 21.19(b)(2)(A)–(D).

[19] *See* proposed EDGX Rule 21.19(b)(2)(E).

[20] *See* proposed EDGX Rule 21.19(b)(5).

[21] *See* proposed EDGX Rule 21.19(b)(3).

[22] The Exchange noted that Post Only Orders would participate in an Auction in the same manner as any other unrelated order even if the Post Only Order would be considered to be removing liquidity from the Auction. *See* Amendment No. 1, *supra* note 5.

[23] ''Intermarket Sweep Orders'' or ''ISO'' Orders are limit orders that are designated as ISOs in the manner prescribed by EDGX and are executed within the System at one or multiple price levels without regard to Protected Quotations of other Eligible Exchanges as defined in EDGX Rule 27.1. ISOs are not eligible for routing pursuant to EDGX Rule 21.9. In Amendment No. 1, the Exchange described in greater detail how a BAM ISO would be handled if any better priced interest arrived on the Exchange's order book after the BAM ISO was sent but before the corresponding Auction commenced. *See* Amendment No. 1, *supra* note 5 (stating that in this circumstance, any better priced interest in the order book at the time of such BAM Auction would be executed pursuant to the proposed Auction functionality).

[24] *See* proposed EDGX Rule 21.19(b)(6).

[25] *See* Notice, *supra* note 3, at 69176–78 and Amendment No. 1, *supra* note 5, for examples illustrating trade allocations under various auction scenarios.

[26] The Initiating Participant shall receive additional allocation only if contracts remain after any allocation pursuant to proposed EDGX Rule 21.19(b)(4).

[27] *See* proposed EDGX Rule 21.19(b)(4)(B)(iii). Priority Order status is only valid for the duration of the particular Auction.

[28] *See* proposed EDGX Rule 21.19(b)(4)(B)(iv).

[29] *See* Notice, *supra* note 3, at 69176. *See also* Amendment No. 1, *supra* note 5 and proposed Interpretation and Policy .03 to EDGX Rule 21.19.

[30] *See* proposed Interpretation and Policy .05 to EDGX Rule 21.19.

[31] *See* Notice, *supra* note 3, at 69176. *See also* Amendment No. 1, *supra* note 5.

[32] *See* Notice, *supra* note 3, at 69176; Amendment No. 1, *supra* note 5. *See also* proposed Interpretation and Policy .05 to EDGX Rule 21.19.

(iii) The number of orders of 50 contracts or greater entered into BAM Auctions; and

(iv) The number of orders of fewer than 50 contracts entered into BAM Auctions.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with Section 6(b) of the Act.[33] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[34] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect customers, issuers, brokers and dealers. The Commission believes that the Exchange's proposal to establish the BAM may increase competition among those options exchanges that offer similar price improvement mechanisms. The Commission further believes that allowing EDGX Members to enter orders into the BAM will provide additional opportunities for such orders to receive price improvement over the NBBO and, in some instances, will result in such orders receiving price improvement over the NBBO.

In particular, the Commission notes that, in order to initiate an Auction, the Initiating Member must stop the entire Agency Order as principal or with a solicited order at a price in an increment of $0.01 such that if the Agency Order is for less than 50 option contracts and the difference between the NBB and NBO is $0.01, the Initiating Member must stop the entire Agency Order at one minimum price improvement increment better than the NBBO, which increment shall be determined by the Exchange but may not be smaller than $0.01. The Commission believes that guaranteed price improvement for Agency Orders of fewer than 50 contracts when the difference between the NBB and NBO is $0.01 will benefit such Agency Orders. The Commission notes further that, for any other Agency Order, the Initiating Member must stop the entire Agency Order at the better of the NBBO or the Agency Order's limit price (if the order is a limit order). Accordingly, the proposed rule change will provide customers with an opportunity for price improvement over the NBBO in those instances.

If the EDGX BBO on the same side of the market as the Agency Order represents a Priority Customer order on the book, the stop price must be at least $0.01 better than the booked order's limit price. If the EDGX BBO on the same side of the market as the Agency Order represents a quote or order that is not a Priority Customer order on the book, the stop price must be at least $0.01 better than the booked order's limit price unless the Agency Order is a Priority Customer order and the Customer Overlay set forth in Exchange Rule 21.8(d)(1) is in effect. The Commission notes that the Exchange has represented that this condition is consistent with the operation of the Exchange generally, where the Customer Overlay is currently in effect with respect to all options traded on the Exchange, and Priority Customer Orders have first priority over other orders at the same price.

With respect to Agency Orders for less than 50 contracts, only one BAM Auction may be ongoing at any given time in a series and Auctions in the same series may not queue or overlap in any manner. However, BAM Auctions for Agency Orders of 50 contracts or more will be allowed to occur at the same time as other Auctions in the same series. The Commission notes that the BAM rules regarding the processing of overlapping BAM Auctions for Agency Orders of 50 contracts or more have been made transparent in the proposed rule change and are reasonable, given that the electronic nature of BAM makes the sequence of auction start times readily discernable.[35] In particular, the Commission notes that a BAM response will only be considered for its specified Auction. Each BAM response must specifically identify the BAM Auction for which it is targeted, and if not fully executed, the BAM response will be cancelled back at the conclusion of the auction.

All BAM Auctions will last for a period of no less than 100 milliseconds and no more than one second, as determined by the Exchange and announced on the Exchange's Web site. As the Exchange discussed in its proposal, the Exchange conducted a survey of active EDGX market maker firms and other active liquidity providers inquiring as to the timeframe within which these market participants respond to an auction with a duration time ranging from less than fifty (50) milliseconds to more than one (1) second. According to the Exchange, a majority of the market maker firms and active liquidity providers on EDGX Options that responded to the survey indicated that they were capable of responding to auctions with a duration time of at least 50 milliseconds.[36] Based on the Exchange's statements, the Commission believes that the proposed duration of the BAM Auction could facilitate the prompt execution of orders in the BAM, while providing market participants with an opportunity to compete for exposed bids and offers. The Commission notes that other exchanges' price improvement auctions provide for auction response periods within the range of the response duration proposed by EDGX.[37]

The Commission believes that the Exchange's proposed matching algorithm is sufficiently clear regarding how orders are to be allocated in the BAM Auction and is designed in a manner that should facilitate a competitive auction process. The Commission further believes that permitting Priority Orders to have enhanced priority may encourage EDGX Users to quote aggressively with additional size outside of the BAM Auction and, therefore, may enhance competition and liquidity on the EDGX market.

Under the proposal, the BAM Auction would be available for orders of fewer

[33] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[34] 15 U.S.C. 78f(b)(5).

[35] *See* proposed Interpretation and Policy .04 to EDGX Rule 21.19.

[36] Of the ten (10) active EDGX market maker firms that were surveyed, eight (8) of these market makers responded to the survey. In addition, because EDGX is a relatively new options exchange and is still encouraging market makers to register and participate on the Exchange as such, and to increase the sample size, the Exchange included six (6) additional liquidity providers that are not active EDGX market makers but are active participants on EDGX Options. Thirteen (13) of the fourteen (14) respondents, or 93% indicated that that their firm could respond to auctions with a duration time of at least 50 milliseconds, though one of these firms indicated a preference of auctions with a duration of 100 milliseconds. The remaining firm indicated that it could respond to auctions with a duration of at least 100 milliseconds. This survey was conducted in September of 2016.

[37] *See* Chapter VI, Section 9(ii)(A)(3) of the BX Rules (auction period between 100 milliseconds and 1 section), International Securities Exchange, LLC (''ISE'') Rule 723(c)(5) (auction period of 500 milliseconds), CBOE Rule 6.74A(b)(1)(C) (auction period of 1 second), and BOX Options Exchange LLC (''BOX'') Rule 7150(f)(1) (auction period of 100 milliseconds).

than 50 contracts. There would be no minimum size requirement for orders entered into the BAM Auction for a pilot period expiring on January 18, 2017. The Exchange has represented its commitment to submit certain data on BAM Auctions at the request of Commission staff. The Commission expects such data to be used, by both the Exchange and the Commission staff, to assess the performance of the BAM Auction, including, among other things, to study whether there is meaningful competition for all size orders with the BAM, the degree of price improvement for all orders executed through the BAM, and whether there is an active and liquid market functioning on the Exchange outside of the BAM. The data provided will enable the Commission, as well as the Exchange itself, to evaluate the BAM Auction to determine its performance and possible impact on EDGX and options market structure in general and the degree to which it is beneficial to customers and to the options market as a whole.

IV. Section 11(a) of the Act

Section 11(a)(1) of the Act [38] prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or an account over which it or its associated person exercises investment discretion (collectively, ''covered accounts'') unless an exception applies. Rule 11a2–2(T) under the Act,[39] known as the ''effect versus execute'' rule, provides exchange members with an exemption from the Section 11(a)(1) prohibition. Rule 11a2–2(T) permits an exchange member, subject to certain conditions, to effect transactions for covered accounts by arranging for an unaffiliated member to execute transactions on the exchange. To comply with Rule 11a2–2(T)'s conditions, a member: (i) must transmit the order from off the exchange floor; (ii) may not participate in the execution of the transaction once it has been transmitted to the member performing the execution; [40] (iii) may not be affiliated with the executing member; and (iv) with respect to an account over which the member or an associated person has investment discretion, neither the member nor its associated person may retain any compensation in connection with effecting the transaction except as provided in the Rule. For the reasons set forth below, the Commission believes that Exchange members entering orders into the BAM Auction would satisfy the requirements of Rule 11a2–2(T).

The Rule's first condition is that orders for covered accounts be transmitted from off the exchange floor. In the context of automated trading systems, the Commission has found that the off-floor transmission requirement is met if a covered account order is transmitted from a remote location directly to an exchange's floor by electronic means.[41] EDGX represents that the EDGX trading system and the proposed BAM Auction receive all orders electronically through remote terminals or computer-to-computer interfaces.[42] The Exchange also represents that orders for covered accounts from Members will be transmitted from a remote location directly to the proposed BAM mechanism by electronic means. Because no Exchange members may submit orders into the BAM Auction from on the floor of the Exchange, the Commission believes that the BAM Auction satisfies the off-floor transmission requirement.

Second, the Rule requires that the member and any associated person not participate in the execution of its order after the order has been transmitted. The Exchange represents that at no time following the submission of an order is a Member able to acquire control or influence over the result or timing of the order's execution.[43] According to the Exchange, the execution of an order sent to the BAM mechanism is determined by what other orders are present and the priority of those orders.[44] Accordingly, the Commission believes that a member does not participate in the execution of an order submitted to the BAM mechanism.

Third, Rule 11a2–2(T) requires that the order be executed by an exchange member who is unaffiliated with the member initiating the order. The Commission has stated that this requirement is satisfied when automated exchange facilities, such as the BAM mechanism, are used, as long as the design of these systems ensures that members do not possess any special or unique trading advantages in handling their orders after transmitting them to the exchange.[45] EDGX represents that the BAM Auction is designed so that no Member has any special or unique trading advantage in the handling of its orders after transmitting its orders to the mechanism.[46] Based on the Exchange's representation, the Commission believes that the BAM mechanism satisfies this requirement.

Fourth, in the case of a transaction effected for an account with respect to which the initiating member or an associated person thereof exercises investment discretion, neither the initiating member nor any associated person thereof may retain any compensation in connection with effecting the transaction, unless the person authorized to transact business for the account has expressly provided otherwise by written contract referring to Section 11(a) of the Act and Rule 11a2–2(T) thereunder.[47] EDGX

[38] 15 U.S.C. 78k(a)(1).

[39] 17 CFR 240.11a2–2(T).

[40] This prohibition also applies to associated persons. The member may, however, participate in clearing and settling the transaction.

[41] *See, e.g.,* Securities Exchange Act Release Nos. 61419 (January 26, 2010), 75 FR 5157 (February 1, 2010) (SR–BATS–2009–031) (approving BATS options trading); 59154 (December 23, 2008), 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48) (approving equity securities listing and trading on BSE); 57478 (March 12, 2008), 73 FR 14521 (March 18, 2008) (SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080) (approving NOM options trading); 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (approving The Nasdaq Stock Market LLC); 44983 (October 25, 2001), 66 FR 55225 (November 1, 2001) (SR–PCX–00–25) (approving Archipelago Exchange); 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991) (SR–NYSE–90–52 and SR–NYSE–90–53) (approving NYSE's Off-Hours Trading Facility); and 15533 (January 29, 1979), 44 FR 6084 (January 31, 1979) (''1979 Release'').

[42] *See* Notice, *supra* note 3, at 69179–80. *See also* Amendment No. 1, *supra* note 5.

[43] *See* Notice, *supra* note 3, at 69180. *See also* Amendment No. 1, *supra* note 5 (also representing, among other things, that: 1) no Member, including the Initiating Member, will see a BAM response submitted into BAM and therefore will not be able to influence or guide the execution of their Agency Orders, 2) the Last Priority feature will not permit a Member to have any control over an order, and the election to Last Priority an order is available prior to the submission of the order, will not be broadcast and further, the Last Priority option may not be modified by the Initiating Member during the auction).

[44] *See* Notice, *supra* note 3, at 69180. *See also* Amendment No. 1, *supra* note 5. The Exchange notes that a Member may not cancel or modify an order after it has been submitted into BAM.

[45] In considering the operation of automated execution systems operated by an exchange, the Commission noted that, while there is not an independent executing exchange member, the execution of an order is automatic once it has been transmitted into the system. Because the design of these systems ensures that members do not possess any special or unique trading advantages in handling their orders after transmitting them to the exchange, the Commission has stated that executions obtained through these systems satisfy the independent execution requirement of Rule 11a2–2(T). *See* 1979 Release, *supra* note 41.

[46] *See* Notice, *supra* note 3, at 69180. *See also* Amendment No. 1, *supra* note 5.

[47] In addition, Rule 11a2–2(T)(d) requires a member or associated person authorized by written contract to retain compensation, in connection with effecting transactions for covered accounts over which such member or associated persons thereof exercises investment discretion, to furnish at least annually to the person authorized to transact business for the account a statement setting forth the total amount of compensation retained by the member or any associated person thereof in connection with effecting transactions for the

represents that Members relying on Rule 11a2–2(T) for transactions effected through the BAM Auction must comply with this condition of the Rule and that the Exchange will enforce this requirement pursuant to its obligations under Section 6(b)(1) of the Act to enforce compliance with federal securities laws.[48]

V. Accelerated Approval of Proposal, as Modified by Amendment No. 1

The Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act, to approve the proposal, as modified by Amendment No. 1, prior to the 30th day after publication of Amendment No. 1 in the **Federal Register**. In Amendment No. 1, EDGX revised the original proposal to make the changes discussed in detail above. Notably, in Amendment No. 1, EDGX revises its proposal to restrict an Auction from commencing with a stop price equal to a same side resting order except in limited circumstances, as described above, and prohibit an Initiating Order from being a solicited order for the account of an Options Market Maker assigned in the affected series on the Exchange. EDGX also made changes to clarify and add detail to its proposal and the proposed rule text. The Commission believes that Amendment No. 1 does not raise any novel regulatory issues and instead better aligns EDGX's proposed Auction functionality with existing functionality on the Exchange and with that of similar auction mechanisms operated by other options exchanges, and provides additional clarity in the rule text, which is consistent with EDGX's original proposal and supports EDGX's analysis of how its proposal is consistent with the Act, thus facilitating the Commission's ability to make the findings set forth above to approve the proposal. Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by Amendment No. 1, on an accelerated basis.

VI. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsEDGX–2016–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsEDGX–2016–41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–41 and should be submitted on or before January 30, 2017.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[49] that the proposed rule change (SR-BatsEDGX–2016–41), as modified by Amendment No. 1, be and hereby is approved on an accelerated basis, except that there shall be no minimum size requirement for orders to be eligible for the Auction for a pilot period expiring on January 18, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Eduardo A. Aleman,

Assistant Secretary.

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account during the period covered by the statement. *See* 17 CFR 240.11a2–2(T)(d). *See also* Securities Exchange Act Release No. 14563 (March 14, 1978), 43 FR 11542 (March 17, 1978) (stating ''[t]he contractual and disclosure requirements are designed to assure that accounts electing to permit transaction-related compensation do so only after deciding that such arrangements are suitable to their interests'').

[48] *See* Notice, *supra* note 3, at 69180. *See also* Amendment No. 1, *supra* note 5.

[49] 15 U.S.C. 78s(b)(2).

[50] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79721; File No. SR–ISE–2016–32]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rules To Extend a Pilot Program

January 3, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 23, 2016, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules to extend a pilot program to quote and to trade certain options classes in penny increments.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under the Penny Pilot Program, the minimum price variation for all participating options classes, except for the Nasdaq–100 Index Tracking Stock (''QQQQ''), the SPDR S&P 500 Exchange Traded Fund (''SPY'') and the iShares Russell 2000 Index Fund (''IWM''), is $0.01 for all quotations in options series that are quoted at less than $3 per contract and $0.05 for all quotations in options series that are quoted at $3 per contract or greater. QQQQ, SPY and IWM are quoted in $0.01 increments for all options series. The Penny Pilot Program is currently scheduled to expire on December 31, 2016.[3] The Exchange proposes to extend the Penny Pilot Program through June 30, 2017, and to provide a revised date for adding replacement issues to the Penny Pilot Program. The Exchange proposes that any Penny Pilot Program issues that have been delisted may be replaced on the second trading day following January 1, 2017. The replacement issues will be selected based on trading activity for the most recent six month period excluding the month immediately preceding the replacement (*i.e.,* beginning June 1, 2016, and ending November 30, 2016). This filing does not propose any substantive changes to the Penny Pilot Program: All classes currently participating will remain the same and all minimum increments will remain unchanged. The Exchange believes the benefits to public customers and other market participants who will be able to express their true prices to buy and sell options have been demonstrated to outweigh any increase in quote traffic.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[4] Specifically, the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] because it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed rule change, which extends the Penny Pilot Program for an additional six months, will enable public customers and other market participants to express their true prices to buy and sell options to the benefit of all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[6] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Penny Pilot Program, the proposed rule change will allow for further analysis of the Penny Pilot Program and a determination of how the Penny Pilot Program should be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[9] normally does not become operative prior to 30 days after the date of the filing.[10] However, pursuant to Rule 19b–4(f)(6)(iii),[11] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so will allow the Pilot Program to continue without interruption in a manner that is consistent with the Commission's prior approval of the extension and expansion of the Pilot Program and will allow the Exchange and the Commission additional time to analyze the impact of the Pilot Program. Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.[12]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[3] *See* Exchange Act Release No. 78203 (June 30, 2016), 81 FR 44404 (July 7, 2016) (SR–ISE–2016–15).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78f(b)(8).

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this pre-filing requirement.

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–ISE–2016–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2016–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the ISE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–32 and should be submitted by January 30, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00099 Filed 1–6–17; 8:45 am]

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[14] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2016–0063]

Rate for Assessment on Direct Payment of Fees to Representatives in 2017

AGENCY: Social Security Administration (SSA).

ACTION: Notice.

SUMMARY: We are announcing that the assessment percentage rate under sections 206(d) and 1631(d)(2)(C) of the Social Security Act (Act), 42 U.S.C. 406(d) and 1383(d)(2)(C), is 6.3 percent for 2017.

FOR FURTHER INFORMATION CONTACT: Jeffrey C. Blair, Associate General Counsel for Program Law, Office of the General Counsel, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401. Phone: (410) 965–3157, email *Jeff.Blair@ssa.gov.*

SUPPLEMENTARY INFORMATION: A claimant may appoint a qualified individual as a representative to act on his or her behalf in matters before the Social Security Administration (SSA). If the claimant is entitled to past-due benefits and was represented either by an attorney or by a non-attorney representative who has met certain prerequisites, the Act provides that we may withhold up to 25 percent of the past-due benefits and use that money to pay the representative's approved fee directly to the representative.

When we pay the representative's fee directly to the representative, we must collect from that fee payment an assessment to recover the costs we incur in determining and paying representatives' fees. The Act provides that the assessment we collect will be the lesser of two amounts: A specified dollar limit; or the amount determined by multiplying the fee we are paying by the assessment percentage rate. (Sections 206(d), 206(e), and 1631(d)(2) of the Act, 42 U.S.C. 406(d), 406(e), and 1383(d)(2).)

The Act initially set the dollar limit at $75 in 2004 and provides that the limit will be adjusted annually based on changes in the cost-of-living. (Sections 206(d)(2)(A) and 1631(d)(2)(C)(ii)(I) of the Act, 42 U.S.C. 406(d)(2)(A) and 1383(d)(2)(C)(ii)(I).) The maximum dollar limit for the assessment currently is $91, as we announced in the **Federal Register** on October 27, 2016 (81 FR 74854).

The Act requires us each year to set the assessment percentage rate at the lesser of 6.3 percent or the percentage rate necessary to achieve full recovery of the costs we incur to determine and pay representatives' fees. (Sections 206(d)(2)(B)(ii) and 1631(d)(2)(C)(ii)(II) of the Act, 42 U.S.C. 406(d)(2)(B)(ii) and 1383(d)(2)(C)(ii)(II).)

Based on the best available data, we have determined that the current rate of 6.3 percent will continue for 2017. We will continue to review our costs for these services on a yearly basis.

Michelle King,

Acting Deputy Commissioner for Budget, Finance, Quality, and Management.

[FR Doc. 2017–00136 Filed 1–6–17; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Tenth RTCA SC–229 406 MHz ELT Plenary Joint with WG–98

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Tenth RTCA SC–229 406 MHz ELT Plenary Joint with WG–98.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Tenth RTCA SC–229 406 MHz ELT Plenary Joint with WG–98.

DATES: The meeting will be held March 14–17, 2017 09:00 a.m.–05:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Tenth RTCA SC–229 406 MHz ELT Plenary Joint with WG–98. The agenda will include the following:

Tuesday, March 13, 2017—9:00 a.m.–5:00 p.m.

1. Welcome/Introductions/Administrative Remarks
2. Agenda overview and approval
3. Fort Lauderdale meeting review and approval
4. Review Action Items from Fort Lauderdale meeting
5. ''Phasing in'' RTCA/DO–204B, EUROCAE/ED–62B—Timeline and ToR
6. EASA presentation
   - EASA approval process
   - EU rules on aircraft tracking and location of aircraft in distress
7. Briefing of: ICAO GADSS–AG, COSPAS–SARSAT, activities
8. Other Industry coordination and presentations

9. Working group of the whole meeting (rest of the day)

Wednesday, March 14, 2017—9:00 a.m.–5:00 p.m.

Working group of the whole meeting

Thursday, March 15, 2017—9:00 a.m.–5:00 p.m.

Working group of the whole meeting

Friday, March 17, 2017—9:00 a.m.–4:00 p.m.

1. Plenary meeting in the morning
2. WGs' reports
2. Action item review
3. Future meeting plans and dates
4. Industry coordination and presentations (if any)
5. Other business
6. Adjourn

Attendance is open to the interested public for plenary discussion, but limited to space availability. Registration for this meeting is required. Working group of the whole items are closed to the public. With the approval of the chairman, members of the public may present oral statements at the plenary meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time. Issued in Washington, DC on January 4, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–00117 Filed 1–6–17; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Ninth RTCA SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics Plenary

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Ninth RTCA SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Ninth RTCA SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics Plenary.

DATES: The meeting will be held February 07–09, 2017, 08:30 a.m.–04:30 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Ninth RTCA SC–233 Addressing Human Factors/Pilot Interface Issues for Avionics Plenary. The agenda will include the following:

Tuesday, February 7, 2017—8:30 a.m.–4:30 p.m.

1. Introduction, Upcoming PMC Dates and Deliverable
2. Review of TOR
3. September meeting summary approval
4. December meeting summary approval
5. Roadmap for remaining items to be completed; notional schedule of activities remaining
6. Working group of the whole—Address Comments

Tuesday, February 8, 2017—8:30 a.m.–4:30 p.m.

7. Working group of the whole—Address Comments

Thursday, February 9, 2017—8:30 a.m.–4:30 p.m.

8. Working Group of the whole—Address Comments
9. Summary report of working group of the whole meetings on February 7th and 8th
10. Other Business
11. Action Items
12. Review of key dates
13. Adjourn

Attendance is open to the interested public for plenary items, but limited to space availability. Working group of the whole items are closed to the public. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 4, 2017.

Mohannad Dawoud

Management & Program Analyst, Partnership Contracts Branch, ANG–A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–00112 Filed 1–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2016–0033]

Motorcyclist Advisory Council to the Federal Highway Administration

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Establishment of the Motorcyclist Advisory Council to the Federal Highway Administration; Request for Nominations.

SUMMARY: The FHWA announces the establishment of the Motorcyclist Advisory Council (MAC) for a 2-year period. The MAC will coordinate with and advise the FHWA Administrator on infrastructure issues of concern to motorcyclists, including: (1) Barrier design; (2) road design, construction, and maintenance practices; and (3) the architecture and implementation of intelligent transportation system technologies. The FHWA seeks member nominations for the MAC.

DATES: The deadline for nominations for MAC membership is February 23, 2017.

ADDRESSES: All nomination materials should be emailed to *MAC-FHWA@dot.gov* or mailed attention to Mr. Michael Griffith, Federal Highway Administration, Office of Safety, Room E71–312, 1200 New Jersey Ave. SE., Washington, DC 20590. Any person needing accessibility accommodations should contact Michael Griffith at (202) 366–9469.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Griffith, Office of Safety, (202) 366–9469 or *MAC-FHWA@dot.gov;* 1200 New Jersey Ave. SE., Washington, DC 20590; or Ms. Seetha Srinivasan, Office of the Chief Counsel—Legislation, Regulation, and General Law Division, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–4099 or *Seetha.Srinivasan@dot.gov.*

SUPPLEMENTARY INFORMATION: Section 1426 of the Fixing America's Surface Transportation Act (Pub. L. 114–94) requires the establishment of a Motorcyclist Advisory Council (MAC). The Secretary, acting through the Administrator of the FHWA, is required

to appoint a MAC to coordinate with and advise the Administrator on infrastructure issues of concern to motorcyclists, including:

(1) Barrier design;

(2) Road design, construction, and maintenance practices; and

(3) The architecture and implementation of intelligent transportation system technologies.

Pursuant to Section 9(a)(2) of the Federal Advisory Committee Act (FACA), and in accordance with 41 CFR 102–3.65, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the MAC will be established for up to a 2-year period.

The MAC shall comprise not more than 10 members appointed by the Secretary of Transportation for terms of up to 2 years. Members serve at the pleasure of the Secretary. The Secretary may extend appointments and may appoint replacements for members who have resigned outside of a stated term, as necessary. Members may continue to serve until their replacements have been appointed.

The MAC seeks to have a fairly balanced membership with expertise in highway engineering, safety analysis, and motorcycling. Specifically, the following are the categories of members that shall be included in the MAC:

(1) Experts from State/local government in highway engineering issues, including:

(A) Barrier design;

(B) Road design, construction, maintenance; and/or

(C) Intelligent Transportation Systems;

(2) State/local traffic and safety engineers, design engineers, or other transportation department officials who are motorcyclists;

(3) A representative from a national motorcyclist association;

(4) A roadway safety data expert on crash testing/analysis; and

(5) A member of a national safety organization that represents the traffic safety systems industry.

This document gives notice of this process to potential participants and affords them the opportunity to request representation on the MAC. The procedure for requesting such representation is set out below. The FHWA is aware that there are many more potential organizations and participants than there are membership slots on the MAC. Organizations and participants should be prepared to support their participation on the MAC.

It is important to recognize that interested parties who are not selected to membership on the MAC can make valuable contributions to the work of the MAC in any of several ways. Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

Any member of the public is welcome to attend the MAC meetings, and, as provided in FACA, speak to the MAC. Time will be set aside during each meeting for this purpose, consistent with the MAC's need for sufficient time to complete its deliberations.

The MAC meetings will be held approximately twice per Federal fiscal year, once in-person and once by web conference. Notice of each meeting shall be published in the **Federal Register** at least 15 calendar days prior to the date of the meeting. The meeting agenda and all relevant meeting information will be posted in advance of each meeting on the Web site (*http://safety.fhwa.dot.gov/motorcycles*).

Every effort will be made to select MAC members who are objective and support the functions to be performed by the MAC. A balance is needed and weight is given to a variety of factors including, but not limited to, geographical distribution, gender, minority status, organization, and expertise. Some MAC members may be appointed as Special Government Employees and will be subject to certain ethical restrictions, and such members will be required to submit certain information in connection with the appointment process. With the exception of travel and per diem for official travel, members will serve without compensation.

A potential member may self-nominate or be nominated by an interested organization. Each nomination for membership should submit a letter of application that includes the following:

(1) The name, title, and relevant contact information (including phone and email address) of the nominee;

(2) a brief statement detailing interest for involvement in the MAC;

(3) A brief professional summary or résumé, including years of experience; relevant professional experience; geographic representation; and examples of previous leadership role in related committees, organizations, or advisory panels;

(4) A detailed description of the nominee's experience and expertise of the subject matter categories described above;

(5) Evidence that the nominee is authorized to represent parties related to the interest the person proposes to represent;

(6) An affirmative statement that the nominee meets all MAC eligibility requirements; and

(7) Optional support materials to emphasize interest and experience. This may include letters of recommendations, up to 3 references, publications and/or research.

Please do not send company, trade association, or organization brochures or any similar information. Should more information be needed, DOT staff will contact the nominee, obtain information from the nominee's past affiliations, or obtain information from publicly available sources, such as the Internet.

Nominations may be emailed to *MAC-FHWA@dot.gov* or mailed to the attention of Michael Griffith, Federal Highway Administration, Office of Safety, Room E71–312, 1200 New Jersey Ave. SE., Washington, DC 20590. Nominations must be received by February 23, 2017. Nominees selected for appointment to the MAC will be notified by return email and by a letter of appointment.

A selection team comprising representatives from DOT offices will review the nomination packages. The Federal Highway Administrator will submit a list of recommended candidates to the Secretary of Transportation for review and selection of MAC members. The selection team will make recommendations regarding membership to the Secretary of Transportation through the Federal Highway Administrator based on criteria including: (1) Professional or academic expertise, experience, and knowledge relevant to the MAC activities described above; (2) the member categories described above; and (3) availability and willingness to serve.

Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical handicap, marital status, or sexual orientation. To ensure that recommendations to the Secretary take into account the needs of the diverse groups served by DOT, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Issued on: December 21, 2016.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2017–00125 Filed 1–6–17; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0297]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 38 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions was effective on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

II. Background

On November 15, 2016, FMCSA published a notice announcing its decision to renew exemptions for 38 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (81 FR 80161). The public comment period ended on December 15, 2016, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to driver a CMV if that person:

> Has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this preceding.

VI. Conclusion

As of November 9, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 36 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (63 FR 196; 63 FR 30285; 65 FR 20245; 65 FR 33406; 65 FR 57230; 65 FR 57234; 65 FR 66293; 66 FR 53826; 66 FR 66966; 67 FR 46016; 67 FR 57266; 67 FR 57267; 67 FR 67234; 68 FR 69434; 69 FR 51346; 69 FR 52741; 69 FR 53493; 69 FR 62741; 69 FR 62742; 70 FR 74102; 71 FR 50970; 71 FR 53489; 71 FR 62147; 71 FR 62148; 73 FR 35196; 73 FR 36955; 73 FR 46973; 73 FR 48270; 73 FR 48275; 73 FR 51336; 73 FR 51689; 73 FR 54888; 73 FR 61925; 73 FR 63047; 73 FR 74565; 75 FR 25919; 75 FR 36779; 75 FR 39725; 75 FR 39729; 75 FR 44051; 75 FR 47883; 75 FR 50799; 75 FR 52061; 75 FR 52062; 75 FR 52063; 75 FR 54958; 75 FR 59327; 75 FR 61833; 75 FR 63257;75 FR 64396; 75 FR 66423; 75 FR 70078; 77 FR 7657; 77 FR 22059; 77 FR 27852; 77 FR 38384; 77 FR 39379; 77 FR 40946; 77 FR 46153; 77 FR 48590; 77 FR 52381; 77 FR 52388; 77 FR 52389; 77 FR 60010; 77 FR 64582; 77 FR 64583; 77 FR 64841; 77 FR 68199; 77 FR 68200; 79 FR 27681; 79 FR 35212; 79 FR 35218; 79 FR 38649; 79 FR 38659; 79 FR 45868; 79 FR 46153; 79 FR 46300; 79 FR 47175; 79 FR 51643; 79 FR 53514; 79 FR 56097; 79 FR 56099; 79 FR 56104; 79 FR 56117; 79 FR 58856; 79 FR 59348; 79 FR 59357; 79 FR 64001; 79 FR 68199; 79 FR 70928; 79 FR 72754:

Charles S. Amyx, Jr. (LA)
John W. Arnold (KY)
Kelvin Frandin Bombu (KY)
Derric D. Burrell (AL)
Kenneth C. Caldwell (NY)
John P. Catalano (NJ)
Lee A. Clason (NE)
Edward Cunningham (MI)
Eric P. Demers (NH)
Louis A. DiPasqua, Jr. (NY)
Roderick L. Duvall (PA)
Tyron O. Friese (MN)
James O. Hancock (IN)
John H. Holmberg (WI)
Stetson W. King (FL)
Donald L. McCraw, Jr. (VA)
Elijah Mitchell (TX)
Charles J. Morman (FL)
Benny R. Morris (WV)
Timothy L. Morton (NC)
Dennis E. Palmer, Jr. (CT)
Jesus Penuelas (AZ)
Larry A. Priewe (ND)
John C. Rodriguez (PA)
Sabahudin Sabic (IA)
Antonio Sanchez (NJ)
Garry R. Setters (KY)
Jimmy E. Settle (MO)
Lawrence Siegler (MN)
Lee F. Taylor (NJ)
Richard T. Traigle (LA)
Wilbert Walden (NC)
Donald Wallace (IL)
Carl V. Wheeler (NC)
Earl L. White, Jr. (NH)
Hubert Whittenburg (MO)

The drivers were included in one of the following dockets: Docket Nos. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–

0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296. Their exemptions are effective as of November 9, 2016 and will expire on November 9, 2018.

As of November 22, 2016 and in accordance with 49 U.S.C. 31136(e) and 31315, the following 2 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (79 FR 63211; 80 FR 2471):

Dewey P. Huffman (OR)
Michael J. Monroe (IA)

The drivers were included in Docket No. FMCSA–2014–0297. Their exemptions are effective as of November 22, 2016, and will expire on November 22, 2018.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: December 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017–00134 Filed 1–6–17; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0389; FMCSA–2012–0294; FMCSA–2013–0109; FMCSA–2013–0442]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions of 11 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were effective on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before February 8, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0389; FMCSA–2012–0294; FMCSA–2013–0109; FMCSA–2013–0442 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number(s) for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for two years if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the two-year period.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person:

> Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

The 11 individuals listed in this notice have requested renewal of their exemptions from the Epilepsy and Seizure Disorders prohibition in 49 CFR 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

II. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse

evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 11 applicants has satisfied the conditions for obtaining an exemption from the Epilepsy and Seizure Disorder requirements and were published in the **Federal Register** (79 FR 70917; 79 FR 73690; 79 FR 23054). In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License information System (CDLIS) and the Motor Carrier Management Information System (MCMIS) are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency (SDLA). These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce.

The 11 drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous two-year exemption period. FMCSA has concluded that renewing the exemptions for each of these applicants is likely to achieve a level of safety equal to that existing without the exemption. Therefore, FMCSA has decided to renew each exemption for a two-year period. In accordance with 49 U.S.C. 31136(e) and 31315, each driver has received a renewed exemption.

As of April 8, 2016, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the Epilepsy and Seizure Disorders prohibition in 49 CFR 391.41(b)(8), from driving CMVs in interstate commerce (79 FR 70917; 79 FR 23054): Jeffrey Ballweg (WI); Michael Ranalli (PA); Lonnie Reicker (IL); and Jay Whitehead (NY). These drivers were included in FMCSA–2011–0389; and FMCSA–2012–0294; FMCSA–2013–0109. The exemptions were effective on April 8, 2016, and will expire on April 8, 2018.

As of April 23, 2016, the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the Epilepsy and Seizure Disorders prohibition in 49 CFR 391.41(b)(8), from driving CMVs in interstate commerce (79 FR 73690):

Charles Blood (NY)
Raymond Lobo (NJ)
Randy Pinto (PA)
Brent Robinson (NC)
Douglas Teigland (MN)
Joseph Thomas (MD)
James Spece (PA)

These drivers were included in FMCSA–2013–0442. The exemptions were effective on April 23, 2016, and will expire on April 23, 2018.

The exemptions are extended subject to the following conditions: (1) Each driver must remain seizure-free and maintain a stable treatment during the two-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

IV. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

V. Conclusion

Based upon its evaluation of the 11 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the Epilepsy and Seizure Disorders requirement in 49 CFR 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: December 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017–00132 Filed 1–6–17; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0107]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions of four individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: The exemptions were effective on November 6, 2015. The exemptions will expire on November 6, 2017. Comments must be received on or before February 8, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2013–0107 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday

through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number(s) for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for two years if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the two-year period.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person:

> Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

The four individuals listed in this notice have requested renewal of their exemptions from the Epilepsy and Seizure Disorders prohibition in 49 CFR 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

II. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application. In accordance with 49 U.S.C. 31136(e) and 31315, each of the four applicants has satisfied the conditions for obtaining an exemption from the Epilepsy and Seizure Disorder requirements and were published in the **Federal Register** (78 FR 67449). In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License information System (CDLIS) and the Motor Carrier Management Information System (MCMIS) are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency (SDLA). These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce.

The four drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous two-year exemption period. FMCSA has concluded that renewing the exemptions for each of these applicants is likely to achieve a level of safety equal to that existing without the exemption. Therefore, FMCSA has decided to renew each exemption for a two-year period. In accordance with 49 U.S.C. 31136(e) and 31315, each driver has received a renewed exemption.

As of November 6, 2015, the following four drivers has satisfied the renewal conditions for obtaining an exemption from the Epilepsy and Seizure Disorders prohibition in 49 CFR 391.41(b)(8), from driving CMVs in interstate commerce (78 FR 67449): Christopher Bird (OH); Edward Nissenbaum (PA); Stephen Stawinsky (PA); and George Webb (MA). The drivers were included in FMCSA–2013–0107. The exemptions were effective on November 6, 2015, and will expire on November 6, 2017.

IV. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must remain seizure-free and maintain a stable treatment during the two-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

V. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the four exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the Epilepsy and Seizure Disorders requirement in 49 CFR 391.41 (b)(8). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: December 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017–00133 Filed 1–6–17; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Transfer of Federally Assisted Land or Facility

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of intent to transfer Federally assisted land or facility.

SUMMARY: Section 5334(h) of the Federal Transit Laws, as codified, 49 U.S.C. 5301, *et seq.,* permits the Administrator of the Federal Transit Administration (FTA) to authorize a recipient of FTA funds to transfer land or a facility to a public body for any public purpose with no further obligation to the Federal Government if, among other things, no Federal agency is interested in acquiring the asset for Federal use. Accordingly, FTA is issuing this Notice to advise Federal Agencies that the Champaign Transit System intends to transfer a 14, 850 square foot, one-story concrete block transit garage building to the Champaign County Sherriff's Department to store the sheriff's department vehicles and equipment. Champaign County currently owns the building.

DATES: *Effective Date:* Any Federal agency interested in acquiring the Facility must notify the FTA Region V Office of its interest by February 8, 2017.

ADDRESSES: Interested parties should notify the Regional Office by writing to Marisol R. Simón, Regional Administrator, Federal Transit Administration, 200 West Adams, Suite 320, Chicago, IL 60606.

FOR FURTHER INFORMATION CONTACT: Kathryn Loster, Regional Counsel, at 312–353–3869.

SUPPLEMENTARY INFORMATION:

Background

49 U.S.C. Section 5334(h) provides guidance on the transfer of assets no longer needed. Specifically, if a recipient of FTA assistance decides an asset acquired at least in part with federal assistance is no longer needed for the purpose for which it was acquired, the Secretary of Transportation may authorize the recipient to transfer the asset to a local governmental authority to be used for a public purpose with no further obligation to the Government. 49 U.S.C. Section 5334(h)(l).

Determinations

The Secretary may authorize a transfer for a public purpose other than public transportation only if the Secretary decides:

(A) The asset will remain in public use for at least 5 years after the date the asset is transferred;

(B) There is no purpose eligible for assistance under this chapter for which the asset should be used;

(C) The overall benefit of allowing the transfer is greater than the interest of the Government in liquidation and return of the financial interest of the Government in the asset, after considering fair market value and other factors; and

(D) Through an appropriate screening or survey process, that there is no interest in acquiring the asset for Government use if the asset is a facility or land.

Federal Interest in Acquiring Land or Facility

This document implements the requirements of 49 U.S.C. Section 5334(h)(l)(D). Accordingly, FTA hereby provides notice of the availability of the Facility further described below. Any Federal agency interested in acquiring the affected facility should promptly notify the FTA.

If no Federal agency is interested in acquiring the existing Facility, FTA will make certain that the other requirements specified in 49 U.S.C. Section 5334(h)(1)(A) through (C) are met before permitting the asset to be transferred.

The facility is located at 308 Miami Street, Urbana, Ohio and consists of approximately a 14,850 square foot, one-story, concrete block, 12-bay transit garage building. The building was built in 1994 being approximately and has poured concrete footers and concrete slab floor. Other site improvements consist of a concrete apron on approximately 3,262 SF which has approximately 8 lined diagonal spaces of parking and 145 lineal feet of guard rail along the rear of the building.

If no Federal agency is interested in acquiring the existing Facility, FTA will make certain that the other requirements specified in 49 U.S.C. Section 5334(h)(1)(A) through (C) are met before permitting the asset to be transferred.

Marisol Simón,

Regional Administrator, FTA Region V.

[FR Doc. 2017–00078 Filed 1–6–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2015–0012; Notice No. 169]

Importation of Distilled Spirits, Wine, Beer, Malt Beverages, Tobacco Products, Processed Tobacco, and Cigarette Papers and Tubes; Cancellation of Pilot Program Testing Electronic Collection of Import Data

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of cancellation of pilot program.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) is cancelling a pilot program in which importers, U.S. Customs and Border Protection (CBP), and TTB tested, as part of the International Trade Data System (ITDS) project, the electronic collection of import-related data required by TTB and the transfer of that data to TTB. TTB has amended its regulations to permanently provide importers with the option to file import-related data electronically along with the filing of the entry or entry summary with CBP, making the pilot program no longer necessary.

DATES: The cancellation of the pilot program is effective December 31, 2016.

FOR FURTHER INFORMATION CONTACT: John Kyranos, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone (202) 453–1039, extension 001; or email *itds@ttb.gov.*

For technical questions related to the Automated Commercial Environment (ACE) or Automated Broker Interface (ABI) transmissions, contact Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION: In Notice No. 156, a **Federal Register** notice published on August 7, 2015 (80 FR 47558), the Alcohol and Tobacco Tax and Trade Bureau (TTB) announced a pilot program to test the collection and transfer of certain import data through the Automated Commercial Environment (ACE), which is maintained by U.S. Customs and Border Protection (CBP). This pilot was part of TTB's effort to implement the International Trade Data System (ITDS). The pilot program was open to importers of distilled spirits, wine, beer and malt beverages, tobacco products, processed tobacco, and cigarette papers and tubes, and to U.S. government and industrial alcohol users (referred to in

this document, collectively, as ''importers'').

Notice No. 156 also announced the availability of, and requested comment on, a draft of the ACE Filing Instructions for TTB-Regulated Commodities (Filing Instructions), which contains instructions for proper electronic filing of import data for TTB-regulated commodities. TTB requested comment on the draft Filing Instructions for 60 days ending October 6, 2015. TTB received no written comments by that date. However, TTB's experience administering the pilot program led us to make several changes to the Filing Instructions.

In Industry Circular 2015–01, issued on October 21, 2015, TTB described how importers participating in the pilot program would submit specific information through ACE, either as an approved alternative to procedures prescribed in the TTB regulations or as a means to fulfill or demonstrate compliance with regulatory requirements. At the time, most TTB regulations that required the submission of information to CBP at importation required importers to submit paper documents or paper copies of those documents to CBP. Industry Circular 2015–01 also provided specific information about how to apply to participate in the pilot program.

In T.D. TTB–145, a final rule published in the **Federal Register** on December 22, 2016 (81 FR 94186), and effective December 31, 2016, TTB amended its regulations to clarify and streamline import procedures, and support the implementation of ITDS and the filing of import information electronically. The amendments include providing the option for importers to file import-related data electronically when filing entry or entry summary data electronically with CBP. As a result, as of December 31, 2016, the TTB regulations provide all TTB-regulated importers with the same option to file import-related information through ACE that participants in the pilot program had.

For this reason, this document announces the cancellation of the pilot program and Industry Circular 2015–01, effective December 31, 2016. On that date, importers who have been participating in the pilot program must follow TTB's regulations with regard to submitting data through ACE for importation of TTB-regulated commodities. Importers who have not been participating in the pilot program also must follow TTB's amended regulations to submit required information on paper or electronically.

In addition to the changes TTB made to the Filing Instructions due to the experience gained through the pilot program, TTB has also updated the Filing Instructions to reflect the regulatory changes made in T.D. TTB–145. The latest version of the Filing Instructions can be found on *https://www.cbp.gov* by searching for its title.

TTB notes that transmissions to ACE must be through a CBP-approved electronic data interchange system. For more information on submission of import-related information and forms through ACE, please see CBP's home page on use of ACE at *https://www.cbp.gov/trade/automated.*

For more general information on TTB's implementation of ITDS, see *https://www.ttb.gov/importers/learn-more-itds.shtml.*

Drafting Information

Andrew Malone of the Regulations and Rulings Division drafted this notice.

Signed: January 3, 2017.

John J. Manfreda,

Administrator.

[FR Doc. 2017–00083 Filed 1–6–17; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice and Request for Public Comment

Announcement Type: Notice and Request for Public Comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). Currently, the Community Development Financial Institutions Fund (CDFI Fund), U.S. Department of the Treasury, is soliciting comments concerning the New Markets Tax Credit Program (NMTC Program) Allocation Application.

DATES: Written comments must be received on or before March 10, 2017 to be assured of consideration.

ADDRESSES: Submit your comments via email to Robert Ibanez, NMTC Program Manager, CDFI Fund, at *nmtc@cdfi.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Robert Ibanez, NMTC Program Manager, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. The NMTC Allocation Application may be obtained from the CDFI Fund's Web site at *http://www.cdfifund.gov/nmtc.* Other information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's Web site at *http://www.cdfifund.gov.*

SUPPLEMENTARY INFORMATION:

Title: NMTC Program Allocation Application.

OMB Number: 1559–0016.

Abstract: Title I, subtitle C, section 121 of the Community Renewal Tax Relief Act of 2000 (the Act) amended the Internal Revenue Code (IRC) by adding IRC § 45D and created the NMTC Program. The Department of the Treasury, through the CDFI Fund, Internal Revenue Service, and Office of Tax Policy, administers the NMTC Program. In order to claim the NMTC, tax payers make Qualified Equity Investments (QEIs) in Community Development Entities (CDEs) and substantially all of the QEI proceeds must, in turn, be used by the CDE to provide investments in businesses and real estate developments in low-income communities and other purposes authorized under the statute.

The tax credit provided to the investor totals 39 percent of the amount of the investment and is claimed over a seven-year period. In each of the first three years, the investor receives a credit equal to five percent of the total amount paid for the stock or capital interest at the time of purchase. For the final four years, the value of the credit is six percent annually. Investors may not redeem their investments in CDEs prior to the conclusion of the seven-year period without forfeiting any credit amounts they have received.

The CDFI Fund is responsible for certifying organizations as CDEs, and administering the competitive allocation of tax credit authority to CDEs, which it does through annual allocation rounds. As part of the award selection process, CDEs are required to prepare and submit an Allocation Application, which consists of five key sections: Business Strategy; Community Outcomes; Organization Capacity; Capitalization Strategy; and Previous Allocations and Awards. This request for public comment seeks to gather information on the NMTC Allocation Application.

Type of Review: Regular Review.

Affected Public: CDEs applying for allocations of New Markets Tax Credits.

Estimated Number of Respondents: 310.

Estimated Annual Time per Respondent: 263.

Estimated Total Annual Burden Hours: 81,530.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record and may be published on the Fund Web site at *http://www.cdfifund.gov.* Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 26 U.S.C. 45D; 26 CFR 1. 45D–1.

Mary Ann Donovan,

Director, Community Development Financial Institutions Fund.

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DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Joint Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995, the OCC, the Board, and the FDIC (the ''agencies'') may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. On August 15, 2016, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), requested public comment for 60 days on a proposal for a new Consolidated Reports of Condition and Income for Eligible Small Institutions (FFIEC 051). The proposed FFIEC 051 is a streamlined version of the existing Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only (FFIEC 041), which was created by (1) removing certain existing schedules and data items and replacing them with a limited number of data items in a new supplemental schedule, (2) eliminating certain other existing data items, and (3) reducing the reporting frequency of certain data items. The FFIEC 051 generally would be available to institutions with domestic offices only and assets of less than $1 billion, which currently file the FFIEC 041. Of the nearly 6,000 insured depository institutions, approximately 5,200 would be eligible to file the proposed FFIEC 051. When compared to the existing FFIEC 041, the proposed FFIEC 051 shows a reduction in the number of pages from 85 to 61. This decrease is the result of the removal of approximately 950 or about 40 percent of the nearly 2,400 data items in the FFIEC 041. Of the data items remaining from the FFIEC 041, the agencies have reduced the reporting frequency for approximately 100 data items in the proposed FFIEC 051. In addition, the FFIEC and the agencies requested public comment on proposed revisions to the FFIEC 041 and the Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices (FFIEC 031), which are currently approved collections of information. The Consolidated Reports of Condition and Income are commonly referred to as the Call Report.

The comment period for the August 2016 notice ended on October 14, 2016. As described in the **SUPPLEMENTARY INFORMATION** section, after considering the comments received on the proposals, the FFIEC and the agencies will proceed with the implementation of the proposed FFIEC 051, along with the proposed reporting revisions to the FFIEC 041 and FFIEC 031, with some modifications to the proposals for all three versions of the Call Report. With OMB approval, the proposed FFIEC 051 and the proposed reporting changes to the existing FFIEC 031 and FFIEC 041 would become effective as of March 31, 2017.

The agencies also are giving notice that they have sent the collection to OMB for review.

DATES: Comments must be submitted on or before February 8, 2017.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number(s), will be shared among the agencies.

OCC: Because paper mail in the Washington, DC, area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible, to *prainfo@occ.treas.gov.* Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: ''1557–0081, FFIEC 031, 041, and 051,'' 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Board: You may submit comments, which should refer to ''FFIEC 031, FFIEC 041, and FFIEC 051,'' by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include the reporting form numbers in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert DeV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at

www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to ''FFIEC 031, FFIEC 041, and FFIEC 051,'' by any of the following methods:

- *Agency Web site: https://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC's Web site.
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''FFIEC 031, FFIEC 041, and FFIEC 051'' in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Attn: Comments, Room MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503; by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to the Call Report described in this notice, please contact any of the agency staff whose names follow. In addition, copies of the FFIEC 031 and FFIEC 041 Call Report forms and the proposed FFIEC 051 report form can be obtained at the FFIEC's Web site (*https://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Kevin Korzeniewski, Counsel, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898–3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Room MB–3007, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The agencies are proposing to create a new Call Report for eligible small institutions, the foundation for which is a currently approved collection of information for each agency. In addition, the agencies are proposing revisions to data items reported on the FFIEC 041 and FFIEC 031 Call Reports.

Report Title: Consolidated Reports of Condition and Income (Call Report).

Form Numbers: FFIEC 051 (proposed for eligible small institutions), FFIEC 041 (for banks and savings associations with domestic offices only), and FFIEC 031 (for banks and savings associations with domestic and foreign offices).

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

Type of Review: Revision and extension of currently approved collections.

OCC

OMB Control No.: 1557–0081.

Estimated Number of Respondents: 1,383 national banks and federal savings associations.

Estimated Average Burden per Response: 50.03 burden hours per quarter to file.

Estimated Total Annual Burden: 276,766 burden hours to file.

Board

OMB Control No.: 7100–0036.

Estimated Number of Respondents: 825 state member banks.

Estimated Average Burden per Response: 54.00 burden hours per quarter to file.

Estimated Total Annual Burden: 178,200 burden hours to file.

FDIC

OMB Control No.: 3064–0052.

Estimated Number of Respondents: 3,824 insured state nonmember banks and state savings associations.

Estimated Average Burden per Response: 48.08 burden hours per quarter to file.

Estimated Total Annual Burden: 735,432 burden hours to file.

The estimated average burden hours collectively reflect the estimates for the FFIEC 031, the FFIEC 041, and the proposed FFIEC 051 reports. When the estimates are calculated by type of report across the agencies, the estimated average burden hours per quarter are 128.05 (FFIEC 031), 74.88 (FFIEC 041) and 44.94 (FFIEC 051). Furthermore, the estimated burden per response for the quarterly filings of the Call Report is an average that varies by agency because of differences in the composition of the institutions under each agency's supervision (*e.g.,* size distribution of institutions, types of activities in which they are engaged, and existence of foreign offices).

The agencies received ten comments on the burden estimates. One commenter recommended including time to review instructions for the applicable form, even if data items in that form are not applicable to the institution. The agencies also received comments from institutions with estimates of the time it takes their institutions to prepare the current FFIEC 041 Call Report. The majority of these estimates ranged from 40–80 hours per quarter, with one response of 268 hours per quarter. Three commenters stated that preparing the Call Report costs approximately $1,000 annually for software. In response to the comments on methodology, the agencies have revised their calculation for their burden estimates. In addition to the estimated time for gathering and maintaining data in the required form and completing those Call Report data items for which an institution has a reportable (nonzero) amount, which have been included in the agencies' burden estimates, the revised methodology incorporates time for reviewing instructions for all items, even if the institution determines it does not have a reportable amount. The agencies have also added estimated burden hours for verifying the accuracy of amounts reported in the Call Report. As stated earlier, the agencies are also separating the estimated burden by type of report, to highlight the estimated burden reduction between the FFIEC 041 and FFIEC 051 reports. While the agencies' burden estimates are on the lower end of the ranges provided by commenters, these estimates are based on average times to complete each data item factoring in the varying levels of automation versus manual interventions

that exist across institutions for every data item.

One commenter estimated that the incremental burden associated with the one-time conversion from the FFIEC 041 to the FFIEC 051 would be approximately 160 hours, primarily for training, and approximately $350 for software. Due to the various factors that could affect the time and cost of switching to the FFIEC 051, including training needs, the type of existing systems and automation at an institution, and any cost from software vendors to enable an institution to file the new form, the agencies have not provided an estimate of this conversion burden. The agencies reiterate that adopting the FFIEC 051 form is optional, and each institution should weigh the estimated time savings from using that form with the one-time burden to switch to the FFIEC 051 from the FFIEC 041.

General Description of Reports

Institutions submit Call Report data to the agencies each quarter for the agencies' use in monitoring the condition, performance, and risk profile of individual institutions and the industry as a whole. Call Report data serve a regulatory or public policy purpose by assisting the agencies in fulfilling their missions of ensuring the safety and soundness of financial institutions and the financial system and protecting consumer financial rights. The data also serve public policy purposes associated with agency-specific missions affecting national and state-chartered institutions, *e.g.,* monetary policy, financial stability, and deposit insurance. Call Reports are the source of the most current statistical data available for identifying areas of focus for on-site and off-site examinations. The agencies use Call Report data in evaluating institutions' corporate applications, including, in particular, interstate merger and acquisition applications for which, as required by law, the agencies must determine whether the resulting institution would control more than 10 percent of the total amount of deposits of insured depository institutions in the United States. Call Report data also are used to calculate institutions' deposit insurance and Financing Corporation assessments and national banks' and federal savings associations' semiannual assessment fees.

These information collections are mandatory: 12 U.S.C. 161 (for national banks), 12 U.S.C. 324 (for state member banks), 12 U.S.C. 1817 (for insured state nonmember commercial and savings banks), and 12 U.S.C. 1464 (for federal and state savings associations). At present, except for selected data items and text, these information collections are not given confidential treatment.

Current Actions

I. Introduction

On August 15, 2016, the agencies requested comment for 60 days on a proposal for a new Consolidated Reports of Condition and Income for Eligible Small Institutions (FFIEC 051) along with various proposed revisions to the existing Call Report requirements (FFIEC 031 and FFIEC 041).[1] The FFIEC 051 was created by removing items or reducing the frequency of items reported in the FFIEC 041, as detailed in Appendix B. The FFIEC 051 and the revisions to the FFIEC 031 and FFIEC 041 are the result of a formal initiative launched by the FFIEC in December 2014 to identify potential opportunities to reduce burden associated with Call Report requirements for community institutions. The most significant actions under this initiative are community institution outreach efforts, internal surveys of users of Call Report data at FFIEC member entities, and the proposal for a streamlined Call Report for small institutions. Additional information about the initiative can be found in the August 2016 notice, along with two other notices related to actions taken under that initiative.[2]

The comment period for the August 2016 notice ended on October 14, 2016. General comments on the notice are summarized in Section II. In Section III, the agencies provide more details on the comments received on the FFIEC 051 and any changes the agencies are making in response to those comments. In Section IV, the agencies address comments on the proposed changes to the FFIEC 031 and FFIEC 041 Call Reports. In Section V, the agencies provide information about additional specific suggestions received from commenters to improve all versions of the Call Report and any changes the agencies are making in response to those comments. With OMB approval, the effective date for the initial implementation of the FFIEC 051 and the revisions to the existing FFIEC 041 and FFIEC 031 would be March 31, 2017.

II. General Comments on the Proposal

The agencies collectively received comments on the proposal from approximately 1,100 entities, including individuals, banking organizations, bankers' associations, and a government entity.[3] General comments on the proposed FFIEC 051 and existing FFIEC 031 and FFIEC 041 Call Reports are included in this section. The agencies provide information regarding comments on specific aspects of the proposed FFIEC 051 and the proposed revisions to the existing Call Reports in more detail in Sections III and IV, respectively. Additional specific suggestions provided by commenters on the existing Call Reports and the proposed FFIEC 051 are included in Section V.

A. General Comments on the Proposed FFIEC 051

Commenters expressed mixed opinions on the proposed FFIEC 051. Approximately 25 commenters representing banking organizations, bankers' associations, and a government entity supported the effort put forth by the agencies. One bankers' association stated that the initial proposal was ''a positive step in an ongoing, iterative process'' that shows a ''modest but material burden relief to institutions eligible to file the [FFIEC 051] report.'' One institution stated that the proposed FFIEC 051 would assist small banks by reducing preparation time and minimizing confusion by removing schedules related to activities in which the bank does not engage. Another commenter stated that this proposal was a good start by removing items that have no relationship with the reporting institution. Another commenter agreed with the proposal to shorten the length of the Call Report and the instructions, which would reduce the time spent reviewing updates to determine items that may or may not be applicable to the bank. One commenter stated the reduction and the removal of non-relevant data items for noncomplex institutions saves both time and money. The government entity stated it uses certain data items in the Call Report in preparing national economic reports, and encouraged the agencies to continue collecting those items.

On the other hand, the majority of commenters from banking organizations and bankers' associations responded that there was no perceived impact by adopting the FFIEC 051. Many of the banking organizations stated that the data items proposed to be removed were not reported currently by their institutions; therefore, the changes would not impact their burden in preparing the Call Report. Three of the bankers' associations stated that the

[1] See 81 FR 54190 (August 15, 2016).

[2] See 80 FR 56539 (September 18, 2015) and 81 FR 45357 (July 13, 2016).

[3] The agencies received approximately 100 unique letters and 1,000 form letters.

agencies removed items largely not reported, and related to activities not engaged in, by community banks. Another institution responded that by making the change to the FFIEC 051, it would add burden at the conversion date with little time savings in future filings. One commenter stated that the inclusion of the supplemental schedule (Schedule SU) could actually increase burden, as banks must use the same processes or new processes to verify the data (or inapplicability) of the new supplemental items.

The agencies recognize that not all community institutions eligible to file the FFIEC 051 will see an immediate and large reduction in burden by switching to that form. Some of the items that were removed from the FFIEC 041 to create the FFIEC 051 only needed to be reported by institutions with assets of $1 billion or more. Other items not included in the FFIEC 051 applied to institutions of all sizes, but may not have applied to every community institution, due to the nature of each institution's activities. Approximately 100 data items would be collected at a reduced frequency in the FFIEC 051. For example, in creating the FFIEC 051, the agencies have removed from the FFIEC 041 the data items on Schedule RC–L, Derivatives and Off-Balance Sheet Items, in which the more than 700 eligible institutions that have derivative contracts have been required to report the gross positive and negative fair values of these contracts. The agencies also have reduced from quarterly to semiannually the reporting frequency in the FFIEC 051 of Schedule RC–C, Part II, Loans to Small Businesses and Small Farms, which is applicable to the approximately 5,200 institutions eligible to file the FFIEC 051,[4] and Schedule RC–A, Cash and Balances Due from Depository Institutions, which applies to the more than 1,400 eligible institutions that have $300 million or more in total assets. Additionally, as noted earlier, the agencies are shortening the instructions associated with the FFIEC 051, so that community bankers will not need to review as many nonapplicable instructions, or the associated changes to those instructions that may occur in the future. Taken together, the agencies believe these changes are a positive step toward providing meaningful Call Report burden relief to community institutions.

A majority of the commenters that did not favor the proposed FFIEC 051 suggested the agencies adopt a ''short-form'' Call Report to be filed in the first and third quarters. The short-form Call Report recommended by commenters would consist only of an institution's balance sheet, income statement, and statement of changes in equity capital. The institution would file a full Call Report including all supporting schedules in the second and fourth quarters.

The agencies recognize that the information requested in the Call Report is often more granular than information presented in standard financial statements, including the notes to the financial statements, and can require refining or subdividing the information contained in accounts reported in an institution's general ledger system or core processing systems. This process may be burdensome, particularly when account balances have not materially changed from the prior quarter. However, one element that sets banking apart from other industries is the regulatory framework, particularly the provision of Federal deposit insurance and the important role of financial intermediation, which requires safety and soundness supervision and examination. A key component of bank supervision is reviewing granular financial data about an institution's activities to identify changes in those activities and in the institution's condition, performance, and risk profile from quarter to quarter that suggest areas for further investigation by the institution's supervisory agency. For example, granular data on loan categories, past due and nonaccrual loans, and loan charge-offs and recoveries[5] feed into an analysis of credit risk, while data on loan, security, time deposit, and other borrowed money maturities and repricing dates[6] feed into analyses of interest rate risk and liquidity risk. Much of this analysis occurs off-site, so an institution may not be aware of the extent of this process unless it identifies anomalies or other ''red flags'' at the institution. Even then, some anomalies and other ''red flags'' may be discussed immediately with the institution, while other concerns are flagged for investigation at the next on-site examination. The earlier that anomalies, upon immediate follow-up, are found to evidence deficiencies in risk management or deterioration in an institution's condition, the less difficult it will be for the institution to implement appropriate corrective action. In this context, with full-scope on-site examinations occurring no less than once during each 18-month period for institutions that have total assets of less than $1 billion and meet certain other criteria, quarterly data are necessary for many of the data items in the Call Report in order for an institution's supervisory agency to have a sufficient number of data points to both identify and distinguish between one-time anomalies and developing trends at the institution. Moreover, the agencies note that extending the examination cycle to 18 months for certain qualifying institutions is discretionary, and the analysis of trends in a particular institution's Call Report data is a significant factor in deciding whether to exercise that discretion with respect to that institution.

In addition to supporting the identification of higher-risk situations, enabling timely corrective action for such cases, and justifying the extended examination cycle, the quarterly reporting of the more granular Call Report items also aids in the identification of low-risk areas prior to on-site examinations, allowing the agencies to improve the allocation of their supervisory resources and increase the efficiency of supervisory assessments, which reduces the scope of examinations in these areas, thereby reducing regulatory burden. While the quarterly monitoring process enabled by the more granular Call Report items historically has focused on raising ''red flags,'' similar emphasis has also been placed on the identification of low-risk situations. A six-month reporting cycle for the more granular Call Report items would hamper the agencies' ability to form timely risk assessments and so could stymie efforts to improve the focus of on-site examinations for low-risk institutions. In this manner, an effort to reduce regulatory burden by lengthening the reporting cycle for the more granular Call Report items could limit the agencies' opportunities to reduce burden for on-site examinations.

In addition to safety and soundness data, other data items are required quarterly due to various statutes or regulations. Leverage ratios based on average quarterly assets and risk-based capital ratios are necessary under the prompt corrective action framework established under 12 U.S.C. 1831o.[7] Data on off-balance sheet assets and liabilities are required every quarter for which an institution submits a balance sheet to the agencies pursuant to 12 U.S.C. 1831n.[8] Granular data on deposit liabilities and data affecting risk assessments for deposit insurance are

[4] See Section III for further discussion of this change in reporting frequency.

[5] Reported on Schedules RI–B; RC–C, Part I; and RC–N.

[6] Reported on Schedules RC–B; RC–C, Part I; RC–E; and RC–M.

[7] Reported on Schedules RC–K and RC–R.

[8] Reported on Schedule RC–L.

required four times per year under 12 U.S.C. 1817.[9]

Further, the public availability of most quarterly Call Report information from institutions that are not publicly held is desired by their depositors (particularly those whose deposits are not fully insured), other creditors, investors, and other institutions. An institution's depositors and other creditors may use quarterly Call Report information to perform their own assessments of the condition of the institution. Existing and potential investors may evaluate Call Report data to assess an institution's condition and future prospects; the absence of quarterly information could impair the institution's ability to raise capital or could limit the liquidity of the institution's shares for existing stockholders. Other institutions that engage in transactions with the reporting institution may utilize Call Report information to assess the condition of their counterparties to these transactions. In addition, some institutions use peer analysis to benchmark against local competitors using data obtained from their Call Reports directly, or by using third-party vendors who often leverage information from the agencies' repository of Call Report data. For example, as part of their financial control structures, some institutions analyze their allowance for loan and lease losses (ALLL) by comparing their delinquency ratios and their ratios of ALLL to loans and leases to peer group ranges and averages.

While the agencies understand the commenters' desire for a ''short-form'' Call Report, for the reasons stated above, the agencies did not adopt this suggestion. In addition to the basic financial statements, the most streamlined quarterly report possible must also include quarterly data required by statute or regulation, along with quarterly data necessary for adequate supervision by the agencies. However, as part of the continuing burden reduction efforts, the agencies will continue to review the quarterly data collected in the proposed FFIEC 051 and existing FFIEC 031 and FFIEC 041 reports that go beyond the statutory or regulatory requirements or essential supervisory needs. For example, as described in Section III, the agencies are revising Schedule RC–C, Part II, in the FFIEC 051 to reduce its reporting frequency from quarterly to semiannual for all institutions that file the FFIEC 051.

[9] Reported on Schedules RC–E and RC–O.

B. General Comments on the Call Report Initiatives

The agencies are still engaged in the statutorily mandated review of the existing Call Report data items (Full Review).[10] The agencies are conducting the Full Review as a series of nine surveys of internal users of Call Report data within the FFIEC member entities. Proposed changes resulting from the first three surveys were included in the August 2016 proposal, and a summary of the member entities' uses of the data items retained in the Call Report schedules covered in these three surveys is included as Appendix A. The agencies are analyzing the results of four additional surveys, and still need to collect and review data from the final two surveys to determine any future proposed revisions to the FFIEC 031, FFIEC 041, and FFIEC 051. Burden-reducing reporting changes to these three versions of the Call Report from the remaining six surveys will be proposed in future **Federal Register** notices with an anticipated implementation date of March 31, 2018. The agencies described this staged approach to proposing changes to the FFIEC 031, FFIEC 041, and FFIEC 051 resulting from the Full Review in their August 2016 proposal, but asked whether it would be less burdensome to delay all the changes to the Call Report until the completion of the Full Review.

The agencies received comments about the burden reduction initiative and the Full Review. On the timing of future revisions, one commenter stated that it would not matter, while another commenter wanted the changes implemented as soon as possible. Three commenters recommended adopting all of the changes at once. These commenters stated it is more burdensome to deal with more frequent changes to the Call Report, even if those changes would reduce burden. Six commenters sought a better understanding for the agencies' use of the Call Report data items submitted by institutions. Two bankers' associations requested a published report of how the data are used either by individual line item or by schedule.

The agencies are cognizant of the burden caused by frequent changes to the Call Report, but also must consider the ongoing burden imposed until the completion of the review by collecting data items the agencies have agreed are no longer necessary. In an attempt to balance those concerns, the agencies plan to propose changes related to the user surveys in two future notices. The agencies already included the results from the first three user surveys in the August 2016 notice. The next notice would include changes from a second set of user surveys and is expected to be issued in early 2017. The last notice would include any changes from a third and final set of user surveys and is expected to be issued in late 2017. The proposed effective date for changes in both future notices would be March 31, 2018.

[10] Section 604 of the Financial Services Regulatory Relief Act of 2006 (12 U.S.C. 1817(a)(11)) mandates that this review occur every five years.

As described earlier in this section and in response to specific comments in Sections III and V, a significant amount of the data collected in the Call Report is used for safety and soundness purposes, especially for quarterly off-site monitoring and reviews between on-site examinations. Additional data items are required by statute or regulation. A lesser number of data items are used for consumer financial protection purposes or for specific agency missions, such as deposit insurance and monetary policy. To provide additional detail on the uses of Call Report schedules and data elements, the agencies are including, in Appendix A, a summary of the FFIEC member entities' uses of specific schedules and data items from the first three user surveys conducted in the Full Review. The agencies plan to publish similar summaries when proposing additional changes based on the results of the second two sets of Full Review surveys in future notices.

Finally, while it may not directly reduce burden at this time, as described in the August 2016 notice, the agencies will apply a set of guiding principles in evaluating potential future additions and revisions to the Call Report. Those principles are: (1) The data items serve a long-term regulatory or public policy purpose by assisting the FFIEC member entities in fulfilling their missions of ensuring the safety and soundness of financial institutions and the financial system and the protection of consumer financial rights, as well as agency-specific missions affecting national and state-chartered institutions; (2) the data items to be collected maximize practical utility and minimize, to the extent practicable and appropriate, burden on financial institutions; and (3) equivalent data items are not readily available through other means. The agencies intend to apply these principles with rigor for items proposed to be added to the Call Reports, with the goal of minimizing future burden increases.

III. Specific Comments on the Proposed FFIEC 051

A. Eligibility

The agencies proposed to make the FFIEC 051 available as an option to eligible small institutions. For purposes of the FFIEC 051 Call Report, the agencies proposed to define ''eligible small institutions'' as institutions with total assets less than $1 billion and domestic offices only. Total assets for eligibility would be measured as of June 30 each year to determine the institution's eligibility to file the FFIEC 051 beginning in March of the following year. In addition, for an institution otherwise eligible to file the FFIEC 051, the institution's primary federal regulatory agency, jointly with the state chartering authority, if applicable, may require the institution to file the FFIEC 041 instead based on supervisory needs. In making this determination, the appropriate agency will consider criteria including, but not limited to, whether the eligible institution is significantly engaged in complex, specialized, or other higher risk activities.[11] The agencies anticipate making such determinations only in a limited number of cases.

The agencies received numerous comments on eligibility for the FFIEC 051. Eight commenters supported expanding the threshold. One commenter suggested using the FDIC's definition of a ''community bank'' (from the FDIC's Community Banking Study), which is based on deposit and lending activity and certain other criteria rather than solely asset size, while another commenter suggested expanding the FFIEC 051 to all institutions that do not engage in complex activities. Another commenter suggested tying the asset threshold to the definition of ''small bank'' under the Community Reinvestment Act (currently, $1.216 billion and indexed for inflation). Two commenters recommended using a $10 billion asset threshold, with one of those commenters suggesting that the asset threshold be automatically adjusted for inflation in the future.

At this time, the agencies are retaining their proposed $1 billion asset-size threshold to be eligible for the FFIEC 051. This threshold is consistent with one of the eligibility criteria established by Congress for community institutions to be eligible for an 18-month examination cycle rather than the standard 12-month cycle.[12] The agencies are considering other size thresholds and other eligibility criteria, such as whether relevant criteria could be developed for determining that an institution should be considered a ''community'' institution for Call Report purposes; however, an asset-size threshold tied to an existing statutory basis was chosen to keep the initial eligibility criteria simple and transparent, and avoid delaying the proposed March 31, 2017, initial implementation date for those eligible institutions interested in beginning to file the FFIEC 051 as of that date while the agencies evaluate additional potential eligibility criteria. The agencies plan to review additional data in determining whether to propose any changes to the initial eligibility threshold in the future. The agencies are also making one revision to the eligibility criteria to disallow advanced approaches institutions[13] from being eligible to use the FFIEC 051.[14] Even though such an institution may be under the $1 billion asset-size threshold, it is part of a consolidated banking organization with assets greater than $250 billion and as such the agencies do not believe such an institution shares the same risks as eligible small institutions.

The agencies also asked whether filing the FFIEC 051 by eligible institutions should be mandatory or optional. Six commenters supported allowing the FFIEC 051 to be optional. The agencies agree with the commenters and will continue to offer it as an option to eligible small institutions that would otherwise need to file the FFIEC 041. If an institution is eligible for and chooses to adopt the FFIEC 051, the agencies expect the institution will continue filing that version of the report going forward as long as it remains eligible.[15] If an institution's assets increase to $1 billion or more as of June 30 of any calendar year, the institution must return to filing the FFIEC 041 beginning with the first quarter of the following calendar year.

The agencies received three comments on the proposed reservation of authority for filing the FFIEC 051. Two commenters opposed this reservation of authority, stating that the language was too broad and would allow too much discretion to examiners to arbitrarily make institutions change their version of the Call Report. One of these commenters suggested a process where any determination by an examiner that an institution must revert to the FFIEC 041 should be automatically appealable to the agency's Ombudsman. The other commenter recommended more clearly defining and limiting the scenarios in which the agencies would consider making an institution revert to filing the FFIEC 041. The agencies acknowledge the criteria to use the reservation of authority listed in the notice could be interpreted more broadly than the agencies intended. The agencies would consider using the reservation of authority if an institution has a large amount of activity in one or more complex activities that would be reported on one of the schedules or items proposed to be eliminated in the FFIEC 051. These schedules include Schedules RC–D (trading activity), RC–L (off-balance sheet derivatives), RC–P (mortgage banking), RC–Q (fair value measurements), RC–S (servicing, securitization, and asset sale activities), and RC–V (variable interest entities). The agencies do not intend to use this reservation of authority widely, or to apply it to institutions that engage only in activities that are fully reported on the FFIEC 051. Furthermore, the exercise of the reservation of authority would require a decision by a member of the appropriate agency's senior management and would not be at the discretion of examination staff.

B. Implementation Date

The agencies proposed implementing the FFIEC 051 beginning March 31, 2017, for all eligible small institutions. Nine commenters indicated the lead time was sufficient because most of the changes between the FFIEC 041 and FFIEC 051 did not affect their institutions. Three commenters suggested delaying the implementation date. One commenter suggested setting

[11] This proposed reservation of authority is consistent with the reservation of authority applicable to a holding company with consolidated total assets of less than $1 billion that would otherwise file the Board's FR Y–9SP, Parent Company Only Financial Statements for Small Holding Companies (OMB No. 7100–0128). See page GEN–1 of the instructions for the FR Y–9SP.

[12] See 12 U.S.C. 1820(d), as amended by Section 83001 of the Fixing America's Surface Transportation Act, Public Law 114–94, 129 Stat. 1312 (2015). The $1 billion asset-size threshold for the proposed FFIEC 051 also is consistent with the incremental approach taken by Congress when increasing the threshold for the Board's Small Bank Holding Company and Savings and Loan Holding Company Policy Statement; see Public Law 113–250 (December 18, 2014).

[13] See 12 CFR 3.100(b) (OCC); 12 CFR 217.100(b) (Board); 12 CFR 324.100(b) (FDIC).

[14] As a consequence, the data items in Schedule RC–R that are applicable only to advanced-approaches institutions would be removed from the FFIEC 051.

[15] An institution whose assets remain below $1 billion as of June 30 of any year may choose to file the FFIEC 041 instead of the FFIEC 051 beginning with the first quarter of the following calendar year. An institution's primary federal supervisory agency may approve an institution's request to change to the FFIEC 041 in a later quarter of a calendar year on a case-by-case basis.

the date at least six months from the start of the quarter in which the final changes are published. Another commenter stated a minimum of one quarter is needed after the final FFIEC 051 is approved. One institution suggested a June 30, 2017, implementation date.

The agencies believe that it is important to offer this new report form as an option as early as feasibly possible, to reduce burden for those eligible institutions that are able to switch to the FFIEC 051 beginning with the March 31, 2017, report date. The conversion to the FFIEC 051 is optional, and initial eligibility would be determined by an institution's asset size as of June 30, 2016. For an institution that qualifies to use the FFIEC 051 and desires to use that form, but is unable to do so for the March 31, 2017, report date, the institution may begin reporting on the FFIEC 051 as of the June 30, 2017, report date or in a subsequent quarter of 2017. Alternatively, the institution could wait until March 31, 2018, to begin reporting on the FFIEC 051, assuming it continues to meet the eligibility criteria.

C. Comments on Schedule RC–R, Regulatory Capital

The agencies received approximately 30 comment letters that highlighted the burden required to prepare Schedule RC–R, Regulatory Capital. The agencies received similar comments during their banker outreach efforts, as well as in comment letters submitted under a review of agency regulations required by the Economic Growth and Regulatory Paperwork Reduction Act (EGRPRA).[16]

An institution must calculate its capital ratios quarterly pursuant to the prompt corrective action provisions of statute and the agencies' regulations. The agencies revised Schedule RC–R in March 2015 to include the data items that would be necessary for an institution to calculate its regulatory capital ratios under the agencies' revised capital rules. The greater detail of those rules requires a degree of categorization, recordkeeping, and reporting that is greater than under the previously applicable capital rules. While many of the data fields on Schedule RC–R may not be applicable to community institutions not engaged in complex activities, some community institutions do engage in activities that would need to be reported in those fields to perform the correct calculation under the capital rules. The agencies are developing responses to the concerns about the burden of the regulatory capital rules raised during the EGRPRA comment process and the associated reporting requirements on Schedule RC–R. If the agencies propose modifications to the regulatory capital rules, the agencies would also propose modifications to the associated reporting requirements on Schedule RC–R.

D. Comments on Schedule RC–C, Loans and Lease Financing Receivables

Twelve commenters emphasized Schedule RC–C as a significant contributor to the reporting burden for smaller institutions. Five banking organizations specifically highlighted Schedule RC–C, Part II, Loans to Small Businesses and Small Farms, as particularly burdensome and suggested eliminating the schedule or reducing the frequency of the data collected. During the agencies' banker outreach efforts, community institutions similarly highlighted the burden of Schedule RC–C, and particularly Part II of the schedule.

In developing the proposed FFIEC 051, the agencies removed 38 items from Schedule RC–C, Part I, that are currently reported in the FFIEC 041 and were identified as having lesser utility for institutions eligible to file the new report.

The remaining loan and lease data in Schedule RC–C, Part I, are critical inputs to assessing the safety and soundness of individual institutions through analysis of the institutions' credit risk, interest rate risk, and liquidity risk, including the identification and analysis of lending concentrations. The granularity of the loan categories is also essential for peer group analysis and industry analysis. Loan and lease information is also an important component of agency statistical models that assess the risk profile of an institution. In addition, many community institutions use the Call Report loan categories when they measure the estimated credit losses that have been incurred on groups of loans with similar risk characteristics in their calculations of the ALLL each quarter under U.S. generally accepted accounting principles (GAAP).

Finally, loan and lease information assists the agencies in fulfilling their specific missions. The Board, as part of its monetary policy mission, relies on the loan data in Schedule RC–C, Part I, to provide information on credit availability and lending conditions not available elsewhere. Loan and lease detail at all sizes of institutions is necessary for monitoring the overall health of the economy. Reducing loan detail or data frequency for smaller institutions would limit the ability to monitor credit availability and lending conditions widely, including in response to any changes in monetary policy. At times, loan availability and lending conditions may be different at smaller institutions than at larger institutions. Furthermore, Schedule RC–C, Part I, data are used to benchmark weekly loan data collected by the Board from a sample of both small and large institutions; the weekly data are used to estimate weekly loan aggregates for the banking sector as a whole to provide more timely input for the purposes of monitoring the macroeconomy.

The FDIC's deposit insurance assessment system for ''established small banks'' relies on information reported by individual institutions for the Schedule RC–C, Part I, standardized loan categories in the determination of the loan mix index in the financial ratios method, which is used to determine assessment rates for such institutions.[17]

The data collected in Schedule RC–C, Part II, is based on a statutory requirement to collect data on small business and small farm loans on an annual basis and began in 1993.[18] In 2010, the FFIEC changed the reporting frequency for Schedule RC–C, Part II, from annual to quarterly. At that time, the agencies approved the more frequent collection of these data to improve the Board's ability to monitor credit conditions facing small businesses and small farms and contribute to its ability to develop policies intended to address any problems that arise in credit markets. The U.S. Department of the Treasury also identified a particular need for these data as they worked to develop policies to ensure that more small businesses and small farms would have access to credit. The Board also found the more frequent data valuable for monitoring the macroeconomy and credit availability in particular for the purposes of monetary policymaking. However, after extensive analysis by the Board, the agencies agreed in the August 2016 proposal to reduce the frequency of Schedule RC–C, Part II, to semiannually in June and December for institutions with assets of less than $50 million.

The agencies received five comments stating that Schedule RC–C, Part II, was particularly burdensome for their institutions due to the level of manual

[16] Public Law 104–208 (1996), codified at 12 U.S.C. 3311.

[17] See 81 FR 32186–32188 and 32208 (May 20, 2016).

[18] See Section 122 of the Federal Deposit Insurance Corporation Improvement Act of 1991, Public Law 102–242.

intervention required to report the data. This schedule requests the number and amount currently outstanding of existing loans in each of these categories, but categorized by the loans' original amounts. One banker noted that their bank had to manually stratify loan data into the three loan size categories for each type of loan according to the loans' original amounts, and then manually adjust for lines of credit and participations purchased and sold to accurately report the amount currently outstanding. One bank questioned how valuable the small business and small farm loan data are for setting monetary policy, particularly since the Board had been setting monetary policy for many years before the FFIEC began requiring quarterly data in 2010 and also because the Call Report data collected in Schedule RC–C, Part II, does not capture significant nonbank funding sources for small businesses such as credit cards and vendor financing. The agencies received similar comments about burden from banker outreach efforts conducted by the FFIEC member entities and through the EGRPRA process. After additional review, the Board has determined that semiannual reporting by all institutions filing the FFIEC 051 would be of sufficient frequency to meet their data needs. Therefore, the agencies will collect this loan information from all institutions filing the FFIEC 051 in the June and December quarterly reports only.

E. Coordination With Other Reports

Two commenters from multibank holding companies stated that the FFIEC 051 does not provide any relief for their institutions, because many of the items removed from the FFIEC 041 must still be reported on the holding company's FR Y–9C [19] report and therefore must still be collected at the bank level. One of these commenters noted that unless all banks in a multibank holding company can use the FFIEC 051, likely none of them will, as it may be more difficult to consolidate the information from different Call Report forms when completing the FR Y–9C. The Board notes that for most holding companies with total assets less than $1 billion, the holding company can file the FR Y–9SP, which does not require data being removed from the FFIEC 051. For holding companies with total assets of $1 billion or more, the FR Y–9C does require a significant amount of information that is being removed from the FFIEC 051. The Board believes this information is necessary on the FR Y–9C, even if the activity is spread among multiple subsidiary institutions, some of which may have assets less than $1 billion, for the effective supervision of the consolidated holding company. In those cases, the holding company and its subsidiary institutions can best determine whether there is any burden saved at the institution level by filing the FFIEC 051 rather than the FFIEC 041.

Four commenters stated that the agencies should reduce duplication between the Call Report and other regulatory reports collected by the agencies. Commenters noted perceived duplication of one or more data items with the following reports: FR 2900,[20] FR 2644,[21] the FDIC's annual Summary of Deposits survey,[22] and loan data provided to the institution's Federal Home Loan Bank for access to advances. The agencies do not believe data collected in these collections are duplicative of Call Report data. The FR 2900 collects select data on cash and deposit liabilities for reserve requirement purposes, from most institutions on a weekly basis, which may not coincide with the reporting date for the Call Report. The FR 2644 collects data on loans, securities, and borrowings from a small sample of banks on a weekly basis, which may not coincide with the reporting date for the Call Report. The FDIC's Summary of Deposits survey collects data on deposits stratified by branch location from institutions with branch offices annually as of each June 30. Deposit data categorized by branch location is not available elsewhere. The Federal Home Loan Banks are not government agencies, and any data they may collect in connection with various lending programs are not readily available for use by FFIEC member entities.

IV. Proposed Call Report Revisions to the FFIEC 041 and the FFIEC 031

The agencies proposed revisions to some of the schedules in the FFIEC 041 and FFIEC 031 Call Reports in response to the findings of the first three user surveys at FFIEC member entities conducted under the Full Review. Specifically, the following schedules in the FFIEC 041 and FFIEC 031 versions of the Call Report would have data items removed or subject to new or higher reporting thresholds as a result of these surveys (see Appendices C and D for a complete listing of the affected data items based on the September 30, 2016, FFIEC 031 and FFIEC 041 Call Reports, respectively):

- Schedule RI—Income Statement
- Schedule RI–B—Charge-offs and Recoveries on Loans and Leases and Changes in Allowance for Loan and Lease Losses
- Schedule RC–C—Loans and Lease Financing Receivables
- Schedule RC–E—Deposit Liabilities
- Schedule RC–M—Memoranda
- Schedule RC–N—Past Due and Nonaccrual Loans, Leases, and Other Assets

The agencies did not receive any comments on the specific changes to the FFIEC 041 and FFIEC 031 in the proposal, and plan to implement those changes as proposed.

V. Additional Suggested Revisions

Twelve commenters recommended additional specific changes for the agencies to consider on various schedules of the Call Report. Many of these commenters did not direct their comments at a specific version of the Call Report, so the agencies considered these comments to improve both the existing FFIEC 031 and FFIEC 041 Call Reports and proposed FFIEC 051.

One commenter suggested the agencies revise Schedule RI–C (Disaggregated Data on the Allowance for Loan and Lease Losses) to align with the loan categories reported on Schedule RC–C, Part I. The agencies did not adopt this suggestion. Aligning the categories would require collecting additional granular data on Schedule RI–C, adding approximately 20 categories and 60 total items. The agencies proposed collecting disaggregated ALLL data for key Schedule RC–C, Part I, loan categories when they proposed to add Schedule RI–C to the Call Report in 2011. However, commenters on that proposal questioned the reporting of ALLL data for these key Call Report loan categories. They recommended reducing the number of loan categories and using broader portfolio segments that would better align with their loan loss allowance methodologies, which the agencies did in the final implementation of Schedule RI–C in 2013. The agencies do not believe that changing the schedule to require additional granularity of data is necessary for the supervision of the institutions to which this schedule is currently applicable. In this regard, the agencies do not collect Schedule RI–C from institutions with assets less than $1 billion and it would not be included in the FFIEC 051.

[19] Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128).

[20] Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900; OMB No. 7100–0087).

[21] Weekly Report of Selected Assets and Liabilities of Domestically Chartered Commercial Banks and U.S. Branches and Agencies of Foreign Banks (FR 2644; OMB No. 7100–0075).

[22] Summary of Deposits, OMB No. 3064–0061.

Three commenters suggested revisions to Schedule RI–E (Explanations). One commenter suggested adjusting the criteria to separately disclose individual components of other noninterest income and other noninterest expense. The agencies' current criteria require separate disclosure if a component within one of those income statement categories is greater than $100,000 and 3 percent of the total balance of that category.[23] The commenter suggested adjusting the criteria to the greater of $100,000 and 5 to 7 percent of the total balance. Another commenter suggested reporting Schedule RI–E detail on other noninterest income and other noninterest expense annually on the December 31 Call Report, as the commenter stated the data are primarily useful on an annual rather than quarterly basis. Another commenter suggested providing definitions for each of the components of other noninterest income and other noninterest expense for which preprinted captions are provided in Schedule RI–E. The agencies plan to review the threshold for separately disclosing individual components and the frequency of the data collection as part of the ongoing Full Review. The agencies do not plan to provide specific definitions for the components of other noninterest income and other noninterest expense represented by preprinted captions. The agencies added preprinted captions for these components to assist all institutions, including community institutions, as they were the most frequently disclosed components. Not having preprinted captions for such components would necessitate each institution manually entering its own captions for those components of other noninterest income and other noninterest expense exceeding the reporting threshold. However, the agencies do not want to impose a regulatory definition for these individual components, which could require institutions to adjust their internal definitions to line up with the agencies' definitions. The agencies use this information primarily for the supervision of individual institutions rather than for peer group comparison, so imposing uniform definitions across institutions is not necessary for supervisory review. Detailed lists of components of other noninterest income and other noninterest expense can be found in the instructions for Schedule RI, items 5.1 and 7.d, respectively. The agencies plan to clarify the instructions for these two Schedule RI data items to better indicate the linkage between the components of other noninterest income and other noninterest expense listed in these instructions and the preprinted captions provided in Schedule RI–E.

One commenter suggested the agencies review the intangible asset breakout on Schedule RC, item 10, and Schedule RC–M, item 2, and suggested combining goodwill and other intangible assets on Schedule RC. The agencies need additional time to consider this request, and will consider it within the next set of proposed Call Report revisions.

Six commenters stated that Schedule RC–E (Deposit Liabilities) and RC–O (Other Data for Deposit Insurance and FICO Assessments) were particularly burdensome and suggested simplifying or consolidating the deposit data on these schedules. Some commenters specifically noted the breakout of deposit information by source, use, and balance as time-consuming, especially for Memorandum items 1 through 4 on Schedule RC–E. Two commenters noted that the FDIC's deposit insurance assessments currently are calculated based on average total assets and average tangible equity, so the deposit data is not necessary for the vast majority of banks.[24] Three commenters also questioned why the agencies maintain a stratification of certain deposits in Schedule RC–E into those with balances less than $100,000, $100,000 through $250,000, and more than $250,000 even though the deposit insurance limit is currently $250,000, and stated this stratification was particularly burdensome as it required a significant amount of manual intervention. Two commenters stated that separating out Individual Retirement Accounts (IRA) data from general deposits on Schedule RC–O was particularly burdensome, with one commenter noting their bank had to further identify and separate out Coverdell Education Savings Accounts (formerly called Education IRAs) from the bank's other IRA account balances to add back to the non-retirement accounts.

Schedule RC–E categorizes deposits based on source (brokered or non-brokered) and type of account (time deposit, demand deposit, savings deposit), and by deposit size within certain of those categories. The reporting of deposit data for some of these categories is required by statute.[25] Reporting of time deposits with balances less than $100,000 in Schedule RC–E, including certain Memorandum items to adjust that amount, is tied to the Board's measurement of the money supply.[26] Schedule RC–O, Memorandum item 1, categorizes deposits based on purpose (for retirement or not for retirement) and subdivided by deposit size, as the deposit insurance limit applies separately to retirement and non-retirement accounts. These deposit data also are necessary for the FDIC to calculate the reserve ratio each quarter, which is the ratio of the net worth of the Deposit Insurance Fund (DIF) to the aggregate estimated insured deposits.[27] The agencies previously approved revisions to Schedule RC–E (and Schedules RI and RC–K) to replace most segmentations of deposits less than $250,000 that are not needed to calculate the money supply with segmentations based on deposits of more than $250,000 for consistency with the deposit insurance limits currently in effect. These revisions will be implemented beginning March 31, 2017.[28] The agencies are not making any revisions to the classification of Coverdell accounts, as the reporting of deposits by purpose is tied to the FDIC's provision of deposit insurance.

One commenter stated that the data on Schedules RC–F (Other Assets) and RC–G (Other Liabilities) did not change significantly for community banks from quarter to quarter and should be reported annually instead. The agencies did propose reducing the frequency by which institutions must report the significant components of all other assets and all other liabilities on these two schedules to semiannual in the FFIEC 051 in the August 2016 notice. The agencies will be considering both the data items and frequency of reporting for these two schedules for all versions of the Call Report in the Full Review, and will consider the commenter's suggestions in that process.

One commenter stated that Schedule RC–K (Quarterly Averages) was particularly burdensome, as the bank's general ledger provides point-in-time

[23] Prior to 2001, the agencies required separate disclosure of components greater than 10 percent of all other noninterest income or other noninterest expense. In 2001, the agencies revised the threshold to 1 percent of total interest income plus total noninterest income. In 2008, the agencies changed the threshold to 3 percent of other noninterest income or other noninterest expense with a $25,000 floor. The floor was raised to $100,000 effective September 30, 2016, while retaining the percentage threshold.

[24] Deposit data affects the assessments at certain institutions, such as bankers' banks and custodial banks.

[25] For example, 12 U.S.C. 1817(a)(5) and (9).

[26] See definition of M2, *https://www.federalreserve.gov/faqs/money_12845.htm.*

[27] See 12 U.S.C. 1813(y)(3).

[28] See 81 FR 45357 (July 13, 2016).

amounts and manual intervention is needed to calculate quarterly averages. The agencies note that average total assets is necessary for various purposes, including prompt corrective action and deposit insurance assessments.[29] The agencies will be considering both the data items and frequency of reporting for this schedule in the Full Review, and will consider the commenter's suggestions in that process.

Three commenters stated that Schedule RC–L (Derivatives and Off-Balance Sheet Items) was particularly difficult to complete, as some items defined in that schedule do not align with definitions for similar items in Schedule RC–R, particularly for over-the-counter (OTC) derivatives. The commenters also noted certain items included in Schedule RC–L, such as ''commitments to make a commitment,'' are difficult to define and track. One commenter suggested lining up the loan commitment categories on Schedule RC–L with the loan categories on Schedule RC–C, Part I. The agencies are investigating alternatives to the current definitions in Schedule RC–L, and whether they can be more closely aligned with definitions used in the agencies' regulatory capital rules, which is the basis for Schedule RC–R, for inclusion in a future notice. The agencies do not plan to align the loan categories between Schedules RC–L and RC–C, Part I. The loan categories on Schedule RC–C, Part I, are much more granular than in Schedule RC–L. Reducing the granularity of categories on Schedule RC–C, Part I, would impair the agencies' ability to use that data for safety and soundness monitoring, while increasing the granularity on Schedule RC–L would impose additional burden to collect items the agencies do not believe are necessary.

One commenter recommended reducing the frequency of certain data items in Schedule RC–M (Memoranda) to annual. Specifically, items 7 through 9, 11, and 12 do not change from quarter to quarter at the commenter's bank. Item 7 collects data on assets under management in proprietary mutual funds and annuities. Item 8 collects information on an institution's internet Web site addresses and trade names. Item 9 asks about internet Web site transactional capability. Items 11 and 12 collect information on certain bank powers. The agencies proposed in the August 2016 notice to reduce the frequency for items 7, 9, 11, and 12 from quarterly to annual. The agencies will continue collecting item 8 on a quarterly basis to provide more accurate, timely, and complete information to the FDIC, depositors, and the general public on the insured status of entities identifying themselves as FDIC-insured depository institutions than would occur through annual reporting.

One commenter requested that the agencies add control totals to Schedule RC–N for past due and nonaccrual loans, leases, and other assets to allow easier validation of the accuracy of the reported data to the institution's own records. The agencies also noted during their on-site banker outreach efforts that some institutions appended their own control totals on this form. The agencies agree with the suggestion, and plan to revise Schedule RC–N on the FFIEC 031, 041, and 051. For the same reason, the agencies will also revise Schedule RC–C, Part I, and Schedule RC–N to add control totals for troubled debt restructurings in Memorandum item 1 of each schedule. While these changes would add additional data items to these two schedules, the data items would be simple mathematical totals of existing data items and would not require the institution to obtain any additional data.

Five commenters requested that the agencies improve the clarity and usefulness of the Call Report instructions and highlight any changes made to the instructions each quarter. One commenter also recommended improving internal consistency within the Call Report. The agencies agree that the current Call Report instructions could be made more useful, and will start by incorporating hyperlinks to cited documents in the instructions for the FFIEC 051.[30] In addition, the agencies will post ''redlined'' documents on the FFIEC Web site[31] that clearly indicate any changes to the instructions made since the previous quarter in both versions of the Call Report instructions. The agencies note that the description in the Call Report forms and instructions for ''loans and leases, net of unearned income'' and ''loans and leases held for investment'' are intended to have the same reported amounts. Accordingly, the agencies will replace the former description with the latter description in affected data item captions and related instructions for clarity and internal consistency. The agencies will continue to consider additional changes to improve the clarity and usefulness of the Call Report instructions and the internal consistency of the report.

VI. Request for Comment

Public comment is requested on all aspects of this joint notice. Comment is invited on:

(a) Whether the proposed revisions to the collections of information that are the subject of this notice are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this joint notice will be shared among the agencies. All comments will become a matter of public record.

Appendix A

Summary of the FFIEC Member Entities' Uses of the Data Items in the Call Report Schedules in Full Review Surveys 1 Through 3

Schedule RC (Balance Sheet)

Schedule RC collects high-level information on various balance sheet categories, including assets, liabilities, and equity accounts every quarter. These categories are aligned with the categories typically reported on a basic balance sheet prepared under U.S. generally accepted accounting principles (GAAP).

Schedule RI (Income Statement)

Schedule RI collects information on various income and expense categories every quarter. In general, these categories are aligned with the categories typically reported on a basic income statement and in the notes to the financial statements prepared under U.S. GAAP.

The Memorandum items collect an assortment of information on items related to the income statement. Some items provide additional detail for certain categories of income or expense, while other items are not directly tied to earnings measures. Memorandum items on tax-exempt income and nondeductible interest expense are used to convert components of reported earnings to a tax-equivalent basis to improve the comparability of income statement information across institutions for purposes

[29] See 12 U.S.C. 1831o and 12 CFR 327.5.

[30] The agencies have already begun to add such hyperlinks to the existing set of instructions for the FFIEC 031 and FFIEC 041.

[31] *https://www.ffiec.gov/ffiec_report_forms.htm.*

of analyzing institutions' earnings. An institution's Subchapter S status for federal income tax purposes assists examiners and other users in understanding the amounts, if any, reported for applicable income taxes. It also serves as a flag for adjusting after-tax earnings when measuring return on assets to improve the comparability of this ratio across institutions with differing tax statuses. The count of full-time equivalent employees is used to calculate efficiency ratios and average personnel expenses per employee to identify institutions with higher expense levels for further review. The existence of other-than-temporary impairment losses on debt securities recognized in earnings provides an indication of heightened credit risk in an institution's investment securities, which may warrant supervisory follow-up, and assists in the scoping of the review of the securities portfolio during on-site examinations. Data on the composition of trading revenue is used in evaluating the variability and volatility of this revenue source for institutions with significant trading activity in off-site reviews and for pre-examination planning and as part of industry analysis of trading activity.

Schedule RC–C, Part I (Loans and Lease Financing Receivables)

Schedule RC–C, Part I, requests information on loan and lease financing activities, segmented into detailed loan categories. The memoranda items request additional information, including scheduled maturities and repricing dates for certain loan types and fair value estimates.

Schedule RC–C details loan volumes, segmentations, and structures, all of which facilitate the assessment of an institution's inherent risk, performance risk, and structure risk in its primary earning assets and its primary source of credit risk. Schedule RC–C is often reviewed in conjunction with Schedules RI, RI–B, and RC–N. This granular data enables examiners to analyze and assess the institution's loan portfolio diversification, credit quality, concentration exposure, and overall risk profile. These schedules are critical to the credit quality analysis performed by examiners to identify early warning signs of deterioration in the financial condition of institutions. Asset quality ratios from the Uniform Bank Performance Report (UBPR) that are calculated using data from Schedule RC–C and related loan schedules are also helpful to examiners in determining how an institution is performing relative to its peers and relative to its own risk profile based on its loan portfolio composition. In addition, these ratios are useful to examiners in assessing the institution's credit risk management practices relative to its peers. Elevated charge-offs or increases in nonaccrual loans in relation to loan balances provide information to users of the data on potential weak underwriting in prior periods, deterioration of asset quality, or the indication that the institution is recovering from a period of stress. If there are concerns about the allowance for loan and lease losses (ALLL) methodology or the appropriateness of the ALLL level, then there is a focus on the provision expense relative to the charge-offs as well as to the growth and quality of certain portfolios, depending on the institution's risk characteristics. All of these inputs are essential in the review of the balance sheet, the liquidity of the institution, and the asset-liability management of the institution.

The data on Schedule RC–C are needed for on-site and off-site examination purposes and also are used in the systemic analysis of the banking system. Because the loan portfolio is the primary source of credit risk in institutions, the breakdown of the portfolio by loan type is essential in the review of asset quality. An understanding of an institution's lending activity is needed to ensure the safety and soundness of the financial institution by indicating whether the institution is increasing concentrations or incorporating a change to its lending strategy. The loan segmentation information is essential for planning and staffing examinations by considering each institution's lending activities. The information also allows the examination teams to determine if the lending volume constitutes a concentration of credit, which could require additional monitoring, measuring, and risk mitigation strategies by bank management. In addition, the loan detail is important for loan scoping and trend analysis of the entire portfolio, which are essential in determining an institution's risk profile. On a broader perspective, the loan segmentation allows regulatory staff to identify concentration risks across institutions.

Along with related data in Schedule RC–N, information about troubled debt restructurings in compliance with their modified terms can assist the assessment of management's ability to work out different categories of problem loans.

Maturity and repricing information on loans and leases, together with the maturity and repricing information collected in other schedules for other types of assets and liabilities, are needed to evaluate the liquidity and interest rate risk of the institution and to aid in evaluating the strategies institutions take to mitigate these risks. Liquidity and interest rate risk indicators that are calculated by agency models from an institution's Call Report data and exceed specified parameters or change significantly between examinations are red flags that call for timely examiner off-site review. The institution's risk profile in these areas is considered during pre-examination planning to determine the appropriate scoping and staffing for examinations.

In addition, Schedule RC–C and related loan schedules assisted the Consumer Financial Protection Bureau's (CFPB) efforts to develop required estimates for various Title XIV mortgage reform rulemakings under the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203) (Dodd-Frank Act). Going forward, data items in these schedules are critical for continuous monitoring of the mortgage market. The CFPB uses these items to understand the intricacies of the mortgage market that are essential to assessing institutional participation in regulated consumer financial services markets and to assess regulatory impact associated with recent and proposed policies, as required by that agency's statutory mandate.

Finally, loan and lease information assists the agencies in fulfilling their specific missions. The Board, as part of its monetary policy mission, relies on institution-specific Call Report data to provide information on credit availability and lending conditions not available elsewhere. Loan and lease detail at all sizes of institutions is necessary for monitoring economic conditions.

Reducing loan detail or data frequency for smaller institutions would limit the ability to monitor credit availability and lending conditions widely, including changes in credit and lending related to changes in monetary policy. At times, loan availability and lending conditions may be different at smaller institutions than at larger institutions. Furthermore, Schedule RC–C, Part I, data are used to benchmark weekly loan data collected by the Board from a sample of both small and large institutions; the weekly data are used to estimate weekly loan aggregates for the banking sector as a whole to provide a more timely input for purposes of monitoring the macroeconomy.

The FDIC's deposit insurance assessment system for ''established small banks'' relies on information reported by individual institutions for the Schedule RC–C, Part I, standardized loan categories in the determination of the loan mix index in the financial ratios method, as recently amended, which is used to determine assessment rates for such institutions.

Schedule RC–C, Part II (Loans to Small Businesses and Small Farms)

Schedule RC–C, Part II, requests data on loans to small businesses and small farms, including stratification by original loan amount.

Call Report small business and small farm lending data are an invaluable resource for understanding credit conditions facing these sectors of the economy. Quarterly collection of these data improves the Board's ability to monitor credit conditions facing small businesses and small farms and significantly contributes to its ability to develop policies intended to address any problems that arise in credit markets. The institution-level Call Report data provide information that cannot be obtained from other indicators of small business and small farm credit conditions. For example, during a period of credit contraction, the Call Report data can be used to identify which types of institutions are reducing the volume of their loans to small businesses and small farms. This is important information for the Board, as having detailed data on the characteristics of affected institutions is crucial to building a sufficiently informative picture of the strength of economic activity. Moreover, there is evidence that small business lending by small institutions does not correlate with lending by larger institutions.

Monetary policymaking benefits importantly from timely information on small business credit conditions and flows. To determine how best to adjust the federal funds rate over time, the Board must continuously assess the prospects for real economic activity and inflation in coming

quarters. Credit conditions have an important bearing on the evolution of those prospects over time, and so the Board pays close attention to data from Call Reports and other sources. In trying to understand the implications of aggregate credit data for the macroeconomic outlook, it is helpful to be able to distinguish between conditions facing small firms and those affecting other businesses, for several reasons. First, small businesses comprise a substantial portion of the nonfinancial business sector, and so their hiring and investment decisions have an important influence on overall real activity. Second, because small businesses tend to depend more heavily on depository institutions for external financing, they likely experience material swings in their ability to obtain credit relative to larger firms. Third, the relative opacity of small businesses and their consequent need to provide collateral for loans is thought to create a ''credit'' channel for monetary policy to influence real activity. Specifically, changes in monetary policy may alter the value of assets used as collateral for loans, thereby affecting the ability of small businesses to obtain credit, abstracting from the effects of any changes in loan rates. Finally, the credit conditions facing small businesses and small farms differ substantially from those facing large businesses, making it necessary to collect indicators that are specific to these borrowers. Large businesses may access credit from a number of different sources, including the corporate bond market and the commercial paper market. In contrast, small businesses and small farms rely more heavily on credit provided through depository institutions. The dependence of small businesses and small farms on lending by depository institutions—particularly from smaller institutions—highlights the importance of Call Report data.

Schedule RC–N (Past Due and Nonaccrual Loans, Leases, and Other Assets)

Schedule RC–N requests data on past due and nonaccrual assets by detailed categories for loans and leases and, on a combined basis, for debt securities and other assets.

Data collected on Schedule RC–N is essential to the oversight function of the FFIEC member entities. The loan portfolio is the largest asset type and the primary source of credit risk at most financial institutions. Past due and nonaccrual loan information provides significant insights into the overall credit quality of a financial institution's loan portfolio and potential areas of credit quality concerns on which to focus for monitoring and assessing the credit risk management and overall safety and soundness of an institution. A high level of past due or nonaccrual loans often precedes adverse changes in an institution's earnings, liquidity, and capital adequacy. This information can also have an impact on consumer protection law compliance and agency rulemaking.

Information collected on Schedule RC–N is integral to both on-site and off-site review processes at the FFIEC member entities. Trends in past due and nonaccrual loans alert examiners to possible weaknesses in bank management's loan underwriting and credit administration practices. This information is a significant factor in assessing the portfolio's collectability and in estimating the appropriate level for an institution's ALLL, as well as the adequacy of its capital levels. The ability to compare results and trends across financial institutions is important to distinguish systemic issues from institution-specific concerns. Past due and nonaccrual loan information can serve as an indicator of areas of increasing credit risk within the loan portfolio. The segmentation of past due and nonaccrual information by loan category is necessary to pinpoint where the credit risk in an institution's loan portfolio exists. Comparing the past due level in different loan portfolios to other risk characteristics in that portfolio such as concentration, charge-offs, or growth can help to determine the overall level of risk to the safety and soundness of an institution. This data can also provide more insight on credit risks or weak underwriting practices associated with a specific loan category, which helps direct the scope of an exam.

Memorandum items in Schedule RC–N also provide important information about credit risk management, including the past due or nonaccrual status of troubled debt restructurings, which can assist the assessment of management's ability to work out different categories of problem loans. Data regarding delinquent derivative contracts provides important information for assessing a financial institution's asset quality, capital level, earnings, market risk, and operational risk.

Past due and nonaccrual information is also utilized in the assessment of compliance with consumer protection laws and regulations. Items reported on Schedule RC–N are used to inform rule writing and policy efforts, including the CFPB's Title XIV mortgage reform rulemakings under the Dodd-Frank Act. Past due information can identify potential areas of disparate treatment in relation to the Fair Housing Act (Pub. L. 90–284). Additionally, past due levels can highlight areas of potential unfair practices under the principles in section 1031 of the Dodd-Frank Act, which are similar to those under section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

Schedule RI–B, Parts I and II (Charge-offs and Recoveries on Loans and Leases and Changes in Allowance for Loan and Lease Losses)

Schedule RI–B, Part I, collects information on charge-offs and recoveries on loans and leases, while Part II collects information on changes in the ALLL during the year-to-date reporting period in a manner consistent with the disclosure of the activity in the allowance required under U.S. GAAP.

The data items on Schedule RI–B provide information critical to the missions of the FFIEC member entities. Charge-off amounts, in conjunction with any associated recoveries, for the various loan categories are needed to assess the safety and soundness of the financial institution by indicating the credit quality of the loan portfolio and the potential credit risk of the institution. The data items are also used to assess the strength of the institution's credit administration practices, along with the institution's loan underwriting practices. The data items also support the agencies' rule writing and policy efforts.

Schedule RI–B data play an integral role in reviewing the asset quality of an institution. The net charge-offs help in the assessment of the level of credit risk in the loan portfolio, both in aggregate and by loan type. Above average or increasing net charge-offs may be a signal of weak underwriting in prior periods, which in turn may be an indicator of future risks to earnings and capital. In addition, the separate reporting of gross charge-offs and recoveries allows users of the data to evaluate whether high recovery rates are masking underlying loss levels and trends, which may have future earnings implications, and the charge-off and recovery data also aid in the planning of on-site examinations and in the scoping of the loan review to be conducted during these examinations.

Schedule RI–B is also important in assessing the strength of an institution's underwriting and credit administration practices. The data items allow for the agencies to highlight loan categories with a large or sudden change in charge-off rates, which is often a key indicator of weaknesses in these areas, while information on recoveries provides support in evaluating an institution's ability to collect on prior charge-offs.

The segmentation of the charge-off and recovery data by loan category in Schedule RI–B is essential for many reasons. Consistent segmentation by loan category allows for comparability between institutions, as well as within an institution from quarter to quarter, allowing for the evaluation of changes and trends in charge-offs and recoveries that may or may not be institution-specific. This evaluation facilitates on-site examination planning. It also allows for better off-site monitoring of the existing types of lending and shifts in types of lending. The granularity and consistency of data items helps in the determination of whether weaknesses are confined to a particular portfolio segment and are unique to the institution or whether they are representative of a more widespread systemic weakness in a particular loan category. The detail by loan category is critical as losses in certain portfolios vary based on several factors and aggregating the data items would impair the ability to analyze data by loan category. The Memorandum items request further detail on charge-offs and recoveries or additional loan categories, which assists in the assessment of credit risk in these areas.

Schedule RI–B data items are used in rule writing and policy efforts. In particular, the items are used to assess institutional participation in regulated consumer financial services markets and to assess regulatory impact associated with recent and proposed policies, as required by the CFPB's mandate. Also, the information reported in Schedule RI–B, Part I, was integral in various Title XIV mortgage reform rulemakings under the Dodd-Frank Act and continues to be critical for the continuous monitoring of the mortgage markets.

Schedule RC–E, Parts I and II (Deposit Liabilities)

Schedule RC–E, Part I, requests data on deposits, segmented between transaction and nontransaction accounts. The Memoranda section of the schedule requests additional detail on retirement account deposits, brokered deposits, deposit size, and time deposit maturity and repricing dates. Schedule RC–E, Part II, requests data on foreign deposits and is included only in the FFIEC 031.

Schedule RC–E, Part I, provides detail necessary for supervisory purposes, including for identifying material deposit elements and providing detail needed to analyze cost of funds. Deposit detail as to the type, nature, and maturity of deposits, including deposits from non-core sources, is critical to the agencies' asset-liability management, interest rate risk, and liquidity analyses. A number of agency analysis tools routinely use quarterly deposit data for trend analysis and timely identification of deposit shifts, including changes in an institution's use of brokered and listing service deposits. Schedule RC–E, Part I, data are also used to estimate the contribution to the U.S. monetary aggregates for over 1,000 depository institutions that do not file these data directly to the Board.

The Schedule RC–E, Part I, Memorandum items provide information needed for off-site monitoring and pre-examination planning, particularly for analyses related to brokered deposits and time deposits, the results of which may signal the existence of higher-risk funding strategies. The resolution process for failed institutions requires sufficient deposit detail to estimate the least costly alternative to liquidation. Brokered deposit data are used as inputs in the calculation of deposit insurance assessment rates and to assure compliance with safety and soundness regulations tied to limits on those types of deposits.

Maturity and repricing information on time deposits, together with the maturity and repricing information collected in other schedules for other types of assets and liabilities, are needed to evaluate the liquidity and interest rate risk of the institution and to aid in evaluating the strategies institutions take to mitigate these risks. Liquidity and interest rate risk indicators that are calculated by agency models from an institution's Call Report data and exceed specified parameters or change significantly between examinations are red flags that call for timely examiner off-site review. The institution's risk profile in these areas is considered during pre-examination planning to determine the appropriate scoping and staffing for examinations.

Schedule RC–E, Part II, data on foreign deposits provides the extent of and exposure to such balances, and is used in similar analyses for institutions with foreign operations.

Schedule RC–O (Other Data for Deposit Insurance and FICO Assessments)

Schedule RC–O requests data for deposit insurance purposes and serves three primary purposes for the FDIC: Calculating the FDIC's DIF reserve ratio, calculating the assessment base of FDIC-insured institutions, and calculating the risk-based assessment rate of FDIC-insured institutions.

Schedule RC–O data are collected in the Call Report to provide unique information used in the calculation of the FDIC's reserve ratio to satisfy the statutory requirements related to maintaining the DIF. Information related to deposit liabilities on Schedule RC–O is needed to estimate insured deposits. Schedule RC–O is the only place on the Call Report where information is available to estimate insured and uninsured deposits for individual institutions and equivalent data items are not readily available from other sources.

Schedule RC–O data that are not available elsewhere enable the FDIC to calculate the quarterly deposit insurance assessment base for each FDIC-insured institution. Pursuant to the Dodd-Frank Act, the assessment base is defined as average consolidated total assets minus average tangible equity, both of which are reported in Schedule RC–O. Custodial banks and banker's banks also receive an additional adjustment to the assessment base using Schedule RC–O data. The FDIC must be able to calculate the assessment base in order to meet the statutory requirements for collecting quarterly insurance assessments from all FDIC-insured institutions.

Most of the data reported on Schedule RC–O is used to determine the risk-based insurance assessment for individual institutions in accordance with FDIC regulations implementing the statutory requirement for risk-based assessments first enacted in 1991. With the adoption of the risk-based scorecards for large and highly complex institutions, additional reporting is required on Schedule RC–O in data items applicable only to these institutions. In addition, some Schedule RC–O data items are used for determining the assessment rate of all FDIC-insured institutions.

Supervisory uses of Schedule RC–O data include incorporating the data on the maturity structure of external borrowings in agency interest rate risk models to determine the impact of interest rate movements on income and economic value of equity. Interest rate risk indicators that exceed specified parameters or change significantly between examinations are triggers for timely off-site review. The indicated level of interest rate risk is considered during pre-examination planning to determine the appropriate scoping and staffing for examinations. Data on reciprocal brokered deposits supplements on- and off-site analyses of liquidity ratios, including the net non-core funding dependence and net short-term non-core funding dependence, both of which include brokered deposits in their calculation, because reciprocal brokered deposits may have characteristics that differ from other brokered deposits.

Appendix B

Proposed FFIEC 051 for March 31, 2017: Changes Made to the FFIEC 041 (Based on the FFIEC 041 for September 30, 2016)

Schedules Replaced by Schedule SU—Supplemental Information

Schedule RC–D—Trading Assets and Liabilities
Schedule RC–P—1–4 Family Residential Mortgage Banking Activities
Schedule RC–Q—Assets and Liabilities Measured at Fair Value on a Recurring Basis
Schedule RC–S—Servicing, Securitization, and Asset Sale Activities
Schedule RC–V—Variable Interest Entities

Schedules with a Change in Frequency of Collection

1. Schedule RC–C, Part II—Loans to Small Businesses and Small Farms—For all institutions that file the FFIEC 051, the frequency of collection will move from quarterly to semiannual (June and December).

2. Schedule RC–A—Cash and Balances Due from Depository Institutions—Institutions with less than $300 million in total assets are already exempt from completing this schedule. For all other FFIEC 051 filers, the frequency of collection will move from quarterly to semiannual (June and December).

Data Items Removed

Note: In the following list of ''Data Items Removed'' from the proposed FFIEC 051, existing FFIEC 041 data items that institutions with less than $1 billion in total assets are currently exempt from reporting are marked with an asterisk (" *"). In addition, the list excludes two Call Report data items that have been approved for removal by OMB effective March 31, 2017, in accordance with the agencies' July 13, 2016, **Federal Register** notice (81 FR 45357): Schedule RI, Memorandum items 14.a and 14.b.

Schedule	Item	Item name	MDRM No.
RI	1.a.(4)	Loans to foreign governments and official institutions	RIAD4056.
RI	1.e	Interest income from trading assets	RIAD4069.
RI	2.c	Interest on trading liabilities and other borrowed money	RIAD4185.
RI	2.d	Interest on subordinated notes and debentures	RIAD4200.
		Note: Items 2.c and 2.d of Schedule RI will be combined into one data item for "Other interest expense."	
RI	5.c	Trading revenue	RIADA220.
RI	5.e	Venture capital revenue	RIADB491.

Schedule	Item	Item name	MDRM No.
RI	M2*	Income from the sale and servicing of mutual funds and annuities (included in Schedule RI, item 8).	RIAD8431.
RI	M8.a	Interest rate exposures	RIAD8757.
RI	M8.b	Foreign exchange exposures	RIAD8758.
RI	M8.c	Equity security and index exposures	RIAD8759.
RI	M8.d	Commodity and other exposures	RIAD8760.
RI	M8.e	Credit exposures	RIADF186.
RI	M8.f*	Impact on trading revenue of changes in the creditworthiness of the bank's derivatives counterparties on the bank's derivative assets (included in Memorandum items 8.a through 8.e).	RIADK090.
RI	M8.g*	Impact on trading revenue of changes in the creditworthiness of the bank on the bank's derivative liabilities (included in Memorandum items 8.a through 8.e)..	RIADK094.
RI	M9.a	Net gains (losses) on credit derivatives held for trading	RIADC889.
RI	M9.b	Net gains (losses) on credit derivatives held for purposes other than trading.	RIADC890.
RI	M10	Credit losses on derivatives	RIADA251.
RI	M13.a.(1)	Estimated net gains (losses) on loans attributable to changes in instrument-specific credit risk.	RIADF552.
RI	M13.b.(1)	Estimated net gains (losses) on liabilities attributable to changes in instrument-specific credit risk.	RIADF554.
RI	M15.a*	Consumer overdraft-related service charges levied on those transaction account and non-transaction savings account deposit products intended primarily for individuals for personal, household, or family use.	RIADH032.
RI	M15.b*	Consumer account periodic maintenance charges levied on those transaction account and non-transaction savings account deposit products intended primarily for individuals for personal, household, or family use.	RIADH033.
RI	M15.c*	Consumer customer automated teller machine (ATM) fees levied on those transaction account and non-transaction savings account deposit products intended primarily for individuals for personal, household, or family use.	RIADH034.
RI	M15.d*	All other service charges on deposit accounts	RIADH035.
RI–B, Part I	2	Loans to depository institutions and acceptances of other banks (Columns A and B).	RIAD4481, RIAD4482.
RI–B, Part I	6	Loans to foreign governments and official institutions (Columns A and B).	RIAD4643, RIAD4627.
RI–B, Part I	M2.a	Loans secured by real estate to non-U.S. addressees (domicile) (included in Schedule RI–B, part I, item 1) (Columns A and B).	RIAD4652, RIAD4662.
RI–B, Part I	M2.b	Loans to and acceptances of foreign banks (included in Schedule RI–B, part I, item 2) (Columns A and B).	RIAD4654, RIAD4664.
RI–B, Part I	M2.c	Commercial and industrial loans to non-U.S. addressees (domicile) (included in Schedule RI–B, part I, item 4) (Columns A and B).	RIAD4646, RIAD4618.
RI–B, Part I	M2.d	Leases to individuals for household, family, and other personal expenditures (included in Schedule RI–B, part I, item 8) (Columns A and B).	RIADF185, RIADF187.
RI–B, Part II	M1	Allocated transfer risk reserve included in Schedule RI–B, part II, item 7.	RIADC435.
RI–C	1.a*	Construction loans (Columns A through F)	RCONM708, RCONM709, RCONM710,RCONM711, RCONM712,RCONM713.
RI–C	1.b*	Commercial real estate loans (Columns A through F)	RCONM714, RCONM715, RCONM716, RCONM717, RCONM719, RCONM720.
RI–C	1.c*	Residential real estate loans (Columns A through F)	RCONM721, RCONM722, RCONM723, RCONM724, RCONM725, RCONM726.
RI–C	2*	Commercial loans (Columns A through F)	RCONM727, RCONM728, RCONM729, RCONM730, RCONM731, RCONM732.
RI–C	3*	Credit cards (Columns A through F)	RCONM733, RCONM734, RCONM735, RCONM736, RCONM737, RCONM738.
RI–C	4*	Other consumer loans (Columns A through F)	RCONM739, RCONM740, RCONM741, RCONM742, RCONM743, RCONM744.
RI–C	5*	Unallocated, if any	RCONM745.
RI–C	6*	Total (for each column, sum of items 1.a through 5) (Columns A through F).	RCONM746, RCONM747, RCONM748, RCONM749, RCONM750, RCONM751.

Schedule	Item	Item name	MDRM No.
RC–B	M5.a *	Credit card receivables (Columns A through D)	RCONB838, RCONB839, RCONB840, RCONB841.
RC–B	M5.b *	Home equity lines (Columns A through D)	RCONB842, RCONB843, RCONB844, RCONB845.
RC–B	M5.c *	Automobile loans (Columns A through D)	RCONB846, RCONB847, RCONB848, RCONB849.
RC–B	M5.d *	Other consumer loans (Columns A through D)	RCONB850, RCONB851, RCONB852, RCONB853.
RC–B	M5.e *	Commercial and industrial loans (Columns A through D)	RCONB854, RCONB855, RCONB856, RCONB857.
RC–B	M5.f *	Other (Columns A through D)	RCONB858, RCONB859, RCONB860, RCONB861.
RC–C, Part I	2a.(1)	To U.S. branches and agencies of foreign banks	RCONB532.
RC–C, Part I	2a.(2)	To other commercial banks in the U.S.	RCONB533.
RC–C, Part I	2.b	To other depository institutions in the U.S.	RCONB534.
RC–C, Part I	2.c.(1)	To foreign branches of other U.S. banks	RCONB536.
RC–C, Part I	2.c.(2)	To other banks in foreign countries	RCONB537.
RC–C, Part I	4.a	To U.S. addressees (domicile)	RCON1763.
RC–C, Part I	4.b	To non-U.S. addressees (domicile)	RCON1764.
RC–C, Part I	7	Loans to foreign governments and official institutions (including foreign central banks).	RCON2081.
RC–C, Part I	9.b.(1)	Loans for purchasing or carrying securities (secured and unsecured).	RCON1545.
RC–C, Part I	9.b.(2)	All other loans (exclude consumer loans)	RCONJ451.
RC–C, Part I	10.a	Leases to individuals for household, family, and other personal expenditures (i.e., consumer leases).	RCONF162.
RC–C, Part I	10.b	All other leases	RCONF163.
RC–C, Part I	M1.e.(1)	To U.S. addressees (domicile)	RCONK163.
RC–C, Part I	M1.e.(2)	To non-U.S. addressees (domicile)	RCONK164.
RC–C, Part I	M5	Loans secured by real estate to non U.S. addressees (domicile).	RCONB837.
RC–C, Part I	M10.a.(1)	Construction, land development, and other land loans	RCONF578.
RC–C, Part I	M10.a.(2)	Secured by farmland (including farm residential and other improvements).	RCONF579.
RC–C, Part I	M10.a.(3)(a)	Revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit.	RCONF580.
RC–C, Part I	M10.a.(3)(b)(1)	Secured by first liens	RCONF581.
RC–C, Part I	M10.a.(3)(b)(2)	Secured by junior liens	RCONF582.
RC–C, Part I	M10.a.(4)	Secured by multifamily (5 or more) residential properties	RCONF583.
RC–C, Part I	M10.a.(5)	Secured by nonfarm nonresidential properties	RCONF584.
RC–C, Part I	M10.b	Commercial and industrial loans	RCONF585.
RC–C, Part I	M10.c.(1)	Credit cards	RCONF586.
RC–C, Part I	M10.c.(2)	Other revolving credit plans	RCONF587.
RC–C, Part I	M10.c.(3)	Automobile loans	RCONK196.
RC–C, Part I	M10.c.(4)	Other consumer loans	RCONK208.
RC–C, Part I	M10.d	Other loans	RCONF589.
RC–C, Part I	M11.a.(1)	Construction, land development, and other land loans	RCONF590.
RC–C, Part I	M11.a.(2)	Secured by farmland (including farm residential and other improvements).	RCONF591.
RC–C, Part I	M11.a.(3)(a)	Revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit.	RCONF592.
RC–C, Part I	M11.a.(3)(b)(1)	Secured by first liens	RCONF593.
RC–C, Part I	M11.a.(3)(b)(2)	Secured by junior liens	RCONF594.
RC–C, Part I	M11.a.(4)	Secured by multifamily (5 or more) residential properties	RCONF595.
RC–C, Part I	M11.a.(5)	Secured by nonfarm nonresidential properties	RCONF596.
RC–C, Part I	M11.b	Commercial and industrial loans	RCONF597.
RC–C, Part I	M11.c.(1)	Credit cards	RCONF598.
RC–C, Part I	M11.c.(2)	Other revolving credit plans	RCONF599.
RC–C, Part I	M11.c.(3)	Automobile loans	RCONK195.
RC–C, Part I	M11.c.(4)	Other consumer loans	RCONK209.
RC–C, Part I	M11.d	Other loans	RCONF601.
RC–C, Part I	M12.a	Loans secured by real estate (Columns A through C)	RCONG091, RCONG092, RCONG093.
RC–C, Part I	M12.b	Commercial and industrial loans (Columns A through C)	RCONG094, RCONG095, RCONG096.
RC–C, Part I	M12.c	Loans to individuals for household, family and other personal expenditures (Columns A through C).	RCONG097, RCONG098, RCONG099.
RC–C, Part I	M12.d	All other loans and all leases (Columns A through C) Note: Memorandum items 12.a through 12.d of Schedule RC–C, Part I, will be combined into data items for ''Total loans and leases'' (Columns A through C).	RCONG100, RCONG101, RCONG102.
RC–E	M6.a *	Total deposits in those noninterest-bearing transaction account deposit products intended primarily for individuals for personal, household, or family use.	RCONP753.

Schedule	Item	Item name	MDRM No.
RC–E	M6.b *	Total deposits in those interest-bearing transaction account deposit products intended primarily for individuals for personal, household, or family use.	RCONP754.
RC–E	M6.c *	Total deposits in all other transaction accounts of individuals, partnerships, and corporations.	RCONP755.
RC–E	M7.a.(1) *	Total deposits in those MMDA deposit products intended primarily for individuals for personal, household, or family use.	RCONP756.
RC–E	M7.a.(2) *	Deposits in all other MMDAs of individuals, partnerships, and corporations.	RCONP757.
RC–E	M7.b.(1) *	Total deposits in those other savings deposit account deposit products intended primarily for individuals for personal, household, or family use.	RCONP758.
RC–E	M7.b.(2) *	Deposits in all other savings deposit accounts of individuals, partnerships, and corporations.	RCONP759.
RC–L	1.a.(1)	Unused commitments for Home Equity Conversion Mortgage (HECM) reverse mortgages outstanding that are held for investment (included in item 1.a above).	RCONJ477.
RC–L	1.a.(2)	Unused commitments for proprietary reverse mortgages outstanding that are held for investment (included in item 1.a).	RCONJ478.
RC–L	2.a *	Amount of financial standby letters of credit conveyed to others.	RCON3820.
RC–L	3.a *	Amount of performance standby letters of credit conveyed to others.	RCON3822.
RC–L	7.a.(1)	Credit default swaps (Columns A and B)	RCONC968, RCONC969.
RC–L	7.a.(2)	Total return swaps (Columns A and B)	RCONC970, RCONC971.
RC–L	7.a.(3)	Credit options (Columns A and B)	RCONC972, RCONC973.
RC–L	7.a.(4)	Other credit derivatives (Columns A and B)	RCONC974, RCONC975.
RC–L	7.b.(1)	Gross positive fair value (Columns A and B)	RCONC219, RCONC221.
RC–L	7.b.(2)	Gross negative fair value (Columns A and B)	RCONC220, RCONC222.
RC–L	7.c.(1)(a)	Sold protection	RCONG401.
RC–L	7.c.(1)(b)	Purchased protection	RCONG402.
RC–L	7.c.(2)(a)	Sold protection	RCONG403.
RC–L	7.c.(2)(b)	Purchased protection that is recognized as a guarantee for regulatory capital purposes.	RCONG404.
RC–L	7.c.(2)(c)	Purchased protection that is not recognized as a guarantee for regulatory capital purposes.	RCONG405.
RC–L	7.d.(1)(a)	Investment grade (Columns A through C)	RCONG406, RCONG407, RCONG408.
RC–L	7.d.(1)(b)	Sub-investment grade (Columns A through C)	RCONG409, RCONG410, RCONG411.
RC–L	7.d.(2)(a)	Investment grade (Columns A through C)	RCONG412, RCONG413, RCONG414.
RC–L	7.d.(2)(b)	Sub-investment grade (Columns A through C)	RCONG415, RCONG416, RCONG417.
RC–L	8	Spot foreign exchange contracts	RCON8765.
RC–L	9.b	Commitments to purchase when-issued securities	RCON3434.
RC–L	10.a	Commitments to sell when-issued securities	RCON3435.
RC–L	12.a	Futures contracts (Columns A through D)	RCON8693, RCON8694, RCON8695, RCON8696.
RC–L	12.b	Forward contracts (Columns A through D)	RCON8697, RCON8698, RCON8699, RCON8700.
RC–L	12.c.(1)	Written options (Columns A through D)	RCON8701, RCON8702, RCON8703, RCON8704.
RC–L	12.c.(2)	Purchased options (Columns A through D)	RCON8705, RCON8706, RCON8707, RCON8708.
RC–L	12.d.(1)	Written options (Columns A through D)	RCON8709, RCON8710, RCON8711, RCON8712.
RC–L	12.d.(2)	Purchased options (Columns A through D)	RCON8713, RCON8714, RCON8715, RCON8716.
RC–L	12.e	Swaps (Columns A through D)	RCON3450, RCON3826, RCON8719, RCON8720.
RC–L	13	Total gross notional amount of derivative contracts held for trading (Columns B through D).	RCONA127, RCON8723, RCON8724.
RC–L	14	Total gross notional amount of derivative contracts held for purposes other than trading (Columns B through D).	RCON8726, RCON8727, RCON8728.
RC–L	14.a	Interest rate swaps where the bank has agreed to pay a fixed rate.	RCONA589.
RC–L	15.a.(1)	Gross positive fair value (Columns A through D)	RCON8733, RCON8734, RCON8735, RCON8736.
RC–L	15.a.(2)	Gross negative fair value (Columns A through D)	RCON8737, RCON8738, RCON8739, RCON8740.
RC–L	15.b.(1)	Gross positive fair value (Columns A through D)	RCON8741, RCON8742, RCON8743, RCON8744.

Schedule	Item	Item name	MDRM No.
RC–L	15.b.(2)	Gross negative fair value (Columns A through D)	RCON8745, RCON8746, RCON8747, RCON8748.
RC–L	16.a *	Net current credit exposure (Columns A through E)	RCONG418, RCONG419, RCONG420, RCONG421, RCONG422.
RC–L	16.b.(1) *	Cash—U.S. dollar (Columns A through E)	RCONG423, RCONG424, RCONG425, RCONG426, RCONG427.
RC–L	16.b.(2) *	Cash—Other currencies (Columns A through E)	RCONG428, RCONG429, RCONG430, RCONG431, RCONG432.
RC–L	16.b.(3) *	U.S. Treasury securities (Columns A through E)	RCONG433, RCONG434, RCONG435, RCONG436, RCONG437.
RC–L	16.b.(4) *	U.S. Government agency and U.S. Government-sponsored agency debt securities (Columns A through E).	RCONG438, RCONG439, RCONG440, RCONG441, RCONG442.
RC–L	16.b.(5) *	Corporate bonds (Columns A through E)	RCONG443, RCONG444, RCONG445, RCONG446, RCONG447.
RC–L	16.b.(6) *	Equity securities (Columns A through E)	RCONG448, RCONG449, RCONG450, RCONG451, RCONG452.
RC–L	16.b.(7) *	All other collateral (Columns A through E)	RCONG453, RCONG454, RCONG455, RCONG456, RCONG457.
RC–L	16.b.(8) *	Total fair value of collateral (sum of items 16.b.(1) through (7)) (Columns A through E).	RCONG458, RCONG459, RCONG460, RCONG461, RCONG462.
RC–M	13.a.(1)(a)(1)	1–4 family residential construction loans	RCONK169.
RC–M	13.a.(1)(a)(2)	Other construction loans and all land development and other land loans.	RCONK170.
RC–M	13.a.(1)(b)	Secured by farmland	RCONK171.
RC–M	13.a.(1)(c)(1)	Revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit.	RCONK172.
RC–M	13.a.(1)(c)(2)(a)	Secured by first liens	RCONK173.
RC–M	13.a.(1)(c)(2)(b)	Secured by junior liens	RCONK174.
RC–M	13.a.(1)(d)	Secured by multifamily (5 or more) residential properties	RCONK175.
RC–M	13.a.(1)(e)(1)	Loans secured by owner-occupied nonfarm nonresidential properties.	RCONK176.
RC–M	13.a.(1)(e)(2)	Loans secured by other nonfarm nonresidential properties	RCONK177.
RC–M	13.a.(3)	Commercial and industrial loans	RCONK179.
RC–M	13.a.(4)(a)	Credit cards	RCONK180.
RC–M	13.a.(4)(b)	Automobile loans	RCONK181.
RC–M	13.a.(4)(c)	Other (includes revolving credit plans other than credit cards and other consumer loans).	RCONK182.
RC–M	13.a.(5)	All other loans and all leases	RCONK183.
RC–M	13.b.(1)	Construction, land development, and other land	RCONK187.
RC–M	13.b.(2)	Farmland	RCONK188.
RC–M	13.b.(3)	1–4 family residential properties	RCONK189.
RC–M	13.b.(4)	Multifamily (5 or more) residential properties	RCONK190.
RC–M	13.b.(5)	Nonfarm nonresidential properties	RCONK191.
RC–M	13.c	Debt securities (included in Schedule RC, items 2.a and 2.b)	RCONJ461.
RC–M	13.d	Other assets (exclude FDIC loss-sharing indemnification assets).	RCONJ462.
RC–N	6	Loans to foreign governments and official institutions (Columns A through C).	RCON5389, RCON5390, RCON5391.
RC–N	11.a.(1)(a)	1–4 family residential construction loans (Columns A through C).	RCONK045, RCONK046, RCONK047.
RC–N	11.a.(1)(b)	Other construction loans and all land development and other land loans (Columns A through C).	RCONK048, RCONK049, RCONK050.
RC–N	11.a.(2)	Secured by farmland (Columns A through C)	RCONK051, RCONK052, RCONK053.
RC–N	11.a.(3)(a)	Revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit (Columns A through C).	RCONK054, RCONK055, RCONK056.
RC–N	11.a.(3)(b)(1)	Secured by first liens (Columns A through C)	RCONK057, RCONK058, RCONK059.
RC–N	11.a.(3)(b)(2)	Secured by junior liens (Columns A through C)	RCONK060, RCONK061, RCONK062.
RC–N	11.a.(4)	Secured by multifamily (5 or more) residential properties (Columns A through C).	RCONK063, RCONK064, RCONK065.
RC–N	11.a.(5)(a)	Loans secured by owner-occupied nonfarm nonresidential properties (Columns A through C).	RCONK066, RCONK067, RCONK068.

Schedule	Item	Item name	MDRM No.
RC–N	11.a.(5)(b)	Loans secured by other nonfarm nonresidential properties (Columns A through C).	RCONK069, RCONK070, RCONK071.
RC–N	11.c	Commercial and industrial loans (Columns A through C)	RCONK075, RCONK076, RCONK077.
RC–N	11.d.(1)	Credit cards (Columns A through C)	RCONK078, RCONK079, RCONK080.
RC–N	11.d.(2)	Automobile loans (Columns A through C)	RCONK081, RCONK082, RCONK083.
RC–N	11.d.(3)	Other (includes revolving credit plans other than credit cards and other consumer loans) (Columns A through C).	RCONK084, RCONK085, RCONK086.
RC–N	11.e	All other loans and all leases (Columns A through C)	RCONK087, RCONK088, RCONK089.
RC–N	M1.e.(1)	To U.S. addressees (domicile) (Columns A through C)	RCONK120, RCONK121, RCONK122.
RC–N	M1.e.(2)	To non-U.S. addressees (domicile) (Columns A through C)	RCONK123, RCONK124, RCONK125.
RC–N	M3.a	Loans secured by real estate to non-U.S. addressees (domicile) (included in Schedule RC–N, item 1) (Columns A through C).	RCON1248, RCON1249, RCON1250.
RC–N	M3.b	Loans to and acceptances of foreign banks (included in Schedule RC–N, item 2) (Columns A through C).	RCON5380, RCON5381, RCON5382.
RC–N	M3.c	Commercial and industrial loans to non-U.S. addressees (domicile) (included in Schedule RC–N, item 4) (Columns A through C).	RCON1254, RCON1255, RCON1256.
RC–N	M3.d	Leases to individuals for household, family, and other personal expenditures (included in Schedule RC–N, item 8) (Columns A through C).	RCONF166, RCONF167, RCONF168.
RC–N	M5.b.(1)	Loans measured at fair value: Fair value (Columns A through C).	RCONF664, RCONF665, RCONF666.
RC–N	M5.b.(2)	Loans measured at fair value: Unpaid principal balance (Columns A through C).	RCONF667, RCONF668, RCONF669.
RC–N	M6	Derivative contracts: Fair value of amounts carried as assets (Columns A and B).	RCON3529, RCON3530.
RC–O	M2*	Estimated amount of uninsured deposits, including related interest accrued and unpaid.	RCON5597.
RC–O	M6.a*	Special mention	RCONK663.
RC–O	M6.b*	Substandard	RCONK664.
RC–O	M6.c*	Doubtful	RCONK665.
RC–O	M6.d*	Loss	RCONK666.
RC–O	M7.a*	Nontraditional 1–4 family residential mortgage loans	RCONN025.
RC–O	M7.b*	Securitizations of nontraditional 1–4 family residential mortgage loans.	RCONN026.
RC–O	M8.a*	Higher-risk consumer loans	RCONN027.
RC–O	M8.b*	Securitizations of higher-risk consumer loans	RCONN028.
RC–O	M9.a*	Higher-risk commercial and industrial loans and securities	RCONN029.
RC–O	M9.b*	Securitizations of higher-risk commercial and industrial loans and securities.	RCONN030.
RC–O	M10.a*	Total unfunded commitments	RCONK676.
RC–O	M10.b*	Portion of unfunded commitments guaranteed or insured by the U.S. government (including the FDIC).	RCONK677.
RC–O	M11*	Amount of other real estate owned recoverable from the U.S. government under guarantee or insurance provisions (excluding FDIC loss-sharing agreements).	RCONK669.
RC–O	M12*	Nonbrokered time deposits of more than $250,000 (included in Schedule RC–E, Memorandum item 2.d).	RCONK678.
RC–O	M13.a*	Construction, land development, and other land loans secured by real estate.	RCONN177.
RC–O	M13.b*	Loans secured by multifamily residential and nonfarm nonresidential properties.	RCONN178.
RC–O	M13.c*	Closed-end loans secured by first liens on 1–4 family residential properties.	RCONN179.
RC–O	M13.d*	Closed-end loans secured by junior liens on 1–4 family residential properties and revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit.	RCONN180.
RC–O	M13.e*	Commercial and industrial loans	RCONN181.
RC–O	M13.f*	Credit card loans to individuals for household, family, and other personal expenditures.	RCONN182.
RC–O	M13.g*	All other loans to individuals for household, family, and other personal expenditures.	RCONN183.
RC–O	M13.h*	Non-agency residential mortgage-backed securities	RCONM963.
RC–O	M14*	Amount of the institution's largest counterparty exposure	RCONK673.
RC–O	M15*	Total amount of the institution's 20 largest counterparty exposures.	RCONK674.

Schedule	Item	Item name	MDRM No.
RC–O	M16*	Portion of loans restructured in troubled debt restructurings that are in compliance with their modified terms and are guaranteed or insured by the U.S. government (including the FDIC) (included in Schedule RC–C, part I, Memorandum item 1).	RCONL189.
RC–O	M17.a*	Total deposit liabilities before exclusions (gross) as defined in Section 3(l) of the Federal Deposit Insurance Act and FDIC regulations.	RCONL194.
RC–O	M17.b*	Total allowable exclusions, including interest accrued and unpaid on allowable exclusions.	RCONL195.
RC–O	M17.c*	Unsecured ''Other borrowings'' with a remaining maturity of one year or less.	RCONL196.
RC–O	M17.d*	Estimated amount of uninsured deposits, including related interest accrued and unpaid.	RCONL197.
RC–O	M18.a*	''Nontraditional 1–4 family residential mortgage loans'' as defined for assessment purposes only in FDIC regulations (Columns A through O).	RCONM964, RCONM965, RCONM966, RCONM967, RCONM968, RCONM969, RCONM970, RCONM971, RCONM972, RCONM973, RCONM974, RCONM975, RCONM976, RCONM977, RCONM978.
RC–O	M18.b*	Closed-end loans secured by first liens on 1–4 family residential properties (Columns A through O).	RCONM979, RCONM980, RCONM981, RCONM982, RCONM983, RCONM984, RCONM985, RCONM986, RCONM987, RCONM988, RCONM989, RCONM990, RCONM991, RCONM992, RCONM993.
RC–O	M18.c*	Closed-end loans secured by junior liens on 1–4 family residential properties (Columns A through O).	RCONM994, RCONM995, RCONM996, RCONM997, RCONM998, RCONM999, RCONN001, RCONN002, RCONN003, RCONN004, RCONN005, RCONN006, RCONN007, RCONN008, RCONN009.
RC–O	M18.d*	Revolving, open-end loans secured by 1–4 family residential properties and extended under lines of credit (Columns A through O).	RCONN010, RCONN011, RCONN012, RCONN013, RCONN014, RCONN015, RCONN016, RCONN017, RCONN018, RCONN019, RCONN020, RCONN021, RCONN022, RCONN023, RCONN024.
RC–O	M18.e*	Credit cards (Columns A through O)	RCONN040, RCONN041, RCONN042, RCONN043, RCONN044, RCONN045, RCONN046, RCONN047, RCONN048, RCONN049, RCONN050, RCONN051, RCONN052, RCONN053, RCONN054.
RC–O	M18.f*	Automobile loans (Columns A through O)	RCONN055, RCONN056, RCONN057, RCONN058, RCONN059, RCONN060, RCONN061, RCONN062, RCONN063, RCONN064, RCONN065, RCONN066, RCONN067, RCONN068, RCONN069.
RC–O	M18.g*	Student loans (Columns A through O)	RCONN070, RCONN071, RCONN072, RCONN073, RCONN074, RCONN075, RCONN076, RCONN077, RCONN078, RCONN079, RCONN080, RCONN081, RCONN082, RCONN083, RCONN084.

Schedule	Item	Item name	MDRM No.
RC–O	M18.h *	Other consumer loans and revolving credit plans other than credit cards (Columns A through O).	RCONN085, RCONN086, RCONN087, RCONN088, RCONN089, RCONN090, RCONN091, RCONN092, RCONN093, RCONN094, RCONN095, RCONN096, RCONN097, RCONN098, RCONN099.
RC–O	M18.i *	Consumer leases (Columns A through O)	RCONN100, RCONN101, RCONN102, RCONN103, RCONN104, RCONN105, RCONN106, RCONN107, RCONN108, RCONN109, RCONN110, RCONN111, RCONN112, RCONN113, RCONN114.
RC–O	M18.j *	Total (Columns A through N)	RCONN115, RCONN116, RCONN117, RCONN118, RCONN119, RCONN120, RCONN121, RCONN122, RCONN123, RCONN124, RCONN125, RCONN126, RCONN127, RCONN128.

Data Items With a Change in Frequency of Collection

SEMIANNUAL REPORTING

[June and December]

Schedule	Item	Item name	MDRM No.
RC–B	M6.a through M6.g	Structured financial products by underlying collateral or reference assets (Columns A through D).	RCONG348, RCONG349, RCONG350, RCONG351, RCONG352, RCONG353, RCONG354, RCONG355, RCONG356, RCONG357, RCONG358, RCONG359, RCONG360, RCONG361, RCONG362, RCONG363, RCONG364, RCONG365, RCONG366, RCONG367, RCONG368, RCONG369, RCONG370, RCONG371, RCONG372, RCONG373, RCONG374, RCONG375
RC–C, Part I	M4	Adjustable-rate closed-end loans secured by first liens on 1–4 family residential properties (included in Schedule RC–C, Part I, item 1.c.(2)(a), column B).	RCON5370
RC–F	6.a through 6.i	All other assets: Itemized items greater than $100,000 that exceed 25 percent of this item.	RCON2166, RCON1578, RCONC010, RCONC436, RCONJ448, RCON3549, RCON3550, RCON3551
RC–G	4.a through 4.g	All other liabilities: Itemized items greater than $100,000 that exceed 25 percent of this item.	RCON3066, RCONC011, RCON2932, RCONC012, RCON3552, RCON3553, RCON3554
RC–L	9.c through 9.f	All other off-balance sheet liabilities (exclude derivatives): Itemized items over 25 percent of Schedule RC, item 27.a. ''Total bank equity capital''.	RCONC978, RCON3555, RCON3556, RCON3557
RC–L	10.b through 10.e	All other off-balance sheet assets (exclude derivatives): Itemized items over 25 percent of Schedule RC, item 27.a. ''Total bank equity capital''.	RCONC5592, RCON5593, RCON5594, RCON5595
RC–N	M5.a	Loans and leases held for sale (Columns A through C).	RCONC240, RCONC241, RCONC226

ANNUAL REPORTING

[December]

Schedule	Item	Item name	MDRM No.
RI	M12	Noncash income from negative amortization on closed-end loans secured by 1–4 family residential properties (included in Schedule RI, item 1.a.(1)(a)).	RIADF228
RC–C, Part I	M8.b	Total maximum remaining amount of negative amortization contractually permitted on closed-end loans secured by 1–4 family residential properties.	RCONF231
RC–C, Part I	M8.c	Total amount of negative amortization on closed-end loans secured by 1–4 family residential properties included in the amount reported in Memorandum item 8.a.	RCONF232
RC–M	6	Does the reporting bank sell private label or third-party mutual funds and annuities?	RCONB569
RC–M	7	Assets under the reporting bank's management in proprietary mutual funds and annuities.	RCONB570
RC–M	9	Do any of the bank's Internet websites have transactional capability, i.e., allow the bank's customers to execute transactions on their accounts through the website?	RCON4088
RC–M	11	Does the bank act as trustee or custodian for Individual Retirement Accounts, Health Savings Accounts, and other similar accounts?	RCONG463
RC–M	12	Does the bank provide custody, safekeeping, or other services involving the acceptance of order for the sale or purchase of securities?	RCONG464
RC–M	14.a	Total assets of captive insurance subsidiaries	RCONK193
RC–M	14.b	Total assets of captive reinsurance subsidiaries	RCONK194

DATA ITEMS MOVED TO SCHEDULE SU—SUPPLEMENTAL INFORMATION

Schedule	Item	Item name	MDRM No.
RI	M13.a	Net gains (losses) on assets	RIADF551
RI	M13.b	Net gains (losses) on liabilities	RIADF553
RI–B, Part I	M4	Uncollectible retail credit card fees and finance charges reversed against income (i.e., not included in charge-offs against the allowance for loan and lease losses).	RIADC388
RI–B, Part II	M2	Separate valuation allowance for uncollectible retail credit card fees and finance charges.	RIADC389
RI–B, Part II	M3	Amount of allowance for loan and lease losses attributable to retail credit card fees and finance charges.	RIADC390
RC–C, Part I	M6	Outstanding credit card fees and finance charges included in Schedule RC–C, part I, item 6.a.	RCONC391
RC–L	13	Total gross notional amount of derivative contracts held for trading (Column A)	RCONA126
RC–L	14	Total gross notional amount of derivative contracts held for purposes other than trading (Columns A).	RCON8725
RC–M	13.b.(7)	Portion of covered other real estate owned included in items 13.b.(1) through (5) that is protected by FDIC loss-sharing agreements.	RCONK192
RC–N	11.f	Portion of covered loans and leases included in items 11.a through 11.e that is protected by FDIC loss-sharing agreements (Columns A through C).	RCONK102, RCONK103, RCONK104
RC–S	M4	Outstanding fees and credit card charges included in Schedule RC–S, item 1, column C.	RCONC407

Appendix C

FFIEC 031 for March 31, 2017: Data Items Removed or Change in Reporting Threshold

DATA ITEMS REMOVED

Schedule	Item	Item name	MDRM No.
RI–B, Part I	2.a	Loans to and acceptances of U.S. banks and other U.S. depository institutions (Column A and Column B).	RIAD4653, RIAD4663
RI–B, Part I	2.b	Loans to and acceptances of foreign banks (Column A and Column B)	RIAD4654, RIAD4664
RC–C, Part II	1	Yes/No indicator whether all or substantially all of the dollar volume of 'loans secured by nonfarm nonresidential properties' and 'commercial and industrial loans to U.S. addressees' have original amounts of $100,000 or less.	RCON6999
RC–C, Part II	2.a	Total number of loans secured by nonfarm nonresidential properties currently outstanding.	RCON5562
RC–C, Part II	2.b	Total number of commercial and industrial loans to U.S. addressees currently outstanding.	RCON5563

DATA ITEMS REMOVED—Continued

Schedule	Item	Item name	MDRM No.
RC–C, Part II	5	Yes/No indicator whether all or substantially all of the dollar volume of 'Loans secured by farmland' and 'Loans to finance agricultural production and other loans to farmers' have original amounts of $100,000 or less.	RCON6860
RC–C, Part II	6.a	Total number of loans secured by farmland currently outstanding	RCON5576
RC–C, Part II	6.b	Total number of loans to finance agricultural production and other loans to farmers currently outstanding.	RCON5577
RC–E, Part I	M6.c	Total deposits in all other transaction accounts of individuals, partnerships, and corporations.	RCONP755
RC–M	13.a.(2)	Loans to finance agricultural production and other loans to farmers covered by loss-sharing agreements with the FDIC.	RCFDK178
RC–M	13.a.(3)	Commercial and industrial loans covered by loss-sharing agreements with the FDIC.	RCFDK179
RC–M	13.a.(4)(a)	Credit card loans covered by loss-sharing agreements with the FDIC	RCFDK180
RC–M	13.a.(4)(b)	Automobile loans covered by loss-sharing agreements with the FDIC	RCFDK181
RC–M	13.a.(4)(c)	All other consumer loans covered by loss-sharing agreements with the FDIC	RCFDK182
RC–N	11.b	Loans to finance agricultural production and other loans to farmers covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCFDK072, RCFDK073, RCFDK074
RC–N	11.c	Commercial and industrial loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCFDK075, RCFDK076, RCFDK077
RC–N	11.d.(1)	Credit card loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCFDK078, RCFDK079, RCFDK080
RC–N	11.d.(2)	Automobile loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCFDK081, RCFDK082, RCFDK083
RC–N	11.d.(3)	All other consumer loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCFDK084, RCFDK085, RCFDK086

CHANGE IN REPORTING THRESHOLD

[To be completed by banks with $10 billion or more in total assets]

Schedule	Item	Item name	MDRM No.
RI	M9.a	Net gains (losses) on credit derivatives held for trading	RIADC889
RI	M9.b	Net gains (losses) on credit derivatives held for purposes other than trading	RIADC890
RC–E, Part II	1	Deposits of Individuals, partnerships, and corporations (include all certified and official checks).	RCFNB553
RC–E, Part II	2	Deposits of U.S. banks and other U.S. depository institutions in foreign offices	RCFNB554
RC–E, Part II	3	Deposits of foreign banks in foreign offices	RCFN2625
RC–E, Part II	4	Deposits of foreign governments and official institutions in foreign offices	RCFN2650
RC–E, Part II	5	Deposits of U.S. Government and states and political subdivisions in the U.S. in foreign offices.	RCFNB555
RC–E, Part II	6	Total deposits in foreign offices	RCFN2200

Note: The preceding list of ''Data Items Removed'' from the FFIEC 031 excludes two Call Report data items that have been approved for removal by OMB effective March 31, 2017, in accordance with the agencies' July 13, 2016, **Federal Register** notice (81 FR 45357): Schedule RI, Memorandum items 14.a and 14.b.

CHANGE IN REPORTING THRESHOLD

[To be completed by banks with $10 million or more in average trading assets]

Schedule	Item	Item name	MDRM No.
RI	M8.a	Trading revenue from interest rate exposures	RIAD8757
RI	M8.b	Trading revenue from foreign exchange exposures	RIAD8758
RI	M8.c	Trading revenue from equity security and index exposures	RIAD8759
RI	M8.d	Trading revenue from commodity and other exposures	RIAD8760
RI	M8.e	Trading revenue from credit exposures	RIADF186

Appendix D

FFIEC 041 for March 31, 2017: Data Items Removed or Change in Reporting Threshold

DATA ITEMS REMOVED

Schedule	Item	Item name	MDRM No.
RI	1.a.(4)	Interest on loans to foreign governments and official institutions	RIAD4056
RI	1.e	Interest income from trading assets	RIAD4069
RI–B, Part I	2	Loans to depository institutions and acceptances of other banks (Column A through Column B).	RIAD4481, RIAD4482
RI–B, Part I	6	Loans to foreign governments and official institutions (Column A through Column B).	RIAD4643, RIAD4627
RC–C, Part I	2.a.(1)	Loans to U.S. branches and agencies of foreign banks	RCONB532
RC–C, Part I	2.a.(2)	Loans to other commercial banks in the U.S. Note: Items 2.a.(1) and 2.a.(2) of Schedule RC–C, Part I, will be combined into one data item for total loans to commercial banks in the U.S.	RCONB533
RC–C, Part I	2.c.(1)	Loans to foreign branches of other U.S. banks	RCONB536
RC–C, Part I	2.c.(2)	Loans to other banks in foreign countries Note: Items 2.c.(1) and 2.c.(2) of Schedule RC–C, Part I, will be combined into one data item for total loans to banks in foreign countries.	RCONB537
RC–C, Part I	7	Loans to foreign governments and official institutions (including foreign central banks).	RCON2081
RC–E	M6.c	Total deposits in all other transaction accounts of individuals, partnerships, and corporations.	RCONP755
RC–M	13.a.(3)	Commercial and industrial loans covered by loss-sharing agreements with the FDIC.	RCONK179
RC–M	13.a.(4)(a)	Credit card loans covered by loss-sharing agreements with the FDIC	RCONK180
RC–M	13.a.(4)(b)	Automobile loans covered by loss-sharing agreements with the FDIC	RCONK181
RC–M	13.a.(4)(c)	All other consumer loans covered by loss-sharing agreements with the FDIC	RCONK182
RC–N	6	Loans to foreign governments and official institutions (Column A through Column C).	RCON5389, RCON5390, RCON5391
RC–N	11.c	Commercial and industrial loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCONK075, RCONK076, RCONK077
RC–N	11.d.(1)	Credit card loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCONK078, RCONK079, RCONK080
RC–N	11.d.(2)	Automobile loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCONK081, RCONK082, RCONK083
RC–N	11.d.(3)	All other consumer loans covered by loss-sharing agreements with the FDIC (Column A through Column C).	RCONK084, RCONK085, RCONK086
RC–N	M6	Derivative contracts: Fair value of amounts carried as assets (Column A through Column B).	RCON3529, RCON3530

Note: The preceding list of ''Data Items Removed'' from the FFIEC 041 excludes two Call Report data items that have been approved for removal by OMB effective March 31, 2017, in accordance with the agencies' July 13, 2016, **Federal Register** notice (81 FR 45357): Schedule RI, Memorandum items 14.a and 14.b.

CHANGE IN REPORTING THRESHOLD

[To be completed by banks with $10 billion or more in total assets]

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RI	M8.d	Trading revenue from commodity and other exposures	RIAD8760
RI	M8.e	Trading revenue from credit exposures	RIADF186

Dated: December 30, 2016.

Karen Solomon,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, January 3, 2017.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 3rd day of January, 2017. Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–00085 Filed 1–6–17; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

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Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

Occupational Exposure to Beryllium; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–H005C–2006–0870]

RIN 1218–AB76

Occupational Exposure to Beryllium

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is amending its existing standards for occupational exposure to beryllium and beryllium compounds. OSHA has determined that employees exposed to beryllium at the previous permissible exposure limits face a significant risk of material impairment to their health. The evidence in the record for this rulemaking indicates that workers exposed to beryllium are at increased risk of developing chronic beryllium disease and lung cancer. This final rule establishes new permissible exposure limits of 0.2 micrograms of beryllium per cubic meter of air (0.2 μg/m^3) as an 8-hour time-weighted average and 2.0 μg/m^3 as a short-term exposure limit determined over a sampling period of 15 minutes. It also includes other provisions to protect employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping.

OSHA is issuing three separate standards—for general industry, for shipyards, and for construction—in order to tailor requirements to the circumstances found in these sectors.

DATES: *Effective date:* The final rule becomes effective on March 10, 2017.

Compliance dates: Compliance dates for specific provisions are set in § 1910.1024(o) for general industry, § 1915.1024(o) for shipyards, and § 1926.1124(o) for construction. There are a number of collections of information contained in this final rule (*see* Section IX, OMB Review under the Paperwork Reduction Act of 1995). Notwithstanding the general date of applicability that applies to all other requirements contained in the final rule, affected parties do not have to comply with the collections of information until the Department of Labor publishes a separate document in the **Federal Register** announcing the Office of Management and Budget has approved them under the Paperwork Reduction Act.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates Ann Rosenthal, Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, to receive petitions for review of the final rule.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

For technical inquiries, contact William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION: The preamble to the rule on occupational exposure to beryllium follows this outline:

I. Executive Summary
II. Pertinent Legal Authority
III. Events Leading to the Final Standards
IV. Chemical Properties and Industrial Uses
V. Health Effects
VI. Risk Assessment
VII. Significance of Risk
VIII. Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis
IX. OMB Review Under the Paperwork Reduction Act of 1995
X. Federalism
XI. State-Plan States
XII. Unfunded Mandates Reform Act
XIII. Protecting Children From Environmental Health and Safety Risks
XIV. Environmental Impacts
XV. Consultation and Coordination With Indian Tribal Governments
XVI. Summary and Explanation of the Standards
Introduction
(a) Scope and Application
(b) Definitions
(c) Permissible Exposure Limits (PELs)
(d) Exposure Assessment
(e) Beryllium Work Areas and Regulated Areas (General Industry); Regulated Areas (Maritime); and Competent Person (Construction)
(f) Methods of Compliance
(g) Respiratory Protection
(h) Personal Protective Clothing and Equipment
(i) Hygiene Areas and Practices
(j) Housekeeping
(k) Medical Surveillance
(l) Medical Removal
(m) Communication of Hazards
(n) Recordkeeping
(o) Dates
(p) Appendix A (General Industry)
Authority and Signature
Amendments to Standards

Citation Method

In the docket for the beryllium rulemaking, found at *http://www.regulations.gov,* every submission was assigned a document identification (ID) number that consists of the docket number (OSHA–H005C–2006–0870) followed by an additional four-digit number. For example, the document ID number for OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis is OSHA–H005C–2006–0870–0426. Some document ID numbers include one or more attachments, such as the National Institute for Occupational Safety and Health (NIOSH) prehearing submission (*see* Document ID OSHA–H005C–2006–0870–1671).

When citing exhibits in the docket, OSHA includes the term ''Document ID'' followed by the last four digits of the document ID number, the attachment number or other attachment identifier, if applicable, page numbers (designated ''p.'' or ''Tr.'' for pages from a hearing transcript). In a citation that contains two or more document ID numbers, the document ID numbers are separated by semi-colons. In some sections, such as Section V, Health Effects, author names and year of study publication are included before the document ID number in a citation, for example: (Deubner *et al.,* 2011, Document ID 0527). Where multiple exhibits are listed with author names and year of study publication, document ID numbers after the first are in parentheses, for example: (Elder *et al.,* 2005, Document ID 1537; Carter *et al.,* 2006 (1556); Refsnes *et al.,* 2006 (1428)).

I. Executive Summary

This final rule establishes new permissible exposure limits (PELs) for beryllium of 0.2 micrograms of beryllium per cubic meter of air (0.2 μg/m^3) as an 8-hour time-weighted average (TWA) and 2.0 μg/m^3 as a short-term exposure limit (STEL) determined over a sampling period of 15 minutes. In addition to the PELs, the rule includes provisions to protect employees such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping. OSHA is issuing three separate standards—for general

industry, for shipyards, and for construction—in order to tailor requirements to the circumstances found in these sectors. There are, however, numerous common elements in the three standards.

The final rule is based on the requirements of the Occupational Safety and Health Act (OSH Act) and court interpretations of the Act. For health standards issued under section 6(b)(5) of the OSH Act, OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so. *See* Section II, Pertinent Legal Authority, for a full discussion of OSH Act legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to beryllium. OSHA has also developed estimates of the risk of beryllium-related diseases, assuming exposure over a working lifetime, at the preceding PELs as well as at the revised PELs and action level. Comments received on OSHA's preliminary analysis, and the Agency's final findings, are discussed in Section V, Health Effects, Section VI, Risk Assessment, and Section VII, Significance of Risk. OSHA finds that employees exposed to beryllium at the preceding PELs are at an increased risk of developing chronic beryllium disease (CBD) and lung cancer. As discussed in Section VII, OSHA concludes that exposure to beryllium constitutes a significant risk of material impairment to health and that the final rule will substantially lower that risk. The Agency considers the level of risk remaining at the new TWA PEL to still be significant. However, OSHA did not adopt a lower TWA PEL because the Agency could not demonstrate technological feasibility of a lower TWA PEL. The Agency has adopted the STEL and ancillary provisions of the rule to further reduce the remaining significant risk.

OSHA's examination of the technological and economic feasibility of the rule is presented in the Final Economic Analysis and Regulatory Flexibility Analysis (FEA), and is summarized in Section VIII of this preamble. OSHA concludes that the final PELs are technologically feasible for all affected industries and application groups. Thus, OSHA concludes that engineering and work practice controls will be sufficient to reduce and maintain beryllium exposures to the new PELs or below in most operations most of the time in the affected industries. For those few operations within an industry or application group where compliance with the PELs cannot be achieved even when employers implement all feasible engineering and work practice controls, use of respirators will be required.

OSHA developed quantitative estimates of the compliance costs of the rule for each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide a screening analysis of the economic feasibility of complying with the rule and an evaluation of the economic impacts. Industries with unusually high costs as a percentage of revenues or profits were further analyzed for possible economic feasibility issues. After performing these analyses, OSHA finds that compliance with the requirements of the rule is economically feasible in every affected industry sector.

The final rule includes several major changes from the proposed rule as a result of OSHA's analysis of comments and evidence received during the comment periods and public hearings. The major changes are summarized below and are fully discussed in Section XVI, Summary and Explanation of the Standards. OSHA also presented a number of regulatory alternatives in the Notice of Proposed Rulemaking (80 FR 47566, 47729–47748 (8/7/2015). Where the Agency received substantive comments on a regulatory alternative, those comments are also discussed in Section XVI. A full discussion of all regulatory alternatives can be found in Chapter VIII of the Final Economic Analysis (FEA).

Scope. OSHA proposed to cover occupational exposures to beryllium in general industry, with an exemption for articles and an exemption for materials containing less than 0.1% beryllium by weight. OSHA has made a final determination to cover exposures to beryllium in general industry, shipyards, and construction under the final rule, and to issue separate standards for each sector. The final rule also provides an exemption for materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level of 0.1 $\mu g/m^3$ as an 8-hour TWA under any foreseeable conditions.

Exposure Assessment. The proposed rule would have required periodic exposure monitoring annually where employee exposures are at or above the action level but at or below the TWA PEL; no periodic monitoring would have been required where employee exposures exceeded the TWA PEL. The final rule specifies that exposure monitoring must be repeated within six months where employee exposures are at or above the action level but at or below the TWA PEL, and within three months where employee exposures are above the TWA PEL or STEL. The final rule also includes provisions allowing the employer to discontinue exposure monitoring where employee exposures fall below the action level and STEL. In addition, the final rule includes a new provision that allows employers to assess employee exposures using any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium (*i.e.,* the ''performance option'').

Beryllium Work Areas. The proposed rule would have required the employer to establish and maintain a beryllium work area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure. As discussed in the Summary and Explanation section of this preamble, OSHA has narrowed the definition of beryllium work area in the final rule from the proposal. The final rule now limits the requirement to work areas containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level. The final rule expands the exposure requirement to include work areas containing a process or operation where there is potential dermal contact with beryllium based on comments from public health experts that relying solely on airborne exposure omits the potential contribution of dermal exposure to total exposure. See the Summary and Explanation section of this preamble for a full discussion of the relevant comments and reasons for changes from the proposed standard. Beryllium work areas are not required under the standards for shipyards and construction.

Respiratory Protection. OSHA has added a provision in the final rule requiring the employer to provide a powered air-purifying respirator (PAPR) instead of a negative pressure respirator where respiratory protection is required by the rule and the employee requests a PAPR, provided that the PAPR provides adequate protection.

Personal Protective Clothing and Equipment. The proposed rule would have required use of protective clothing and equipment where employee exposure exceeds, or can reasonably be expected to exceed the TWA PEL or STEL; where employees' clothing or skin may become visibly contaminated with beryllium; and where employees'

skin can reasonably be expected to be exposed to soluble beryllium compounds. The final rule requires use of protective clothing and equipment where employee exposure exceeds, or can reasonably be expected to exceed the TWA PEL or STEL; or where there is a reasonable expectation of dermal contact with beryllium.

Medical Surveillance. The exposure trigger for medical examinations has been revised from the proposal. The proposed rule would have required that medical examinations be offered to each employee who has worked in a regulated area (*i.e.,* an area where an employee's exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL) for more than 30 days in the last 12 months. The final rule requires that medical examinations be offered to each employee who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year. A trigger to offer periodic medical surveillance when recommended by the most recent written medical opinion was also added the final rule. Under the final rule, the licensed physician recommends continued periodic medical surveillance for employees who are confirmed positive for sensitization or diagnosed with CBD. The proposed rule also would have required that medical examinations be offered annually; the final rule requires that medical examinations be offered at least every two years.

The final medical surveillance provisions have been revised to provide enhanced privacy for employees. The rule requires the employer to obtain a written medical opinion from a licensed physician for medical examinations provided under the rule but limits the information provided to the employer to the date of the examination, a statement that the examination has met the requirements of the standard, any recommended limitations on the employee's use of respirators, protective clothing, and equipment, and a statement that the results of the exam have been explained to the employee. The proposed rule would have required that such opinions contain additional information, without requiring employee authorization, such as the physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure, and any recommended limitations upon the employee's exposure to beryllium. In the final rule, the written opinion provided to the employer will only include recommended limitations on the employee's exposure to beryllium, referral to a CBD diagnostic center, a recommendation for continued periodic medical surveillance, or a recommendation for medical removal if the employee provides written authorization. The final rule requires a separate written medical report provided to the employee to include this additional information, as well as detailed information related to the employee's health.

The proposed rule would have required that the licensed physician provide the employer with a written medical opinion within 30 days of the examination. The final rule requires that the licensed physician provide the employee with a written medical report and the employer with a written medical opinion within 45 days of the examination, including any follow-up beryllium lymphocyte proliferation test (BeLPTs).

The final rule also adds requirements for the employer to provide the CBD diagnostic center with the same information provided to the physician or other licensed health care professional who administers the medical examination, and for the CBD diagnostic center to provide the employee with a written medical report and the employer with a written medical opinion. Under the final standard, employees referred to a CBD diagnostic center can choose to have future evaluations performed there. A requirement that laboratories performing BeLPTs be certified was also added to the final rule.

The proposed rule would have required that employers provide low dose computed tomography (LDCT) scans to employees who met certain exposure criteria. The final rule requires LDCT scans when recommended by the physician or other licensed healthcare professional administering the medical exam, after considering the employee's history of exposure to beryllium along with other risk factors.

Dates. OSHA proposed an effective date 60 days after publication of the rule; a date for compliance with all provisions except change rooms and engineering controls of 90 days after the effective date; a date for compliance with change room requirements, which was one year after the effective date; and a date for compliance with engineering control requirements of two years after the effective date.

OSHA has revised the proposed compliance dates. The final rule is effective 60 days after publication. All obligations for compliance commence one year after the effective date, with two exceptions: The obligation for change rooms and showers commences two years after the effective date; and the obligation for engineering controls commences three years after the effective date.[1]

Under the OSH Act's legal standard directing OSHA to set health standards based on findings of significant risk of material impairment and technological and economic feasibility, OSHA does not use cost-benefit analysis to determine the PEL or other aspects of the rule. It does, however, determine and analyze costs and benefits for its own informational purposes and to meet certain Executive Order requirements, as discussed in Section VIII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis and in the FEA. Table I–1—which is derived from material presented in Section VIII of this preamble—provides a summary of OSHA's best estimate of the costs and benefits of the rule using a discount rate of 3 percent. As shown, the rule is estimated to prevent 90 fatalities and 46 new cases of CBD annually once the full effects are realized, and the estimated cost of the rule is $73.9 million annually. Also as shown in Table I–1, the discounted monetized benefits of the rule are estimated to be $560.9 annually, and the rule is estimated to generate net benefits of approximately $487 annually; however, there is a great deal of uncertainty in those benefits due to assumptions made about dental workers' exposures and reductions; see Section VIII of this preamble. As that section shows, benefits significantly exceed costs regardless of how dental workers' exposures are treated.

TABLE I–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD

[3 Percent discount rate, 2015 dollars]

Annualized Costs:	
Control Costs	$12,269,190
Rule Familiarization	180,158
Exposure Assessment	13,748,676
Regulated Areas	884,106

[1] Note that the main analysis of costs and benefits presented in this FEA does not take into account the lag in effective dates but, instead, assumes that the rule takes effect in Year 1. To account for the lag in effective dates, OSHA has provided in the sensitivity analysis in Chapter VII of the FEA an estimate of its separate effects on costs and benefits relative to the main analysis. This analysis, which appears in Table VII–16 of the FEA, indicates that if employers delayed implementation of all provisions until legally required, and no benefits occurred until all provisions went into effect, this would decrease the estimated costs by 3.9 percent; the estimated benefits by 8.5 percent, and the estimated net benefits of the standard by 9.2 percent (to $442 million).

TABLE I–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD—Continued

[3 Percent discount rate, 2015 dollars]

Beryllium Work Areas	129,648
Medical Surveillance	7,390,958
Medical Removal	1,151,058
Written Exposure Control Plan	2,339,058
Protective Work Clothing & Equipment	1,985,782
Hygiene Areas and Practices	2,420,584
Housekeeping	22,763,595
Training	8,284,531
Respirators	320,885
Total Annualized Costs (Point Estimate)	$73,868,230
Annual Benefits: Number of Cases Prevented:	
Fatal Lung Cancers (Midpoint Estimate)	4
Fatal Chronic Beryllium Disease	86
Beryllium-Related Mortality	90
Beryllium Morbidity	46
Monetized Annual Benefits (Midpoint Estimate)	$560,873,424
Net Benefits:	
Net Benefits	$487,005,194

Sources: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (''the Act'' or ''the OSH Act''), is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal Congress authorized the Secretary of Labor (''the Secretary'') ''to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce'' (29 U.S.C. 651(b)(3); *see* 29 U.S.C. 654(a) (requiring employers to comply with OSHA standards), 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 655(b) (authorizing promulgation, modification or revocation of standards pursuant to notice and comment)). The primary statutory provision relied upon by the Agency in promulgating health standards is section 6(b)(5) of the Act; other sections of the OSH Act, however, authorize the Occupational Safety and Health Administration (''OSHA'') to require labeling and other appropriate forms of warning, exposure assessment, medical examinations, and recordkeeping in its standards (29 U.S.C. 655(b)(5), 655(b)(7), 657(c)).

The Act provides that in promulgating standards dealing with toxic materials or harmful physical agents, such as beryllium, the Secretary ''shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life'' (29 U.S.C. 655(b)(5)). Thus, ''[w]hen Congress passed the Occupational Safety and Health Act in 1970, it chose to place pre-eminent value on assuring employees a safe and healthful working environment, limited only by the feasibility of achieving such an environment'' (*American Textile Mfrs. Institute, Inc.* v. *Donovan,* 452 US 490, 541 (1981) (''*Cotton Dust*'')).

OSHA proposed this new standard for beryllium and beryllium compounds and conducted its rulemaking pursuant to section 6(b)(5) of the Act ((29 U.S.C. 655(b)(5)). The preceding beryllium standard, however, was adopted under the Secretary's authority in section 6(a) of the OSH Act (29 U.S.C. 655(a)), to adopt national consensus and established Federal standards within two years of the Act's enactment (*see* 29 CFR 1910.1000 Table Z–1). Any rule that ''differs substantially from an existing national consensus standard'' must ''better effectuate the purposes of this Act than the national consensus standard'' (29 U.S.C. 655(b)(8)). Several additional legal requirements arise from the statutory language in sections 3(8) and 6(b)(5) of the Act (29 U.S.C. 652(8), 655(b)(5)). The remainder of this section discusses these requirements, which OSHA must consider and meet before it may promulgate this occupational health standard regulating exposure to beryllium and beryllium compounds.

Material Impairment of Health

Subject to the limitations discussed below, when setting standards regulating exposure to toxic materials or harmful physical agents, the Secretary is required to set health standards that ensure that ''no employee will suffer material impairment of health or functional capacity. . .'' (29 U.S.C. 655(b)(5)). ''OSHA is not required to state with scientific certainty or precision the exact point at which each type of [harm] becomes a material impairment'' (*AFL–CIO* v. *OSHA,* 965 F.2d 962, 975 (11th Cir. 1992)). Courts have also noted that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm (*AFL–CIO,* 965 F.2d at 975). Thus the Agency has taken the position that ''subclinical'' health effects, which may be precursors to more serious disease, can be material impairments of health that OSHA should address when feasible (43 FR 52952, 52954 (11/14/78) (Lead Preamble)).

Significant Risk

Section 3(8) of the Act requires that workplace safety and health standards be ''reasonably necessary or appropriate to provide safe or healthful employment'' (29 U.S.C. 652(8)). The Supreme Court, in its decision on OSHA's benzene standard, interpreted section 3(8) to mean that before promulgating any standard, the Secretary must evaluate whether ''significant risk[ ]'' exists under current conditions and to then determine whether that risk can be ''eliminated or lessened'' through regulation (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 642 (1980) (plurality opinion) (''*Benzene*'')). The Court's holding is consistent with evidence in the legislative record, with regard to section 6(b)(5) of the Act (29 U.S.C. 655(b)(5)), that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not ''to establish a utopia free from any hazards'' or to address risks comparable to those that exist in virtually any occupation or workplace (116 Cong. Rec. 37614 (1970), Leg. Hist. 480–82). It is also consistent with Section 6(g) of the OSH Act, which states that, in determining regulatory priorities, ''the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments'' (29 U.S.C. 655(g)).

The Supreme Court in *Benzene* clarified that ''[i]t is the Agency's responsibility to determine, in the first instance, what it considers to be a 'significant' risk'' (*Benzene,* 448 U.S. at 655), and that it was not the Court's responsibility to ''express any opinion on the . . . difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate'' (*Benzene,* 448 U.S. at 659). The Court stated, however, that the section 6(f) (29 U.S.C. 655(b)(f)) substantial evidence standard applicable to OSHA's significant risk determination does not require the Agency ''to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene,* 448 U.S. at 656). Rather, OSHA may rely on ''a body of reputable scientific thought'' to which ''conservative assumptions in interpreting the data . . . '' may be applied, ''risking error on the side of

overprotection'' (*Benzene,* 448 U.S. at 656; *see also United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1248 (D.C. Cir. 1980) (''*Lead I*'') (noting the *Benzene* court's application of this principle to carcinogens and applying it to the lead standard, which was not based on carcinogenic effects)). OSHA may thus act with a ''pronounced bias towards worker safety'' in making its risk determinations (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988) (''*Asbestos II*'').

The Supreme Court further recognized that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' (*Benzene,* 448 U.S. at 655) and will be ''based largely on policy considerations'' (*Benzene,* 448 U.S. at 655 n. 62). The Court gave the following example:

> If . . . the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant . . . (*Benzene,* 448 U.S. at 655).

Following *Benzene,* OSHA has, in many of its health standards, considered the one-in-a-thousand metric when determining whether a significant risk exists. Moreover, as ''a prerequisite to more stringent regulation'' in all subsequent health standards, OSHA has, consistent with the *Benzene* plurality decision, based each standard on a finding of significant risk at the ''then prevailing standard'' of exposure to the relevant hazardous substance (*Asbestos II,* 838 F.2d at 1263). The Agency's final risk assessment is derived from existing scientific and enforcement data and its final conclusions are made only after considering all evidence in the rulemaking record. Courts reviewing the validity of these standards have uniformly held the Secretary to the significant risk standard first articulated by the *Benzene* plurality and have generally upheld the Secretary's significant risk determinations as supported by substantial evidence and ''a reasoned explanation for his policy assumptions and conclusions'' (*Asbestos II,* 838 F.2d at 1266).

Once OSHA makes its significant risk finding, the ''more stringent regulation'' (*Asbestos II,* 838 F.2d at 1263) it promulgates must be ''reasonably necessary or appropriate'' to reduce or eliminate that risk, within the meaning of section 3(8) of the Act (29 U.S.C. 652(8)) and *Benzene* (448 U.S. at 642) (*see Asbestos II,* 838 F.2d at 1269). The courts have interpreted section 6(b)(5) of the OSH Act as requiring OSHA to set the standard that eliminates or reduces risk to the lowest feasible level; as discussed below, the limits of technological and economic feasibility usually determine where the new standard is set (*see UAW* v. *Pendergrass,* 878 F.2d 389, 390 (D.C. Cir. 1989)). In choosing among regulatory alternatives, however, ''[t]he determination that [one standard] is appropriate, as opposed to a marginally [more or less protective] standard, is a technical decision entrusted to the expertise of the agency . . . '' (*Nat'l Mining Ass'n* v. *Mine Safety and Health Admin.,* 116 F.3d 520, 528 (D.C. Cir. 1997)) (analyzing a Mine Safety and Health Administration standard under the *Benzene* significant risk standard). In making its choice, OSHA may incorporate a margin of safety even if it theoretically regulates below the lower limit of significant risk (*Nat'l Mining Ass'n,* 116 F.3d at 528 (citing *American Petroleum Inst.* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1982))).

Working Life Assumption

The OSH Act requires OSHA to set the standard that most adequately protects employees against harmful workplace exposures for the period of their ''working life'' (29 U.S.C. 655(b)(5)). OSHA's longstanding policy is to define ''working life'' as constituting 45 years; thus, it assumes 45 years of exposure when evaluating the risk of material impairment to health caused by a toxic or hazardous substance. This policy is not based on empirical data that most employees are exposed to a particular hazard for 45 years. Instead, OSHA has adopted the practice to be consistent with the statutory directive that ''no employee'' suffer material impairment of health ''even if'' such employee is exposed to the hazard for the period of his or her working life (*see* 74 FR 44796 (8/31/09)). OSHA's policy was given judicial approval in a challenge to an OSHA standard that lowered the permissible exposure limit (PEL) for asbestos (*Asbestos II,* 838 F.2d at 1264–1265). In that case, the petitioners claimed that the median duration of employment in the affected industry sectors was only five years. Therefore, according to petitioners, OSHA erred in assuming a 45-year working life in calculating the risk of health effects caused by asbestos exposure. The D.C. Circuit disagreed, stating ''[e]ven if it is only the rare worker who stays with asbestos-related tasks for 45 years, that worker would face a 64/1000 excess risk of contracting cancer; Congress clearly authorized OSHA to protect such a worker'' (*Asbestos II,* 838 F.2d at 1264–1265). OSHA might calculate the health risks of exposure, and the related benefits of lowering the exposure limit, based on an assumption of a shorter working life, such as 25 years, but such estimates are for informational purposes only.

Best Available Evidence

Section 6(b)(5) of the Act requires OSHA to set standards ''on the basis of the best available evidence'' and to consider the ''latest available scientific data in the field'' (29 U.S.C. 655(b)(5)). As noted above, the Supreme Court, in its *Benzene* decision, explained that OSHA must look to ''a body of reputable scientific thought'' in making its material harm and significant risk determinations, while noting that a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge'' (*Benzene,* 448 U.S. at 656).

The courts of appeals have afforded OSHA similar latitude to issue health standards in the face of scientific uncertainty. The Second Circuit, in upholding the vinyl chloride standard, stated: ''[T]he ultimate facts here in dispute are 'on the frontiers of scientific knowledge', and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient'' (*Society of the Plastics Industry, Inc.* v. *OSHA,* 509 F.2d 1301, 1308 (2d Cir. 1975) (quoting *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467, 474 (D.C. Cir. 1974) (''*Asbestos I*''))). The D.C. Circuit, in upholding the cotton dust standard, stated: ''OSHA's mandate necessarily requires it to act even if information is incomplete when the best available evidence indicates a serious threat to the health of workers'' (*Am. Fed'n of Labor & Cong. of Indus. Orgs.* v. *Marshall,* 617 F.2d 636, 651 (D.C. Cir. 1979), *aff'd in part and vacated in part on other grounds, American Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490 (1981)). When there is disputed scientific evidence in the record, OSHA must review the evidence on both sides and ''reasonably resolve'' the dispute (*Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1500 (D.C. Cir. 1986)). The Court in *Public Citizen* further noted that, where ''OSHA has the expertise we lack and it has exercised that expertise by carefully reviewing the scientific data,'' a dispute within the scientific community is not occasion for the reviewing court to take sides about which view is correct (*Pub. Citizen Health Research Grp.,* 796 F.2d

at 1500) or for OSHA or the courts to '' 'be paralyzed by debate surrounding diverse medical opinions' '' (*Pub. Citizen Health Research Grp.,* 796 F.2d at 1497 (quoting H.R. Rep. No. 91–1291, 91st Cong., 2d Sess. 18 (1970), reprinted in Legislative History of the Occupational Safety and Health Act of 1970 at 848 (1971))). Provided the Agency gave adequate notice in the proposal's preamble discussion of potential regulatory alternatives that the Secretary would be considering one or more stated options for regulation, OSHA is not required to prefer the option in the text of the proposal over a given regulatory alternative that was addressed in the rulemaking if substantial evidence in the record supports inclusion of the alternative in the final standard. *See Owner-Operator Independent Drivers Ass'n, Inc.* v. *Federal Motor Carrier Safety Admin.,* 494 F.3d 188, 209 (D.C. Cir. 2007) (notice by agency concerning modification of sleeper-berth requirements for truck drivers was sufficient because proposal listed several options and asked a question regarding the details of the one option that ultimately appeared in final rule); *Kooritzky* v. *Reich,* 17 F.3d 1509, 1513 (D.C. Cir. 1994) (noting that a final rule need not match a proposed rule, as long as ''the agency has alerted interested parties to the possibility of the agency's adopting a rule different than the one proposed'' and holding that agency failed to comply with notice and comment requirements when ''preamble in July offered no clues of what was to come in October'').

Feasibility

The OSH Act requires that, in setting a standard, OSHA must eliminate the risk of material health impairment ''to the extent feasible'' (29 U.S.C. 655(b)(5)). The statutory mandate to consider the feasibility of the standard encompasses both technological and economic feasibility; these analyses have been done primarily on an industry-by-industry basis (*Lead I,* 647 F.2d at 1264, 1301). The Agency has also used application groups, defined by common tasks, as the structure for its feasibility analyses (*Pub. Citizen Health Research Grp.* v. *OSHA,* 557 F.3d 165, 177–179 (3d Cir. 2009)). The Supreme Court has broadly defined feasible as ''capable of being done'' (*Cotton Dust,* 452 U.S. at 509–510).

Although OSHA must set the most protective PEL that the Agency finds to be technologically and economically feasible, it retains discretion to set a uniform PEL even when the evidence demonstrates that certain industries or operations could reasonably be expected to meet a lower PEL. OSHA health standards generally set a single PEL for all affected employers; OSHA exercised this discretion most recently in its final rules on occupational exposure to Chromium (VI) (71 FR 10100, 10337–10338 (2/28/2006) and Respirable Crystalline Silica (81 FR 16285, 16576–16575 (3/25/2016); see also 62 FR 1494, 1575 (1/10/97) (methylene chloride)). In its decision upholding the chromium (VI) standard, including the uniform PEL, the Court of Appeals for the Third Circuit addressed this issue as one of deference, stating ''OSHA's decision to select a uniform exposure limit is a legislative policy decision that we will uphold as long as it was reasonably drawn from the record'' (Chromium (VI), 557 F.3d at 183 (3d Cir. 2009)); see also *Am. Iron & Steel Inst.* v. *OSHA*, 577 F.2d 825, 833 (3d Cir. 1978)). OSHA's reasons for choosing one chromium (VI) PEL, rather than imposing different PELs on different application groups or industries, included: Multiple PELs would create enforcement and compliance problems because many workplaces, and even workers, were affected by multiple categories of chromium (VI) exposure; discerning individual PELs for different groups of establishments would impose a huge evidentiary burden on the Agency and unnecessarily delay implementation of the standard; and a uniform PEL would, by eliminating confusion and simplifying compliance, enhance worker protection (Chromium (VI), 557 F.3d at 173, 183–184). The Court held that OSHA's rationale for choosing a uniform PEL, despite evidence that some application groups or industries could meet a lower PEL, was reasonably drawn from the record and that the Agency's decision was within its discretion and supported by past practice (Chromium (VI), 557 F.3d at 183–184).

Technological Feasibility

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed (*Lead I,* 647 F.2d at 1272; *Amer. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991) (''*Lead II*'')). OSHA's standards may be ''technology forcing,'' *i.e.,* where the Agency gives an industry a reasonable amount of time to develop new technologies, OSHA is not bound by the ''technological status quo'' (*Lead I,* 647 F.2d at 1264). While the test for technological feasibility is normally articulated in terms of the ability of employers to decrease exposures to the PEL, provisions such as exposure measurement requirements must also be technologically feasible (*see Forging Indus. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985)).

In its *Lead* decisions, the D.C. Circuit described OSHA's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance.

> [W]ithin the limits of the best available evidence . . . OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators . . . Insufficient proof of technological feasibility for a few isolated operations within an industry, or even OSHA's concession that respirators will be necessary in a few such operations, will not undermine this general presumption in favor of feasibility. Rather, in such operations firms will remain responsible for installing engineering and work practice controls to the extent feasible, and for using them to reduce . . . exposure as far as these controls can do so (*Lead I,* 647 F.2d at 1272).

Additionally, the D.C. Circuit explained that ''[f]easibility of compliance turns on whether exposure levels at or below [the PEL] can be met in most operations most of the time . . .'' (*Lead II,* 939 F.2d at 990).

Courts have given OSHA significant deference in reviewing its technological feasibility findings. ''So long as we require OSHA to show that any required means of compliance, even if it carries no guarantee of meeting the PEL, will substantially lower . . . exposure, we can uphold OSHA's determination that every firm must exploit all possible means to meet the standard'' (*Lead I,* 647 F.2d at 1273). Even in the face of significant uncertainty about technological feasibility in a given industry, OSHA has been granted broad discretion in making its findings (*Lead I,* 647 F.2d at 1285). ''OSHA cannot let workers suffer while it awaits . . . scientific certainty. It can and must make reasonable [technological feasibility] predictions on the basis of 'credible sources of information,' whether data from existing plants or expert testimony'' (*Lead I,* 647 F.2d at 1266 (quoting *Am. Fed'n of Labor & Cong. of Indus. Orgs.,* 617 F.2d at 658)). For example, in *Lead I,* the D.C. Circuit allowed OSHA to use, as best available evidence, information about new and expensive industrial smelting processes that had not yet been adopted in the U.S. and would require the rebuilding of plants (*Lead I,* 647 F.2d at 1283–1284). Even under circumstances where

OSHA's feasibility findings were less certain and the Agency was relying on its ''legitimate policy of technology forcing,'' the D.C. Circuit approved of OSHA's feasibility findings when the Agency granted lengthy phase-in periods to allow particular industries time to comply (*Lead I,* 647 F.2d at 1279–1281, 1285).

OSHA is permitted to adopt a standard that some employers will not be able to meet some of the time, with employers limited to challenging feasibility at the enforcement stage (*Lead I,* 647 F.2d at 1273 & n. 125; *Asbestos II,* 838 F.2d at 1268). Even when the Agency recognized that it might have to balance its general feasibility findings with flexible enforcement of the standard in individual cases, the courts of appeals have generally upheld OSHA's technological feasibility findings (*Lead II,* 939 F.2d at 980; *see Lead I,* 647 F.2d at 1266–1273; *Asbestos II,* 838 F.2d at 1268). Flexible enforcement policies have been approved where there is variability in measurement of the regulated hazardous substance or where exposures can fluctuate uncontrollably (*Asbestos II,* 838 F.2d at 1267–1268; *Lead II,* 939 F.2d at 991). A common means of dealing with the measurement variability inherent in sampling and analysis is for the Agency to add the standard sampling error to its exposure measurements before determining whether to issue a citation (*e.g.,* 51 FR 22612, 22654 (06/20/86) (Asbestos Preamble)).

Economic Feasibility

In addition to technological feasibility, OSHA is required to demonstrate that its standards are economically feasible. A reviewing court will examine the cost of compliance with an OSHA standard ''in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices . . .'' (*Lead I,* 647 F.2d at 1265 (omitting citation)). As articulated by the D.C. Circuit in *Lead I,* ''OSHA must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms'' (*Lead I,* 647 F.2d at 1272). A reasonable estimate entails assessing ''the likely range of costs and the likely effects of those costs on the industry'' (*Lead I,* 647 F.2d at 1266). As with OSHA's consideration of scientific data and control technology, however, the estimates need not be precise (*Cotton Dust,* 452 U.S. at 528–29 & n. 54) as long as they are adequately explained. Thus, as the D.C. Circuit further explained:

> Standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely. Nor does the concept of economic feasibility necessarily guarantee the continued existence of individual employers. It would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the industry in protecting the health and safety of employees and is consequently financially unable to comply with new standards as quickly as other employers. As the effect becomes more widespread within an industry, the problem of economic feasibility becomes more pressing (*Asbestos I,* 499 F.2d. at 478).

OSHA standards therefore satisfy the economic feasibility criterion even if they impose significant costs on regulated industries so long as they do not cause massive economic dislocations within a particular industry or imperil the very existence of the industry (*Lead II,* 939 F.2d at 980; *Lead I,* 647 F.2d at 1272; *Asbestos I,* 499 F.2d. at 478). As with its other legal findings, OSHA ''is not required to prove economic feasibility with certainty, but is required to use the best available evidence and to support its conclusions with substantial evidence'' ((*Lead II,* 939 F.2d at 980–981) (citing *Lead I,* 647 F.2d at 1267)).

Because section 6(b)(5) of the Act explicitly imposes the ''to the extent feasible'' limitation on the setting of health standards, OSHA is not permitted to use cost-benefit analysis to make its standards-setting decisions (29 U.S.C. 655(b)(5)).

> Congress itself defined the basic relationship between costs and benefits, by placing the ''benefit'' of worker health above all other considerations save those making attainment of this ''benefit'' unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in § 6(b)(5) (*Cotton Dust,* 452 U.S. at 509).

Thus, while OSHA estimates the costs and benefits of its proposed and final rules, these calculations do not form the basis for the Agency's regulatory decisions; rather, they are performed to ensure compliance with requirements such as those in Executive Orders 12866 and 13563.

Structure of OSHA Health Standards

OSHA's health standards traditionally incorporate a comprehensive approach to reducing occupational disease. OSHA substance-specific health standards generally include the ''hierarchy of controls,'' which, as a matter of OSHA's preferred policy, mandates that employers install and implement all feasible engineering and work practice controls before respirators may be used. The Agency's adherence to the hierarchy of controls has been upheld by the courts (*ASARCO, Inc.* v. *OSHA,* 746 F.2d 483, 496–498 (9th Cir. 1984); *Am. Iron & Steel Inst.* v. *OSHA,* 182 F.3d 1261, 1271 (11th Cir. 1999)). In fact, courts view the legal standard for proving technological feasibility as incorporating the hierarchy: ''OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations. . . . The effect of such proof is to establish a presumption that industry can meet the PEL without relying on respirators'' (*Lead I,* 647 F.2d at 1272).

The reasons supporting OSHA's continued reliance on the hierarchy of controls, as well as its reasons for limiting the use of respirators, are numerous and grounded in good industrial hygiene principles (see discussion in Section XVI. Summary and Explanation of the Standards, Methods of Compliance). The hierarchy of controls focuses on removing harmful airborne materials at their source ''to prevent atmospheric contamination'' to which the employee would be exposed, rather than relying on the proper functioning of a respirator as the primary means of protecting the employee (see 29 CFR 1910.134, 1910.1000(e), 1926.55(b)).

In health standards such as this one, the hierarchy of controls is augmented by ancillary provisions. These provisions work with the hierarchy of controls and personal protective equipment requirements to provide comprehensive protection to employees in affected workplaces. Such provisions typically include exposure assessment, medical surveillance, hazard communication, and recordkeeping.

The OSH Act compels OSHA to require all feasible measures for reducing significant health risks (29 U.S.C. 655(b)(5); *Pub. Citizen Health Research Grp.,* 796 F.2d at 1505 (''if in fact a STEL [short-term exposure limit] would further reduce a significant health risk and is feasible to implement, then the OSH Act compels the agency to adopt it (barring alternative avenues to the same result)''). When there is significant risk below the PEL, the D.C. Circuit indicated that OSHA should use its regulatory authority to impose additional requirements on employers when those requirements will result in

a greater than de minimis incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274). The Supreme Court alluded to a similar issue in *Benzene,* pointing out that ''in setting a permissible exposure level in reliance on less-than-perfect methods, OSHA would have the benefit of a backstop in the form of monitoring and medical testing'' (*Benzene,* 448 U.S. at 657). OSHA concludes that the ancillary provisions in this final standard provide significant benefits to worker health by providing additional layers and types of protection to employees exposed to beryllium and beryllium compounds.

III. Events Leading to the Final Standards

The first occupational exposure limit for beryllium was set in 1949 by the Atomic Energy Commission (AEC), which required that beryllium exposure in the workplaces under its jurisdiction be limited to 2 μg/m³ as an 8-hour time-weighted average (TWA), and 25 μg/m³ as a peak exposure never to be exceeded (Document ID 1323). These exposure limits were adopted by all AEC installations handling beryllium, and were binding on all AEC contractors involved in the handling of beryllium.

In 1956, the American Industrial Hygiene Association (AIHA) published a Hygienic Guide which supported the AEC exposure limits. In 1959, the American Conference of Governmental Industrial Hygienists (ACGIH®) also adopted a Threshold Limit Value (TLV®) of 2 μg/m³ as an 8-hour TWA (Borak, 2006). In 1970, ANSI issued a national consensus standard for beryllium and beryllium compounds (ANSI Z37.29–1970). The standard set a permissible exposure limit (PEL) for beryllium and beryllium compounds at 2 μg/m³ as an 8-hour TWA; 5 μg/m³ as an acceptable ceiling concentration; and 25 μg/m³ as an acceptable maximum peak above the acceptable ceiling concentration for a maximum duration of 30 minutes in an 8-hour shift (Document ID 1303).

In 1971, OSHA adopted, under Section 6(a) of the Occupational Safety and Health Act of 1970, and made applicable to general industry, the ANSI standard (Document ID 1303). Section 6(a) provided that in the first two years after the effective date of the Act, OSHA was to promulgate ''start-up'' standards, on an expedited basis and without public hearing or comment, based on national consensus or established Federal standards that improved employee safety or health. Pursuant to that authority, in 1971, OSHA promulgated approximately 425 PELs for air contaminants, including beryllium, derived principally from Federal standards applicable to government contractors under the Walsh-Healey Public Contracts Act, 41 U.S.C. 35, and the Contract Work Hours and Safety Standards Act (commonly known as the Construction Safety Act), 40 U.S.C. 333. The Walsh-Healey Act and Construction Safety Act standards, in turn, had been adopted primarily from ACGIH®'s TLV®s as well as several from United States of America Standards Institute (USASI) [later the American National Standards Institute (ANSI)].

The National Institute for Occupational Safety and Health (NIOSH) issued a document entitled *Criteria for a Recommended Standard: Occupational Exposure to Beryllium* (Criteria Document) in June 1972 with Recommended Exposure Limits (RELs) of 2 μg/m³ as an 8-hour TWA and 25 μg/m³ as an acceptable maximum peak above the acceptable ceiling concentration for a maximum duration of 30 minutes in an 8-hour shift. OSHA reviewed the findings and recommendations contained in the Criteria Document along with the AEC control requirements for beryllium exposure. OSHA also considered existing data from animal and epidemiological studies, and studies of industrial processes of beryllium extraction, refinement, fabrication, and machining. In 1975, OSHA asked NIOSH to update the evaluation of the existing data pertaining to the carcinogenic potential of beryllium. In response to OSHA's request, the Director of NIOSH stated that, based on animal data and through all possible routes of exposure including inhalation, ''beryllium in all likelihood represents a carcinogenic risk to man.''

In October 1975, OSHA proposed a new beryllium standard for all industries based on information from studies finding that beryllium caused cancer in animals (40 FR 48814 (10/17/75)). Adoption of this proposal would have lowered the 8-hour TWA exposure limit from 2 μg/m³ to 1 μg/m³. In addition, the proposal included ancillary provisions for such topics as exposure monitoring, hygiene facilities, medical surveillance, and training related to the health hazards from beryllium exposure. The rulemaking was never completed.

In 1977, NIOSH recommended an exposure limit of 0.5 μg/m³ and identified beryllium as a potential occupational carcinogen. In December 1998, ACGIH published a Notice of Intended Change for its beryllium exposure limit. The notice proposed a lower TLV of 0.2 μg/m³ over an 8-hour TWA based on evidence of CBD and sensitization in exposed workers. Then in 2009, ACGIH adopted a revised TLV for beryllium that lowered the TWA to 0.05 μg/m³ (inhalable) (see Document ID 1755, Tr. 136).

In 1999, the Department of Energy (DOE) issued a Chronic Beryllium Disease Prevention Program (CBDPP) Final Rule for employees exposed to beryllium in its facilities (Document ID 1323). The DOE rule set an action level of 0.2 μg/m³, and adopted OSHA's PEL of 2 μg/m³ or any more stringent PEL OSHA might adopt in the future (10 CFR 850.22; 64 FR 68873 and 68906, Dec. 8, 1999).

Also in 1999, OSHA was petitioned by the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) (Document ID 0069) and by Dr. Lee Newman and Ms. Margaret Mroz, from the National Jewish Health (NJH) (Document ID 0069), to promulgate an Emergency Temporary Standard (ETS) for beryllium in the workplace. In 2001, OSHA was petitioned for an ETS by Public Citizen Health Research Group and again by PACE (Document ID 0069). In order to promulgate an ETS, the Secretary of Labor must prove (1) that employees are exposed to grave danger from exposure to a hazard, and (2) that such an emergency standard is necessary to protect employees from such danger (29 U.S.C. 655(c) [6(c)]). The burden of proof is on the Department and because of the difficulty of meeting this burden, the Department usually proceeds when appropriate with ordinary notice and comment [section 6(b)] rulemaking rather than a 6(c) ETS. Thus, instead of granting the ETS requests, OSHA instructed staff to further collect and analyze research regarding the harmful effects of beryllium in preparation for possible section 6(b) rulemaking.

On November 26, 2002, OSHA published a Request for Information (RFI) for ''Occupational Exposure to Beryllium'' (Document ID 1242). The RFI contained questions on employee exposure, health effects, risk assessment, exposure assessment and monitoring methods, control measures and technological feasibility, training, medical surveillance, and impact on small business entities. In the RFI, OSHA expressed concerns about health effects such as chronic beryllium disease (CBD), lung cancer, and beryllium sensitization. OSHA pointed to studies indicating that even short-term exposures below OSHA's PEL of 2 μg/m³ could lead to CBD. The RFI also cited studies describing the relationship between beryllium sensitization and CBD (67 FR at 70708). In addition,

OSHA stated that beryllium had been identified as a carcinogen by organizations such as NIOSH, the International Agency for Research on Cancer (IARC), and the Environmental Protection Agency (EPA); and cancer had been evidenced in animal studies (67 FR at 70709).

On November 15, 2007, OSHA convened a Small Business Advocacy Review Panel for a draft proposed standard for occupational exposure to beryllium. OSHA convened this panel under Section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*).

The Panel included representatives from OSHA, the Solicitor's Office of the Department of Labor, the Office of Advocacy within the Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. Small Entity Representatives (SERs) made oral and written comments on the draft rule and submitted them to the panel.

The SBREFA Panel issued a report on January 15, 2008 which included the SERs' comments. SERs expressed concerns about the impact of the ancillary requirements such as exposure monitoring and medical surveillance. Their comments addressed potential costs associated with compliance with the draft standard, and possible impacts of the standard on market conditions, among other issues. In addition, many SERs sought clarification of some of the ancillary requirements such as the meaning of ''routine'' contact or ''contaminated surfaces.''

OSHA then developed a draft preliminary beryllium health effects evaluation (Document ID 1271) and a draft preliminary beryllium risk assessment (Document ID 1272), and in 2010, OSHA hired a contractor to oversee an independent scientific peer review of these documents. The contractor identified experts familiar with beryllium health effects research and ensured that these experts had no conflict of interest or apparent bias in performing the review. The contractor selected five experts with expertise in such areas as pulmonary and occupational medicine, CBD, beryllium sensitization, the Beryllium Lymphocyte Proliferation Test (BeLPT), beryllium toxicity and carcinogenicity, and medical surveillance. Other areas of expertise included animal modeling, occupational epidemiology, biostatistics, risk and exposure assessment, exposure-response modeling, beryllium exposure assessment, industrial hygiene, and occupational/environmental health engineering.

Regarding the preliminary health effects evaluation, the peer reviewers concluded that the health effect studies were described accurately and in sufficient detail, and OSHA's conclusions based on the studies were reasonable (Document ID 1210). The reviewers agreed that the OSHA document covered the significant health endpoints related to occupational beryllium exposure. Peer reviewers considered the preliminary conclusions regarding beryllium sensitization and CBD to be reasonable and well presented in the draft health evaluation section. All reviewers agreed that the scientific evidence supports sensitization as a necessary condition in the development of CBD. In response to reviewers' comments, OSHA made revisions to more clearly describe certain sections of the health effects evaluation. In addition, OSHA expanded its discussion regarding the BeLPT.

Regarding the preliminary risk assessment, the peer reviewers were highly supportive of the Agency's approach and major conclusions (Document ID 1210). The peer reviewers stated that the key studies were appropriate and their selection clearly explained in the document. They regarded the preliminary analysis of these studies to be reasonable and scientifically sound. The reviewers supported OSHA's conclusion that substantial risk of sensitization and CBD were observed in facilities where the highest exposure generating processes had median full-shift exposures around 0.2 $\mu g/m^3$ or higher, and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1 $\mu g/m^3$ or below.

In February 2012, the Agency received for consideration a draft recommended standard for beryllium (Materion and USW, 2012, Document ID 0754). This draft standard was the product of a joint effort between two stakeholders: Materion Corporation, a leading producer of beryllium and beryllium products in the United States, and the United Steelworkers, an international labor union representing workers who manufacture beryllium alloys and beryllium-containing products in a number of industries. They sought to craft an OSHA-like model beryllium standard that would have support from both labor and industry. OSHA has considered this proposal along with other information submitted during the development of the Notice of Proposed Rulemaking (NPRM) for beryllium. As described in greater detail in the Introduction to the Summary and Explanation of the final rule, there was substantial agreement between the submitted joint standard and the OSHA proposed standard.

On August 7, 2015, OSHA published its NPRM in the **Federal Register** (80 FR 47565 (8/7/15)). In the NPRM, the Agency made a preliminary determination that employees exposed to beryllium and beryllium compounds at the preceding PEL face a significant risk to their health and that promulgating the proposed standard would substantially reduce that risk. The NPRM (Section XVIII) also responded to the SBREFA Panel recommendations, which OSHA carefully considered, and clarified the requirements about which SERs expressed confusion. OSHA also discussed the regulatory alternatives recommended by the SBREFA Panel in NPRM, Section XVIII, and in the PEA (Document ID 0426).

The NPRM invited interested stakeholders to submit comments on a variety of issues and indicated that OSHA would schedule a public hearing upon request. Commenters submitted information and suggestions on a variety of topics. In addition, in response to a request from the Non-Ferrous Founders' Society, OSHA scheduled an informal public hearing on the proposed rule. The Agency invited interested persons to participate by providing oral testimony and documentary evidence at the hearing. OSHA also welcomed presentation of data and documentary evidence that would provide the Agency with the best available evidence to use in determining whether to develop a final rule.

The public hearing was held in Washington, DC on March 21 and 22, 2016. Administrative Law Judge William Colwell presided over the hearing. The Agency heard testimony from several organizations, such as public health groups, the Non-Ferrous Founders' Society, other industry representatives, and labor unions. Following the hearing, participants who had filed notices of intent to appear were allowed 30 days—until April 21, 2016—to submit additional evidence and data, and an additional 15 days—until May 6, 2016—to submit final briefs, arguments, and summations (Document ID 1756, Tr. 326).

In 2016, in an action parallel to OSHA's rulemaking, DOE proposed to update its action level to 0.05 $\mu g/m^3$ (81 FR 36704–36759, June 7, 2016). The DOE action level triggers workplace precautions and control measures such as periodic monitoring, exposure

reduction or minimization, regulated areas, hygiene facilities and practices, respiratory protection, protective clothing and equipment, and warning signs (Document ID 1323; 10 CFR 850.23(b)). Unlike OSHA's PEL, however, DOE's selection of an action level is not required to meet statutory requirements of technological and economic feasibility.

In all, the OSHA rulemaking record contains over 1,900 documents, including all the studies OSHA relied on in its preliminary health effects and risk assessment analyses, the hearing transcript and submitted testimonies, the joint Materion-USW draft proposed standard, and the pre- and post-hearing comments and briefs. The final rule on occupational exposure to beryllium and beryllium compounds is thus based on consideration of the entire record of this rulemaking proceeding, including materials discussed or relied upon in the proposal, the record of the hearing, and all written comments and exhibits timely received. Based on this comprehensive record, OSHA concludes that employees exposed to beryllium and beryllium compounds are at significant risk of material impairment of health, including chronic beryllium disease and lung cancer. The Agency concludes that the PEL of 0.2 μg/m³ reduces the significant risks of material impairments of health posed to workers by occupational exposure to beryllium and beryllium compounds to the maximum extent that is technologically and economically feasible. OSHA's substantive determinations with regard to the comments, testimony, and other information in the record, the legal standards governing the decision-making process, and the Agency's analysis of the data resulting in its assessments of risks, benefits, technological and economic feasibility, and compliance costs are discussed elsewhere in this preamble. More technical or complex issues are discussed in greater detail in the background documents referenced in this preamble.

IV. Chemical Properties and Industrial Uses

Chemical and Physical Properties

Beryllium (Be; CAS Number 7440–41–7) is a silver-grey to greyish-white, strong, lightweight, and brittle metal. It is a Group IIA element with an atomic weight of 9.01, atomic number of 4, melting point of 1,287 °C, boiling point of 2,970 °C, and a density of 1.85 at 20 °C (Document ID 0389, p. 1). It occurs naturally in rocks, soil, coal, and volcanic dust (Document ID 1567, p. 1). Beryllium is insoluble in water and soluble in acids and alkalis. It has two common oxidation states, Be(0) and Be(+2). There are several beryllium compounds with unique CAS numbers and chemical and physical properties. Table IV–1 describes the most common beryllium compounds.

TABLE IV–1—PROPERTIES OF BERYLLIUM AND BERYLLIUM COMPOUNDS

Chemical name	CAS No.	Synonyms and trade names	Molecular weight	Melting point (°C)	Description	Density (g/cm3)	Solubility
Beryllium metal	7440–41–7	Beryllium; beryllium-9, beryllium element; beryllium metallic.	9.0122	1287	Grey, close-packed, hexagonal, brittle metal.	1.85 (20 °C)	Soluble in most dilute acids and alkali; decomposes in hot water; insoluble in mercury and cold water.
Beryllium chloride.	7787–47–5	Beryllium dichloride	79.92	399.2	Colorless to slightly yellow; orthorhombic, deliques-cent crystal.	1.899 (25 °C).	Soluble in water, ethanol, diethyl ether and pyridine; slightly soluble in benzene, carbon disulfide and chloroform; insoluble in acetone, ammonia, and toluene.
Beryllium fluoride.	7787–49–7 (12323–05–6)	Beryllium difluoride	47.01	555	Colorless or white, amorphous, hygroscopic solid.	1.986	Soluble in water, sulfuric acid, mixture of ethanol and diethyl ether; slightly soluble in ethanol; insoluble in hydrofluoric acid.
Beryllium hydroxide.	13327–32–7 (1304–49–0)	Beryllium dihydroxide	43.3	138 (decomposes to beryllium oxide).	White, amorphous, amphoteric powder.	1.92	Soluble in hot concentrated acids and alkali; slightly soluble in dilute alkali; insoluble in water.
Beryllium sulfate	13510–49–1	Sulfuric acid, beryllium salt (1:1).	105.07	550–600 °C (decomposes to beryllium oxide).	Colorless crystal	2.443	Forms soluble tetrahydrate in hot water; insoluble in cold water.
Beryllium sulfate tetrhydrate.	7787–56–6	Sulfuric acid; beryllium salt (1:1), tetrahydrate.	177.14	100 °C	Colorless, tetragonal crystal.	1.713	Soluble in water; slightly soluble in concentrated sulfuric acid; insoluble in ethanol.
Beryllium Oxide	1304–56–9	Beryllia; beryllium monoxide thermalox TM.	25.01	2508–2547 °C	Colorless to white, hexagonal crystal or amorphous, amphoteric powder.	3.01 (20 °C)	Soluble in concentrated acids and alkali; insoluble in water.
Beryllium carbonate.	1319–43–3	Carbonic acid, beryllium salt, mixture with beryllium hydroxide.	112.05	No data	White powder	No data	Soluble in acids and alkali; insoluble in cold water; decomposes in hot water.
Beryllium nitrate trihydrate.	7787–55–5	Nitric acid, beryllium salt, trihydrate.	187.97	60	White to faintly yellowish, deliquescent mass.	1.56	Very soluble in water and ethanol.
Beryllium phosphate.	13598–15–7	Phosphoric acid, beryllium salt (1:1).	104.99	No data	Not reported	Not reported	Slightly soluble in water.

ATSDR, 2002.

The physical and chemical properties of beryllium were realized early in the 20th century, and it has since gained commercial importance in a wide range of industries. Beryllium is lightweight, hard, spark resistant, non-magnetic, and has a high melting point. It lends strength, electrical and thermal conductivity, and fatigue resistance to alloys (Document ID 0389, p. 1). Beryllium also has a high affinity for oxygen in air and water, which can cause a thin surface film of beryllium oxide to form on the bare metal, making it extremely resistant to corrosion. These properties make beryllium alloys highly suitable for defense, nuclear, and aerospace applications (Document ID 1342, pp. 45, 48).

There are approximately 45 mineralized forms of beryllium. In the United States, the predominant mineral form mined commercially and refined into pure beryllium and beryllium alloys is bertrandite. Bertrandite, while containing less than 1% beryllium compared to 4% in beryl, is easily and efficiently processed into beryllium hydroxide (Document ID 1342, p. 48). Imported beryl is also converted into beryllium hydroxide as the United States has very little beryl that can be economically mined (Document ID 0616, p. 28).

Industrial Uses

Materion Corporation (Materion), formerly called Brush Wellman, is the only producer of primary beryllium in the United States. Beryllium is used in a variety of industries, including aerospace, defense, telecommunications, automotive, electronic, and medical specialty industries. Pure beryllium metal is used in a range of products such as X-ray transmission windows, nuclear reactor neutron reflectors, nuclear weapons, precision instruments, rocket propellants, mirrors, and computers (Document ID 0389, p. 1). Beryllium oxide is used in components such as ceramics, electrical insulators, microwave oven components, military vehicle armor, laser structural components, and automotive ignition systems (Document ID 1567, p. 147). Beryllium oxide ceramics are used to produce sensitive electronic items such as lasers and satellite heat sinks.

Beryllium alloys, typically beryllium/copper or beryllium/aluminum, are manufactured as high beryllium content or low beryllium content alloys. High content alloys contain greater than 30% beryllium. Low content alloys are typically less than 3% beryllium. Beryllium alloys are used in automotive electronics (*e.g.,* electrical connectors and relays and audio components), computer components, home appliance parts, dental appliances (*e.g.,* crowns), bicycle frames, golf clubs, and other articles (Document ID 0389, p. 2; 1278, p. 182; 1280, pp. 1–2; 1281, pp. 816, 818). Electrical components and conductors are stamped and formed from beryllium alloys. Beryllium-copper alloys are used to make switches in automobiles (Document ID 1280, p. 2; 1281, p. 818) and connectors, relays, and switches in computers, radar, satellite, and telecommunications equipment (Document ID 1278, p. 183). Beryllium-aluminum alloys are used in the construction of aircraft, high resolution medical and industrial X-ray equipment, and mirrors to measure weather patterns (Document ID 1278, p. 183). High content and low content beryllium alloys are precision machined for military and aerospace applications. Some welding consumables are also manufactured using beryllium.

Beryllium is also found as a trace metal in materials such as aluminum ore, abrasive blasting grit, and coal fly ash. Abrasive blasting grits such as coal slag and copper slag contain varying concentrations of beryllium, usually less than 0.1% by weight. The burning of bituminous and sub-bituminous coal for power generation causes the naturally occurring beryllium in coal to accumulate in the coal fly ash byproduct. Scrap and waste metal for smelting and refining may also contain beryllium. A detailed discussion of the industries and job tasks using beryllium is included in the Preliminary Economic Analysis (Document ID 0385, 0426).

Occupational exposure to beryllium can occur from inhalation of dusts, fume, and mist. Beryllium dusts are created during operations where beryllium is cut, machined, crushed, ground, or otherwise mechanically sheared. Mists can also form during operations that use machining fluids. Beryllium fume can form while welding with or on beryllium components, and from hot processes such as those found in metal foundries.

Occupational exposure to beryllium can also occur from skin, eye, and mucous membrane contact with beryllium particulate or solutions.

V. Health Effects

Overview of Findings and Supportive Comments

As discussed in detail throughout this section (section V, Final Health Effects) and in Section VI, Final Quantitative Risk Assessment and Significance of Risk, OSHA finds, based upon the best available evidence in the record, that exposure to soluble and poorly soluble forms of beryllium are associated with several adverse health outcomes including sensitization, chronic beryllium disease, acute beryllium disease and lung cancer.

The findings and conclusions in this section are consistent with those of the National Academies of Sciences (NAS), the World Health Organization's International Agency for Research on Cancer (IARC), the U.S. Department of Health and Human Services' (HHS) National Toxicology Program (NTP), the National Institute for Occupational Safety and Health (NIOSH), the Agency for Toxic Substance and Disease Registry (ATSDR), the European Commission on Health, Safety and Hygiene at Work, and many other organizations and individuals, as evidenced in the rulemaking record and further discussed below. Other scientific organizations and governments have recognized the strong body of scientific evidence pointing to the health risks of exposure to beryllium and have deemed it necessary to take action to reduce those risks. In 1999, the Department of Energy (DOE) updated its airborne beryllium concentration action level to 0.2 $\mu g/m^3$ (Document ID 1323). In 2009, the American Conference of Governmental Industrial Hygienists (ACGIH), a professional society that has been recommending workplace exposure limits for six decades, revised its Threshold Limit Value (TLV) for beryllium and beryllium-containing compounds to 0.05 $\mu g/m^3$ (Document ID 1304).

In finalizing this Health Effects preamble section for the final rule, OSHA updated the preliminary Health Effects section published in the NPRM based on the stakeholder response received by the Agency during the public comment period and public hearing. OSHA also corrected several non-substantive errors that were published in the NPRM as well as those identified by NIOSH and Materion including several minor organizational changes made to sections V.D.3 and V.E.2.b (Document ID 1671, pp. 10–11; 1662, pp. 3–5). A section titled ''Dermal Effects'' was added to V.F.5 based on comments received by the American Thoracic Society (ATS), National Jewish Health, and the National Supplemental Screening Program (Document ID 1688, p. 2; 1664, p. 5; 1677, p. 3). Additionally, the Agency responded to relevant stakeholder comments contained in specific sections.

In developing its review of the preliminary health effects from beryllium exposure and assessment of risk for the NPRM, OSHA prepared a

pair of draft documents, entitled ''Occupation Exposure to Beryllium: Preliminary Health Effects Evaluation'' (OSHA, 2010, Document ID 1271) and ''Preliminary Beryllium Risk Assessment'' (OSHA, 2010, Document ID 1272), that underwent independent scientific peer review in accordance with the Office of Management and Budget's (OMB) Information Quality Bulletin for Peer Review. Eastern Research Group, Inc. (ERG), under contract with OSHA, selected five highly qualified experts with collective expertise in occupational epidemiology, occupational medicine, toxicology, immunology, industrial hygiene, and risk assessment methodology.[2] The peer reviewers responded to 27 questions that covered the accuracy, completeness, and understandability of key studies and adverse health endpoints as well as questions regarding the adequacy, clarity and reasonableness of the risk analysis (ERG, 2010; Document ID 1270).

Overall, the peer reviewers found that the OSHA draft health effects evaluation described the studies in sufficient detail, appropriately addressed their strengths and limitations, and drew scientifically sound conclusions. The peer reviewers were also supportive of the Agency's preliminary risk assessment approach and the major conclusions. OSHA provided detailed responses to reviewer comments in its publication of the NPRM (80 FR 47646–47652, 8/7/2015). Revisions to the draft health effects evaluation and preliminary risk assessment in response to the peer review comments were reflected in sections V and VI of the same publication (80 FR 47581–47646, 8/7/2015). OSHA received public comment and testimony on the Health Effects and Preliminary Risk Assessment sections published in the NPRM, which are discussed in this preamble.

The Agency received a wide variety of stakeholder comments and testimony for this rulemaking on issues related to the health effects and risk of beryllium exposure. Statements supportive of OSHA's Health Effects section include comments from NIOSH, the National Safety Council, the American Thoracic Society (ATS), Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, national labor organizations (American Federation of Labor—Congress of Industrial Organizations (AFL–CIO), North American Building Trades Unions (NABTU), United Steelworkers (USW), Public Citizen, ORCHSE, experts from National Jewish Health (Lisa Maier, MD and Margaret Mroz, MSPH), the American Association for Justice, and the National Council for Occupational Safety and Health.

For example, NIOSH commented in its prepared written hearing testimony:

> OSHA has appropriately identified and documented all critical health effects associated with occupational exposure to beryllium and has appropriately focused its greatest attention on beryllium sensitization (BeS), chronic beryllium disease (CBD) and lung cancer . . .

NIOSH went on to say that sensitization was more than a test result with little meaning. It relates to a condition in which the immune system is able to recognize and adversely react to beryllium in a way that increases the risk of developing CBD. NIOSH agrees with OSHA that sensitization is a functional change that is necessary in order to proceed along the pathogenesis to serious lung disease.

The National Safety Council, a congressionally chartered nonprofit safety organization, also stated that ''beryllium represents a serious health threat resulting from acute or chronic exposures.'' (Document ID 1612, p. 5). Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, submitted a statement recognizing that the evidence strongly supports the conclusion that sensitization can occur from exposure to soluble and poorly soluble forms of beryllium (Document ID 1672, p. 3).

OSHA also received supporting statements from ATS and ORCHSE on the inclusion of beryllium sensitization, CBD, skin disease, and lung cancer as major adverse health effects associated with beryllium exposure (Document ID 1688, p. 7; 1691, p. 14). ATS specifically stated:

> . . . the ATS supports the inclusion of beryllium sensitization, CBD, and skin disease as the major adverse health effects associated with exposure to beryllium at or below 0.1 μg/m^3 and acute beryllium disease at higher exposures based on the currently available epidemiologic and experimental studies. (Document ID 1688, p. 2)

In addition, OSHA received supporting comments from labor organizations representing workers exposed to beryllium. The AFL–CIO, NABTU, and USW submitted comments supporting the inclusion of beryllium sensitization, CBD and lung cancer as health effects from beryllium exposure (Document ID 1689, pp. 1, 3; 1679, p. 6; 1681, p. 19). AFL–CIO commented that ''[t]he proposal is based on extensive scientific and medical evidence . . .'' and ''[b]eryllium exposure causes immunological sensitivity, CBD and lung cancer. These health effects are debilitating, progressive and irreversible. Workers are exposed to beryllium through respiratory, dermal and gastrointestinal routes.'' (Document ID 1689, pp. 1, 3). Comments submitted by USW state that ''OSHA has correctly identified, and comprehensively documented the material impairments of health resulting from beryllium exposure.'' (Document ID 1681, p. 19).

Dr. Lisa Maier and Ms. Margaret Mroz of National Jewish Health testified about the health effects of beryllium in support of the beryllium standard:

> We know that chronic beryllium disease often will not manifest clinically until irreversible lung scarring has occurred, often years after exposure, with a latency of 20 to 30 years as discussed yesterday. Much too late to make changes in the work place. We need to look for early markers of health effects, cast the net widely to identify cases of sensitization and disease, and use screening results in concert with exposure sampling to identify areas of increased risk that can be modified in the work place. (Document ID 1756, Tr. 102; 1806).

American Association for Justice noted that:

> Unlike many toxins, there is no threshold below which no worker will become sensitized to beryllium. Worker sensitization to beryllium is a precursor to CBD, but not cancer. The symptoms of chronic beryllium disease (CBD) are part of a continuum of disease that is progressive in nature. Early recognition of and treatment for CBD may lead to a lessening of symptoms and may prevent the disease from progressing further. Symptoms of CBD may occur at exposure levels well below the proposed permissible exposure limit of .2 μg/m^3 and even below the action level of .1 μg/m^3. OSHA has clear authority to regulate health effects across the entire continuum of disease to protect workers. We applaud OSHA for proposing to do so. (Document ID 1683, pp. 1–2).

National Committee for Occupational Safety and Health support OSHA findings of health effects due to beryllium exposure (1690, p. 1). Comments from Public Citizen also support OSHA findings: ''Beryllium is toxic at extremely low levels and exposure can result in BeS, an immune response that eventually can lead to an autoimmune granulomatous lung disease known as CBD. BeS is a necessary prerequisite to the development of CBD, with OSHA's

[2] The five selected peer reviewers were John Balmes, MD, University of California-San Francisco; Patrick Breysse, Ph.D., Johns Hopkins University, Bloomberg School of Public Health; Terry Gordon, Ph.D., New York University School of Medicine; Milton Rossman, MD, University of Pennsylvania School of Medicine; Kyle Steenland, Ph.D., Emory University, Rollins School of Public Health.

NPRM citing studies showing that 31–49 percent of all sensitized workers were diagnosed with CBD after clinical evaluations. Beryllium also is a recognized carcinogen that can cause lung cancer.'' (Document ID 1670, p.2).

In addition to the comments above and those noted throughout this Health Effects section, Materion submitted their correspondence to the National Academies (NAS) regarding the company's assessment of the NAS beryllium studies and their correspondence to NIOSH regarding the Cummings 2009 study (Document 1662, Attachments) to OSHA. For the NAS study, Materion included a series of comments regarding studies included in the NAS report. OSHA has reviewed these comments and found that the comments submitted to the NAS critiquing their review of the health effects of beryllium were considered and incorporated where appropriate. For the NIOSH study Materion included comments regarding 2 cases of acute beryllium disease evaluated in a study published by Cummings *et al.,* 2009. NIOSH also dealt with the comments from Materion as they found appropriate. However, none of the changes recommended by Materion to the NAS or NIOSH altered the overall findings or conclusions from either study. OSHA has taken the Materion comments into account in the review of these documents. OSHA found them not to be sufficient to discount either the findings of the NAS or NIOSH.

Introduction

Beryllium-associated health effects, including acute beryllium disease (ABD), beryllium sensitization (also referred to in this preamble as ''sensitization''), chronic beryllium disease (CBD), and lung cancer, can lead to a number of highly debilitating and life-altering conditions including pneumonitis, loss of lung capacity (reduction in pulmonary function leading to pulmonary dysfunction), loss of physical capacity associated with reduced lung capacity, systemic effects related to pulmonary dysfunction, and decreased life expectancy (NIOSH, 1972, Document ID 1324, 1325, 1326, 1327, 1328; NIOSH, 2011 (0544)).

This Health Effects section presents information on beryllium and its compounds, the fate of beryllium in the body, research that relates to its toxic mechanisms of action, and the scientific literature on the adverse health effects associated with beryllium exposure, including ABD, sensitization, CBD, and lung cancer. OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from no symptomatology at its earliest stage following sensitization to mild symptoms such as a slight almost imperceptible shortness of breath, to loss of pulmonary function, debilitating lung disease, and, in many cases, death. This section also discusses the nature of these illnesses, the scientific evidence that they are causally associated with occupational exposure to beryllium, and the probable mechanisms of action with a more thorough review of the supporting studies.

A. Beryllium and Beryllium Compounds—Particle Characterization

1. Particle Physical/Chemical Properties

Beryllium has two oxidative states: Be(0) and Be(2^+) (Agency for Toxic Substance and Disease Registry (ATSDR) 2002, Document ID 1371). It is likely that the Be(2^+) state is the most biologically reactive and able to form a bond with peptides leading to it becoming antigenic (Snyder *et al.,* 2003) as discussed in more detail in the Beryllium Sensitization section below. Beryllium has a high charge-to-radius ratio, forming various types of ionic bonds. In addition, beryllium has a strong tendency for covalent bond formation (*e.g.,* it can form organometallic compounds such as $Be(CH_3)_2$ and many other complexes) (ATSDR, 2002, Document ID 1371; Greene *et al.,* 1998 (1519)). However, it appears that few, if any, toxicity studies exist for the organometallic compounds. Additional physical/chemical properties, such as solubility, for beryllium compounds that may be important in their biological response are summarized in Table 1 below. Solubility (as discussed in biological fluids in Section V.A.2.A below) is an important factor in evaluating the biological response to beryllium. For comparative purposes, water solubility is used in Table 1. The International Chemical Safety Cards lists water solubility as a way to standardize solubility values among particles and fibers. The information contained within Table 1 was obtained from the International Chemical Safety Cards (ICSC) for beryllium metal (ICSC 0226, Document ID 0438), beryllium oxide (ICSC 1325, Document ID 0444), beryllium sulfate (ICSC 1351, Document ID 0443), beryllium nitrate (ICSC 1352, Document ID 0442), beryllium carbonate (ICSC 1353, Document ID 0441), beryllium chloride (ICSC 1354, Document ID 0440), beryllium fluoride (ICSC 1355, Document ID 0439) and from the hazardous substance data bank (HSDB) for beryllium hydroxide (CASRN: 13327–32–7), and beryllium phosphate (CASRN: 13598–15–7, Document ID 0533). Additional information on chemical and physical properties as well as industrial uses for beryllium can be found in this preamble at Section IV, Chemical Properties and Industrial Uses.

TABLE 1—BERYLLIUM CHARACTERISTICS AND PROPERTIES

Compound name	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Metal	Be	9.0	Combustible; Finely dispersed particles—Explosive.	None.
Beryllium Oxide	BeO	25.0	Not combustible or explosive	Very sparingly soluble.
Beryllium Carbonate	$Be_2CO_3(OH)/Be_2CO_5\ H_2$	181.07	Not combustible or explosive	None.
Beryllium Sulfate	$BeSO_4$	105.1	Not combustible or explosive	Slightly soluble.
Beryllium Nitrate	$BeN_2O_6/Be(NO_3)_2$	133.0	Enhances combustion of other substances	Very soluble (1.66×10^6 mg/L).
Beryllium Hydroxide	$Be(OH)_2$	43.0	Not reported	Slightly soluble $0.8 \times 10^{\text{minus;4}}$ mol/L (3.44 mg/L).
Beryllium Chloride	$BeCl_2$	79.9	Not combustible or explosive	Soluble.
Beryllium Fluoride	BeF_2	47.0	Not combustible or explosive	Very soluble.
Beryllium Phosphate	$Be_3(PO_4)_2$	271.0	Not reported	Soluble.

Beryllium shows a high affinity for oxygen in air and water, resulting in a thin surface film of beryllium oxide on the bare metal. If the surface film is disturbed, it may become airborne and cause respiratory tract exposure or dermal exposure (also referred to as dermal contact). The physical properties of solubility, particle surface area, and particle size of some beryllium compounds are examined in more detail below. These properties have been evaluated in many toxicological studies. In particular, the properties related to the calcination (firing temperatures) and differences in crystal size and solubility are important aspects in their toxicological profile.

2. Factors Affecting Potency and Effect of Beryllium Exposure

The effect and potency of beryllium and its compounds, as for any toxicant, immunogen, or immunotoxicant, may be dependent upon the physical state in which they are presented to a host. For occupational airborne materials and surface contaminants, it is especially critical to understand those physical parameters in order to determine the extent of exposure to the respiratory tract and skin since these are generally the initial target organs for either route of exposure.

For example, solubility has an important part in determining the toxicity and bioavailability of airborne materials as well. Respiratory tract retention and skin penetration are directly influenced by the solubility and reactivity of airborne material. Large particles may have less of an effect in the lung than smaller particles due to reduced potential to stay airborne, to be inhaled, or be deposited along the respiratory tract. In addition, once inhalation occurs particle size is critical in determining where the particle will deposit along the respiratory tract.

These factors may be responsible, at least in part, for the process by which beryllium sensitization progresses to CBD in exposed workers. Other factors influencing beryllium-induced toxicity include the surface area of beryllium particles and their persistence in the lung. With respect to dermal contact or exposure, the physical characteristics of the particle are also important since they can influence skin absorption and bioavailability. This section addresses certain physical characteristics (*i.e.,* solubility, particle size, particle surface area) that influence the toxicity of beryllium materials in occupational settings.

a. Solubility

Solubility has been shown to be an important determinant of the toxicity of airborne materials, influencing the deposition and persistence of inhaled particles in the respiratory tract, their bioavailability, and the likelihood of presentation to the immune system. A number of chemical agents, including metals that contact and penetrate the skin, are able to induce an immune response, such as sensitization (Boeniger, 2003, Document ID 1560; Mandervelt *et al.,* 1997 (1451)). Similar to inhaled agents, the ability of materials to penetrate the skin is also influenced by solubility because dermal absorption may occur at a greater rate for soluble materials than poorly soluble materials (Kimber *et al.,* 2011, Document ID 0534). In post-hearing comments, NIOSH explained:

> In biological systems, solubility is used to describe the rate at which a material will undergo chemical clearance and dissolve in a fluid (airway lining, inside phagolysomes) relative to the rate of mechanical clearance. For example, in the lung a ''poorly soluble'' material is one that dissolves at a rate slower than the rate of mechanical removal via the mucociliary escalator. Examples of poorly soluble forms of beryllium are beryllium silicates, beryllium oxide, and beryllium metal and alloys (Deubner *et al.* 2011; Huang *et al.* 2011; Duling *et al.* 2012; Stefaniak *et al.* 2006, 201la, 2012). A highly soluble material is one that dissolves at a rate faster than mechanical clearance. Examples of highly soluble forms of beryllium are beryllium fluoride, beryllium sulfate, and beryllium chloride. (Document ID 1660–A2, p. 9).

This section reviews the relevant information regarding solubility, its importance in a biological matrix and its relevance to sensitization and beryllium lung disease. The weight of evidence presented below suggests that both soluble and poorly soluble forms of beryllium can induce a sensitization response and result in progression of lung disease.

Beryllium salts, including the chloride ($BeCl_2$), fluoride (BeF_2), nitrate ($Be(NO_3)_2$), phosphate (Be_3 $(PO_4)_2$), and sulfate (tetrahydrate) ($BeSO_4 \cdot 4H_2O$) salts, are all water soluble. However, soluble beryllium salts can be converted to less soluble forms in the lung (Reeves and Vorwald, 1967, Document ID 1309). According to an EPA report, aqueous solutions of the soluble beryllium salts are acidic as a result of the formation of $Be(OH_2)_4$ 2^+, the tetrahydrate, which will react to form poorly soluble hydroxides or hydrated complexes within the general physiological range of pH values (between 5 and 8) (EPA, 1998, Document ID 1322). This may be an important factor in the development of CBD since lower-soluble forms of beryllium have been shown to persist in the lung for longer periods of time and persistence in the lung may be needed in order for this disease to occur (NAS, 2008, Document ID 1355).

Beryllium oxide (BeO), hydroxide ($Be(OH)_2$), carbonate (Be_2 CO_3 $(OH)_2$), and sulfate (anhydrous) ($BeSO_4$) are either insoluble, slightly soluble, or considered to be sparingly or poorly soluble (almost insoluble or having an extremely slow rate of dissolution and most often referred to as poorly soluble in more recent literature). The solubility of beryllium oxide, which is prepared from beryllium hydroxide by calcining (heating to a high temperature without fusing in order to drive off volatile chemicals) at temperatures between 500 and 1,750 °C, has an inverse relationship with calcination temperature. Although the solubility of the low-fired crystals can be as much as 10 times that of the high-fired crystals, low-fired beryllium oxide is still only sparingly soluble (Delic, 1992, Document 1547). In a study that measured the dissolution kinetics (rate to dissolve) of beryllium compounds calcined at different temperatures, Hoover *et al.,* compared beryllium metal to beryllium oxide particles and found them to have similar solubilities. This was attributed to a fine layer of beryllium oxide that coats the metal particles (Hoover *et al.,* 1989, Document ID 1510). A study conducted by Deubner *et al.* (2011) determined ore materials to be more soluble than beryllium oxide at pH 7.2 but similar in solubility at pH 4.5. Beryllium hydroxide was more soluble than beryllium oxide at both pHs (Deubner *et al.,* 2011, Document ID 0527).

Investigators have also attempted to determine how biological fluids can dissolve beryllium materials. In two studies, poorly soluble beryllium, taken up by activated phagocytes, was shown to be ionized by myeloperoxidases (Leonard and Lauwerys, 1987, Document ID 1293; Lansdown, 1995 (1469)). The positive charge resulting from ionization enabled the beryllium to bind to receptors on the surface of cells such as lymphocytes or antigen-presenting cells which could make it more biologically active (NAS, 2008, Document ID 1355). In a study utilizing phagolysosomal-simulating fluid (PSF) with a pH of 4.5, both beryllium metal and beryllium oxide dissolved at a greater rate than that previously reported in water or SUF (simulant fluid) (Stefaniak *et al.,* 2006, Document ID 1398), and the rate of dissolution of the multi-constituent (mixed) particles

was greater than that of the single-constituent beryllium oxide powder. The authors speculated that copper in the particles rapidly dissolves, exposing the small inclusions of beryllium oxide, which have higher specific surface areas (SSA) and therefore dissolve at a higher rate. A follow-up study by the same investigational team (Duling *et al.,* 2012, Document ID 0539) confirmed dissolution of beryllium oxide by PSF and determined the release rate was biphasic (initial rapid diffusion followed by a latter slower surface reaction-driven release). During the latter phase, dissolution half-times were 1,400 to 2,000 days. The authors speculated this indicated bertrandite was persistent in the lung (Duling *et al.,* 2012, Document ID 0539).

In a recent study investigating the dissolution and release of beryllium ions for 17 beryllium-containing materials (ore, hydroxide, metal, oxide, alloys, and processing intermediates) using artificial human airway epithelial lining fluid, Stefaniak *et al.* (2011) found release of beryllium ions within 7 days (beryl ore smelter dust). The authors calculated dissolution half-times ranging from 30 days (reduction furnace material) to 74,000 days (hydroxide). Stefaniak *et al.* (2011) speculated that despite the rapid mechanical clearance, billions of beryllium ions could be released in the respiratory tract via dissolution in airway lining fluid (ALF). Under this scenario, beryllium-containing particles depositing in the respiratory tract dissolving in ALF could provide beryllium ions for absorption in the lung and interact with immune cells in the respiratory tract (Stefaniak *et al.,* 2011, Document ID 0537).

Huang *et al.* (2011) investigated the effect of simulated lung fluid (SLF) on dissolution and nanoparticle generation and beryllium-containing materials. Bertrandite-containing ore, beryl-containing ore, frit (a processing intermediate), beryllium hydroxide (a processing intermediate) and silica (used as a control), were equilibrated in SLF at two pH values (4.5 and 7.2) to reflect inter- and intra-cellular environments in the lung tissue. Concentrations of beryllium, aluminum, and silica ions increased linearly during the first 20 days in SLF, and rose more slowly thereafter, reaching equilibrium over time. The study also found nanoparticle formation (in the size range of 10–100 nm) for all materials (Huang *et al.,* 2011, Document ID 0531).

In an *in vitro* skin model, Sutton *et al.* (2003) demonstrated the dissolution of beryllium compounds (poorly soluble beryllium hydroxide, soluble beryllium phosphate) in a simulated sweat fluid (Document ID 1393). This model showed beryllium can be dissolved in biological fluids and be available for cellular uptake in the skin. Duling *et al.* (2012) confirmed dissolution and release of ions from bertrandite ore in an artificial sweat model (pH 5.3 and pH 6.5) (Document ID 0539).

In summary, studies have shown that soluble forms of beryllium readily dissolve into ionic components making them biologically available for dermal penetration and activation of immune cells (Stefaniak *et al.,* 2011; Document ID 0537). Soluble forms can also be converted to less soluble forms in the lung (Reeves and Vorwald, 1967, Document ID 1309) making persistence in the lung a possibility and increasing the potential for development of CBD (see section V.D.2). Studies by Stefaniak *et al.* (2003, 2006, 2011, 2012) (Document ID 1347; 1398; 0537; 0469), Huang *et al.* (2011), Duling *et al.* (2012), and Deubner *et al.* (2011) have demonstrated poorly soluble forms can be readily dissolved in biological fluids such as sweat, lung fluid, and cellular fluids. The dissolution of beryllium ions into biological fluids increases the likelihood of beryllium presentation to immune cells, thus increasing the potential for sensitization through dermal contact or lung exposure (Document ID 0531; 0539; 0527) (see section V.D.1).

OSHA received comments from the Non-Ferrous Founders' Society (NFFS) contending that the scientific evidence does not support insoluble beryllium as a causative agent for sensitization and CBD (Document ID 1678, p. 6). The NFFS contends that insoluble beryllium is not carcinogenic or a sensitizer to humans, and argues that based on this information, OSHA should consider a bifurcated standard with separate PELs for soluble and poorly soluble beryllium and beryllium compounds and insoluble beryllium metallics (Document ID 1678, p. 7). As evidence supporting its conclusion, the NFFS cited a 2010 statement written by Dr. Christian Strupp commissioned by the beryllium industry (Document ID 1785, 1814), which reviewed selected studies to evaluate the toxic potential of beryllium metal and alloys (Document ID 1678, pp. 7). The Strupp and Furnes statement (2010) cited by the NFFS is the background material and basis of the Strupp (2011a and 2011b) studies in the docket (Document ID 1794; 1795). In response to Strupp 2011 (a and b), Aleks Stefaniak of NIOSH published a letter to the editor refuting some of the evidence presented by Strupp (2011a and b, Document ID 1794; 1795). The first study by Strupp (2011a) evaluated selected animal studies and concluded that beryllium metal was not a sensitizer. Stefaniak (2011) evaluated the validity of the Strupp (2011a) study of beryllium toxicity and noted numerous deficiencies, including deficiencies in the study design, improper administration of beryllium test compounds, and lack of proper controls (Document ID 1793). In addition, Strupp (2011a) omitted numerous key animal and epidemiological studies demonstrating the potential of poorly soluble beryllium and beryllium metal as a sensitizing agent. One such study, Tinkle *et al.* (2003), demonstrated that topical application of poorly soluble beryllium induced skin sensitization in mice (Document ID 1483). Comments from NIOSH and National Jewish Medical Center state that poorly soluble beryllium materials are capable of dissolving in sweat (Document ID 1755; 1756). After evaluating the scientific evidence from epidemiological and animal studies, OSHA finds, based on the best available evidence, that soluble and poorly soluble forms of beryllium and beryllium compounds are causative agents of sensitization and CBD.

b. Particle Size

The toxicity of beryllium as exemplified by beryllium oxide is dependent, in part, on the particle size, with smaller particles (less than 10 μm in diameter) able to penetrate beyond the larynx (Stefaniak *et al.,* 2008, Document ID 1397). Most inhalation studies and occupational exposures involve quite small (less than 1–2 μm in diameter) beryllium oxide particles that can penetrate to the pulmonary regions of the lung (Stefaniak *et al.,* 2008, Document ID 1397). In inhalation studies with beryllium ores, particle sizes are generally much larger, with deposition occurring in several areas throughout the respiratory tract for particles less than 10 μm in diameter.

The temperature at which beryllium oxide is calcined influences its particle size, surface area, solubility, and ultimately its toxicity (Delic, 1992, Document ID 1547). Low-fired (500 °C) beryllium oxide is predominantly made up of poorly crystallized small particles, while higher firing temperatures (1000–1750 °C) result in larger particle sizes (Delic, 1992, Document ID 1547).

In order to determine the extent to which particle size plays a role in the toxicity of beryllium in occupational settings, several key studies are reviewed and detailed below. The findings on particle size have been related, where possible, to work process

and biologically relevant toxicity endpoints of either sensitization or CBD.

Numerous studies have been conducted evaluating the particle size generated during basic industrial and machining operations. In a study by Cohen *et al.* (1983), a multi-cyclone sampler was utilized to measure the size mass distribution of the beryllium aerosol at a beryllium-copper alloy casting operation (Document ID 0540). Briefly, Cohen *et al.* (1983) found variable particle size generation based on the operations being sampled with particle size ranging from 3 to 16 μm. Hoover *et al.* (1990) also found variable particle sizes being generated across different operations (Document ID 1314). In general, Hoover *et al.* (1990) found that milling operations generated smaller particle sizes than sawing operations. Hoover *et al.* (1990) also found that beryllium metal generated higher concentrations than metal alloys. Martyny *et al.* (2000) characterized generation of particle size during precision beryllium machining processes (Document ID 1053). The study found that more than 50 percent of the beryllium machining particles collected in the breathing zone of machinists were less than 10 μm in aerodynamic diameter with 30 percent of those smaller particles being less than 0.6 μm. A study by Thorat *et al.* (2003) found similar results with ore mixing, crushing, powder production and machining ranging from 5.0 to 9.5 μm (Document ID 1389). Kent *et al.* (2001) measured airborne beryllium using size-selective samplers in five furnace areas at a beryllium processing facility (Document ID 1361). A statistically significant linear trend was reported between the alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The study authors suggested that the concentration of alveolar-deposited particles (*e.g.,* <3.5 μm) may be a better predictor of sensitization and CBD than the total mass concentration of airborne beryllium.

A recent study by Virji *et al.* (2011) evaluated particle size distribution, chemistry, and solubility in areas with historically elevated risk of sensitization and CBD at a beryllium metal powder, beryllium oxide, and alloy production facility (Document ID 0465). The investigators observed that historically, exposure-response relationships have been inconsistent when using mass concentration to identify process-related risk, possibly due to incomplete particle characterization. Two separate exposure surveys were conducted in March 1999 and June–August 1999 using multi-stage personal impactor samplers (to determine particle size distribution) and personal 37 mm closed face cassette (CFC) samplers, both located in workers' breathing zones. One hundred and ninety eight time-weighted-average (TWA) personal impactor samples were analyzed for representative jobs and processes. A total of 4,026 CFC samples were collected over the collection period and analyzed for mass concentration, particle size, chemical content and solubility and compared to process areas with high risk of sensitization and CBD. The investigators found that total beryllium concentration varied greatly between workers and among process areas. Analysis of chemical form and solubility also revealed wide variability among process areas, but high risk process areas had exposures to both soluble and poorly soluble forms of beryllium. Analysis of particle size revealed most process areas had particles ranging from 5 to 14 μm mass median aerodynamic diameter (MMAD). Rank order correlating jobs to particle size showed high overall consistency (Spearman $r = 0.84$) but moderate correlation (Pearson $r = 0.43$). The investigators concluded that by considering more relevant aspects of exposure such as particle size distribution, chemical form, and solubility could potentially improve exposure assessments (Virji *et al.,* 2011, Document ID 0465).

To summarize, particle size influences deposition of beryllium particles in the lung, thereby influencing toxicity. Studies by Stefaniak *et al.* (2008) demonstrated that the majority of particles generated by beryllium processing operations were in the respirable range (less than 1–2 μm) (Document ID 1397). However, studies by Virji *et al.* (2011) (Document ID 0465), Cohen *et al.* (1983) (Document ID 0540) and Hoover *et al.* (1990) (Document ID 1314) showed that some operations could generate particle sizes ranging from 3 to 16 μm.

c. Particle Surface Area

Particle surface area has been postulated as an important metric for beryllium exposure. Several studies have demonstrated a relationship between the inflammatory and tumorigenic potential of ultrafine particles and their increased surface area (Driscoll, 1996, Document ID 1539; Miller, 1995 (0523); Oberdorster *et al.,* 1996 (1434)). While the exact mechanism explaining how particle surface area influences its biological activity is not known, a greater particle surface area has been shown to increase inflammation, cytokine production, pro- and anti-oxidant defenses and apoptosis, which has been shown to increase the tumorigenic potential of poorly-soluble particles (Elder *et al.,* 2005, Document ID 1537; Carter *et al.,* 2006 (1556); Refsnes *et al.,* 2006 (1428)).

Finch *et al.* (1988) found that beryllium oxide calcined at 500°C had 3.3 times greater specific surface area (SSA) than beryllium oxide calcined at 1000 °C, although there was no difference in size or structure of the particles as a function of calcining temperature (Document ID 1317). The beryllium-metal aerosol (airborne beryllium particles), although similar to the beryllium oxide aerosols in aerodynamic size, had an SSA about 30 percent that of the beryllium oxide calcined at 1000 °C. As discussed above, a later study by Delic (1992) found calcining temperatures had an effect on SSA as well as particle size (Document ID 1547).

Several studies have investigated the lung toxicity of beryllium oxide calcined at different temperatures and generally have found that those calcined at lower temperatures have greater toxicity and effect than materials calcined at higher temperatures. This may be because beryllium oxide fired at the lower temperature has a loosely formed crystalline structure with greater specific surface area than the fused crystal structure of beryllium oxide fired at the higher temperature. For example, beryllium oxide calcined at 500 °C has been found to have stronger pathogenic effects than material calcined at 1,000 °C, as shown in several of the beagle dog, rat, mouse and guinea pig studies discussed in the section on CBD pathogenesis that follows (Finch *et al.,* 1988, Document ID 1495; Polák *et al.,* 1968 (1431); Haley *et al.,* 1989 (1366); Haley *et al.,* 1992 (1365); Hall *et al.,* 1950 (1494)). Finch *et al.* have also observed higher toxicity of beryllium oxide calcined at 500 °C, an observation they attribute to the greater surface area of beryllium particles calcined at the lower temperature (Finch *et al.,* 1988, Document ID 1495). These authors found that the *in vitro* cytotoxicity to Chinese hamster ovary (CHO) cells and cultured lung epithelial cells of 500 °C beryllium oxide was greater than that of 1,000 °C beryllium oxide, which in turn was greater than that of beryllium metal. However, when toxicity was expressed in terms of particle surface area, the cytotoxicity of all three forms was similar. Similar results were observed in a study comparing the cytotoxicity of beryllium metal particles of various sizes to cultured rat alveolar macrophages, although specific surface

area did not entirely predict cytotoxicity (Finch *et al.,* 1991, Document ID 1535).

Stefaniak *et al.* (2003) investigated the particle structure and surface area of beryllium metal, beryllium oxide, and copper-beryllium alloy particles (Document ID 1347). Each of these samples was separated by aerodynamic size, and their chemical compositions and structures were determined with x-ray diffraction and transmission electron microscopy, respectively. In summary, beryllium-metal powder varied remarkably from beryllium oxide powder and alloy particles. The metal powder consisted of compact particles, in which SSA decreases with increasing surface diameter. In contrast, the alloys and oxides consisted of small primary particles in clusters, in which the SSA remains fairly constant with particle size. SSA for the metal powders varied based on production and manufacturing process with variations among samples as high as a factor of 37. Stefaniak *et al.* (2003) found lesser variation in SSA for the alloys or oxides (Document ID 1347). This is consistent with data from other studies summarized above showing that process may affect particle size and surface area. Particle size and/or surface area may explain differences in the rate of beryllium sensitization and CBD observed in some epidemiological studies. However, these properties have not been consistently characterized in most studies.

B. Kinetics and Metabolism of Beryllium

Beryllium enters the body by inhalation, absorption through the skin, or ingestion. For occupational exposure, the airways and the skin are the primary routes of uptake.

1. Exposure Via the Respiratory System

The respiratory tract, especially the lung, is the primary target of inhalation exposure in workers. Disposition (deposition and clearance) of the particle or droplet along the respiratory tract influences the biological response to the toxicant (Schlesinger *et al.,* 1997, Document ID 1290). Inhaled beryllium particles are deposited along the respiratory tract in a size dependent manner as described by the International Commission for radiological Protection (ICRP) model (Figure 1). In general, particles larger than 10 μm tend to deposit in the upper respiratory tract or nasal region and do not appreciably penetrate lower in the tracheobronchial or pulmonary regions (Figure 1). Particles less than 10 μm increasingly penetrate and deposit in the tracheobronchial and pulmonary regions with peak deposition in the pulmonary region occurring below 5 μm in particle diameter. The CBD pathology of concern is found in the pulmonary region. For particles below 1 μm in particle diameter, regional deposition changes dramatically. Ultrafine particles (generally considered to be 100 nm or lower) have a higher rate of deposition along the entire respiratory system (ICRP model, 1994). However, due to the hygroscopic nature of soluble particles, deposition patterns may be slightly different with an enhanced preference for the tracheobronchial or bronchial region of the lung. Nonetheless, soluble particles are still capable of depositing in the pulmonary region (Schlesinger *et al.,* 1997, Document ID 1290).

Particles depositing in the lung and along the entire respiratory tract may encounter immunologic cells or may move into the vascular system where they are free to leave the lung and can contribute to systemic beryllium concentrations.

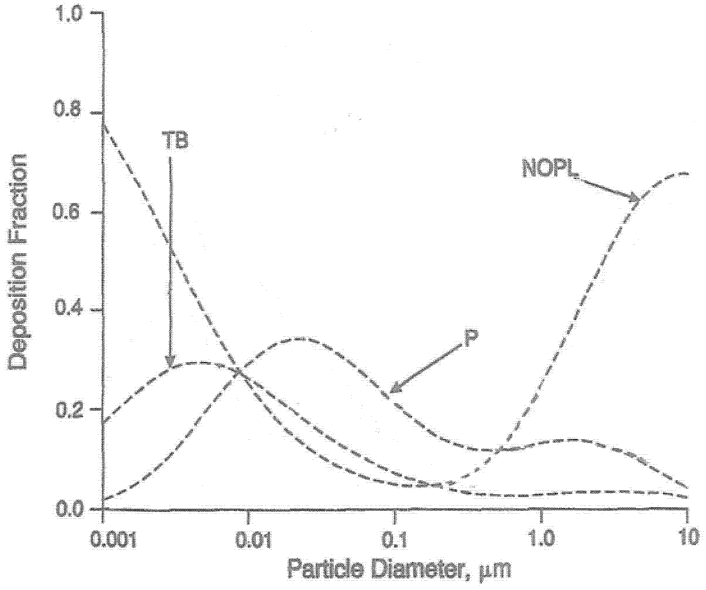


Figure 1, ICRP model: Regional Deposition Model in Humans (Adapted from Yeh et al., 1996, Document ID 0386))

NOPL - naso-oral-pharynolaryngeal region
TB – tracheobronchial region
P – pulmonary region

Beryllium is removed from the respiratory tract by various clearance mechanisms. Soluble beryllium is removed from the respiratory tract via absorption or chemical clearance (Schlesinger, 1997, Document ID 1290). Sparingly soluble or poorly soluble beryllium is removed via mechanical mechanisms and may remain in the

lungs for many years after exposure, as has been observed in workers (Schepers, 1962, Document ID 1414). Clearance mechanisms for sparingly soluble or poorly soluble beryllium particles include: In the nasal passage, sneezing, mucociliary transport to the throat, or dissolution; in the tracheobronchial region, mucociliary transport, coughing, phagocytosis, or dissolution; in the pulmonary or alveolar region, phagocytosis, movement through the interstitium (translocation), or dissolution (Schlesinger, 1997, Document ID 1290). Mechanical clearance mechanisms may occur slowly in humans, which is consistent with some animal and human studies. For example, subjects in the Beryllium Case Registry (BCR), which identifies and tracks cases of acute and chronic beryllium diseases, had elevated concentrations of beryllium in lung tissue (*e.g.,* 3.1 μg/g of dried lung tissue and 8.5 μg/g in a mediastinal node) more than 20 years after termination of short-term (generally between 2 and 5 years) occupational exposure to beryllium (Sprince *et al.,* 1976, Document ID 1405).

Due to physiological differences, clearance rates can vary between humans and animal species (Schlesinger, 1997, Document ID 1290; Miller, 2000 (1831)). However, clearance rates are also dependent upon the solubility, dose, and size of the inhaled beryllium compound. As reviewed in a WHO Report (2001) (Document ID 1282), more soluble beryllium compounds generally tend to be cleared from the respiratory system and absorbed into the bloodstream more rapidly than less soluble compounds (Van Cleave and Kaylor, 1955, Document ID 1287; Hart *et al.,* 1980 (1493); Finch *et al.,* 1990 (1318)). Animal inhalation or intratracheal instillation studies administering soluble beryllium salts demonstrated significant absorption of approximately 20 percent of the initial lung burden with rapid dissolution of soluble compounds from the lung (Delic, 1992, Document ID 1547). Absorption of poorly soluble compounds such as beryllium oxide administered via inhalation or intratracheal instillation was slower and less significant (Delic, 1992, Document ID 1547). Additional animal studies have demonstrated that clearance of poorly soluble beryllium compounds was biphasic: A more rapid initial mucociliary transport phase of particles from the tracheobronchial tree to the gastrointestinal tract, followed by a slower phase via translocation to tracheobronchial lymph nodes, alveolar macrophages uptake, and beryllium particles dissolution (Camner *et al.,* 1977, Document ID 1558; Sanders *et al.,* 1978 (1485); Delic, 1992 (1547); WHO, 2001 (1282)). Confirmatory studies in rats have shown the half-time for the rapid phase to be between 1 and 60 days, while the slow phase ranged from 0.6 to 2.3 years. Studies have also shown that this process was influenced by the solubility of the beryllium compounds: Weeks/months for soluble compounds, months/years for poorly soluble compounds (Reeves and Vorwald, 1967; Reeves *et al.,* 1967; Rhoads and Sanders, 1985). Studies in guinea pigs and rats indicate that 40–50 percent of the inhaled soluble beryllium salts are retained in the respiratory tract. Similar data could not be found for the poorly soluble beryllium compounds or metal administered by this exposure route. (WHO, 2001, Document ID 1282; ATSDR, 2002 (1371).)

Evidence from animal studies suggests that greater amounts of beryllium deposited in the lung may result in slower clearance times. Acute inhalation studies performed in rats and mice using a single dose of inhaled aerosolized beryllium metal showed that exposure to beryllium metal can slow particle clearance and induce lung damage in rats and mice (Finch *et al.,* 1998, Document ID 1317; Haley *et al.,* 1990 (1314)). In another study, Finch *et al.* (1994) exposed male F344/N rats to beryllium metal at concentrations resulting in beryllium lung burdens of 1.8, 10, and 100 μg. These exposure levels resulted in an estimated clearance half-life ranging from 250 to 380 days for the three concentrations. For mice (Finch *et al.,* 1998, Document ID 1317), lung clearance half-lives were 91–150 days (for 1.7– and 2.6–μg lung burden groups) or 360–400 days (for 12- and 34–μg lung burden groups). While the lower exposure groups were quite different for rats and mice, the highest groups were similar in clearance half-lives for both species.

Beryllium absorbed from the respiratory system was shown to distribute primarily to the tracheobronchial lymph nodes via the lymph system, bloodstream, and skeleton (Stokinger *et al.,* 1953, Document ID 1277; Clary *et al.,* 1975 (1320); Sanders *et al.,* 1975 (1486); Finch *et al.,* 1990 (1318)). Studies in rats demonstrated accumulation of beryllium chloride in the skeletal system following intraperitoneal injection (Crowley *et al.,* 1949, Document ID 1551; Scott *et al.,* 1950 (1413)) and accumulation of beryllium phosphate and beryllium sulfate in both non-parenchymal and parenchymal cells of the liver after intravenous administration in rats (Skilleter and Price, 1978, Document ID 1408). Studies have also demonstrated intracellular accumulation of beryllium oxide in bone marrow throughout the skeletal system after intravenous administration to rabbits (Fodor, 1977, Document ID 1532; WHO, 2001 (1282)). Trace amounts of beryllium have also been shown to be distributed throughout the body (WHO, 2001, Document ID 1282).

Systemic distribution of the more soluble compounds was shown to be greater than that of the poorly soluble compounds (Stokinger *et al.,* 1953, Document ID 1277). Distribution has also been shown to be dose dependent in research using intravenous administration of beryllium in rats; small doses were preferentially taken up in the skeleton, while higher doses were initially distributed preferentially to the liver.

Beryllium was later mobilized from the liver and transferred to the skeleton (IARC, 1993, Document ID 1342). A half-life of 450 days has been estimated for beryllium in the human skeleton (ICRP, 1960, Document ID 0248). This indicates the skeleton may serve as a repository for beryllium that may later be reabsorbed by the circulatory system, making beryllium available to the immunological system (WHO, 2001, Document ID 1282). In a recent review of the information, the American Conference of Governmental Industrial Hygienists (ACGIH, 2010) was not able to confirm the association between occupational inhalation and urinary excretion (Document ID 1662, p. 4). However, IARC (2012) noted that an accidental exposure of 25 people to beryllium dust reported in a study by Zorn *et al.* (1986) resulted in a mean serum concentration of 3.5 μg/L one day after the exposure, which decreased to 2.4 μg/L by day six. The IARC report concluded that beryllium from beryllium metal was biologically available for systemic distribution from the lung (IARC, 2012, Document ID 0650).

Based on these studies, OSHA finds that the respiratory tract is a primary pathway for beryllium exposure. While particle size and surface area may contribute to the toxicity of beryllium, there is not sufficient evidence for OSHA to regulate based on size and surface area. However, the Agency finds that both soluble and poorly soluble forms of beryllium and beryllium compounds can contribute to exposure via the respiratory system and therefore can be causative agents of sensitization and CBD.

2. Dermal Exposure

Beryllium compounds have been shown to cause skin irritation and sensitization in humans and certain animal models (Van Ordstrand *et al.,* 1945, Document ID 1383; de Nardi *et al.,* 1953 (1545); Nishimura, 1966 (1435); Epstein, 1991 (0526); Belman, 1969 (1562); Tinkle *et al.,* 2003 (1483); Delic, 1992 (1547)). The Agency for Toxic Substances and Disease Registry (ATSDR) estimated that less than 0.1 percent of beryllium compounds are absorbed through the skin (ATSDR, 2002, Document ID 1371). However, even minute contact and absorption across the skin may directly elicit an immunological response resulting in sensitization (Deubner *et al.,* 2001, Document ID 1543; Toledo *et al.,* 2011 (0522)). Studies by Tinkle *et al.* (2003) showed that penetration of beryllium oxide particles was possible *ex vivo* for human intact skin at particle sizes of less than or equal to 1μm in diameter, as confirmed by scanning electron microscopy (Document ID 1483). Using confocal microscopy, Tinkle *et al.* demonstrated that surrogate fluorescent particles up to 1 μm in size could penetrate the mouse epidermis and dermis layers in a model designed to mimic the flexing and stretching of human skin in motion. Other poorly soluble particles, such as titanium dioxide, have been shown to penetrate normal human skin (Tan *et al.,* 1996, Document ID 1391) suggesting the flexing and stretching motion as a plausible mechanism for dermal penetration of beryllium as well. As earlier summarized, poorly soluble forms of beryllium can be solubilized in biological fluids (*e.g.,* sweat) making them available for absorption through intact skin (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539)).

Although its precise role remains to be elucidated, there is evidence that dermal exposure can contribute to beryllium sensitization. As early as the 1940s it was recognized that dermatitis experienced by workers in primary beryllium production facilities was linked to exposures to the soluble beryllium salts. Except in cases of wound contamination, dermatitis was rare in workers whose exposures were restricted to exposure to poorly soluble beryllium-containing particles (Van Ordstrand *et al.,* 1945, Document ID 1383). Further investigation by McCord in 1951 (Document ID 1448) indicated that direct skin contact with soluble beryllium compounds, but not beryllium hydroxide or beryllium metal, caused dermal lesions (reddened, elevated, or fluid-filled lesions on exposed body surfaces) in susceptible persons. Curtis, in 1951, demonstrated skin sensitization to beryllium with patch testing using soluble and poorly soluble forms of beryllium in beryllium-naïve subjects. These subjects later developed granulomatous skin lesions with the classical delayed-type contact dermatitis following repeat challenge (Curtis, 1951, Document ID 1273). These lesions appeared after a latent period of 1–2 weeks, suggesting a delayed allergic reaction. The dermal reaction occurred more rapidly and in response to smaller amounts of beryllium in those individuals previously sensitized (Van Ordstrand *et al.,* 1945, Document ID 1383). Contamination of cuts and scrapes with beryllium can result in the beryllium becoming embedded within the skin causing an ulcerating granuloma to develop in the skin (Epstein, 1991, Document ID 0526). Soluble and poorly soluble beryllium-compounds that penetrate the skin as a result of abrasions or cuts have been shown to result in chronic ulcerations and skin granulomas (Van Ordstrand *et al.,* 1945, Document ID 1383; Lederer and Savage, 1954 (1467)). Beryllium absorption through bruises and cuts has been demonstrated as well (Rossman *et al.,* 1991, Document ID 1332).

In a study by Ivannikov *et al.* (1982) (as cited in Deubner *et al.,* 2001, Document ID 0023), beryllium chloride was applied directly to three different types of wounded skin: abrasions (superficial skin trauma), cuts (skin and superficial muscle trauma), and penetration wounds (deep muscle trauma). According to Deubner *et al.* (2001) the percentage of the applied dose systemically absorbed during a 24-hour exposure was significant, ranging from 7.8 percent to 11.4 percent for abrasions, from 18.3 percent to 22.9 percent for cuts, and from 34 percent to 38.8 percent for penetration wounds (Deubner *et al.,* 2001, Document ID 0023).

A study by Deubner *et al.* (2001) concluded that exposure across damaged skin can contribute as much systemic loading of beryllium as inhalation (Deubner *et al.,* 2001, Document ID 1543). Deubner *et al.* (2001) estimated dermal loading (amount of particles penetrating into the skin) in workers as compared to inhalation exposure. Deubner's calculations assumed a dermal loading rate for beryllium on skin of 0.43 μg/cm^2, based on the studies of loading on skin after workers cleaned up (Sanderson *et al..,* 1999, Document ID 0474), multiplied by a factor of 10 to approximate the workplace concentrations and the very low absorption rate of beryllium into skin of 0.001 percent (taken from EPA estimates). As cited by Deubner *et al.* (2001), the EPA noted that these calculations did not take into account absorption of soluble beryllium salts that might occur across nasal mucus membranes, which may result from contact between contaminated skin and the nose (Deubner *et al.,* 2001, Document ID 1543).

A study conducted by Day *et al.* (2007) evaluated the effectiveness of a dermal protection program implemented in a beryllium alloy facility in 2002 (Document ID 1548). The investigators evaluated levels of beryllium in air, on workplace surfaces, on cotton gloves worn over nitrile gloves, and on the necks and faces of workers over a six day period. The investigators found a strong correlation between air concentrations determined from sampling data and work surface contamination at this facility. The investigators also found measurable levels of beryllium on the skin of workers as a result of work processes even from workplace areas promoted as ''visually clean'' by the company housekeeping policy. Importantly, the investigators found that the beryllium contamination could be transferred from body region to body region (*e.g.,* hand to face, neck to face) demonstrating the importance of dermal protection measures since sensitization can occur via dermal exposure as well as respiratory exposure. The investigators demonstrated multiple pathways of exposure which could lead to sensitization, increasing risk for developing CBD (Day *et al.,* 2007, Document ID 1548).

The same group of investigators extended their work on investigating multiple exposure pathways contributing to sensitization and CBD (Armstrong *et al.,* 2014, Document ID 0502). The investigators evaluated four different beryllium manufacturing and processing facilities to assess the contribution of various exposure pathways on worker exposure. Airborne, work surface and cotton glove beryllium concentrations were evaluated. The investigators found strong correlations between air and surface concentrations; glove and surface concentrations; and air and glove concentrations at this facility. This work supports findings from Day *et al.* (2007) (Document ID 1548) demonstrating the importance of airborne beryllium concentrations to surface contamination and dermal exposure even at exposures below the

preceding OSHA PEL (Armstrong *et al.,* 2014, Document ID 0502).

OSHA received comments regarding the potential for dermal penetration of poorly soluble particles. Materion contended there is no supporting evidence to suggest that insoluble or poorly soluble particles penetrate skin and stated:

> . . . we were aware that, a hypothesis has been put forth which suggests that being sensitized to beryllium either through a skin wound or via penetration of small beryllium particles through intact skin could result in sensitization to beryllium which upon receiving a subsequent inhalation dose of airborne beryllium could result in CBD. However, there are no studies that skin absorption of insoluble beryllium results in a systemic effect. The study by Curtis, the only human study looking for evidence of a beryllium sensitization reaction occurring through intact human skin, found no sensitization reaction using insoluble forms of beryllium. (Document ID 1661, p. 12).

OSHA disagrees with the assertion that no studies are available indicating skin absorption of poorly soluble (insoluble) beryllium. In addition to the study cited by Materion (Curtis, 1951, Document ID 1273), OSHA reviewed numerous studies on the effects of beryllium solubility and dermal penetration (see section V. B. 2) including the Tinkle *et al.* (2003) (Document ID 1483) study which demonstrated the potential for poorly soluble beryllium particles to penetration skin using an ex vivo human skin model. While OSHA believes that these studies demonstrate poorly soluble beryllium can in fact penetrate intact skin, penetration through intact skin is not the only means for a person to become sensitized through skin contact with poorly soluble beryllium. During the informal hearing proceedings, NIOSH was asked about the role of poorly soluble beryllium in sensitizing workers to beryllium. Aleks Stefaniak, Ph.D., NIOSH, stated that ''intact skin naturally has a barrier that prevents moisture from seeping out of the body and things from getting into the body. Very few people actually have fully intact skin, especially in an industrial environment. So the skin barrier is often compromised, which would make penetration of particles much easier.'' (Document ID 1755, Tr. 36).

As summarized above, poorly soluble beryllium particles have been shown to solubilize in biological fluids (*e.g.,* sweat) releasing beryllium ions and making them available for absorption through intact skin (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.* 2014 (0517); Duling *et al.,* 2012 (0539)). Epidemiological studies evaluating the effectiveness of PPE in facilities working with beryllium (with special emphasis on skin protection) have demonstrated a reduced rate of beryllium sensitization after implementation of this type of control (Day *et al.,* 2007, Document ID 1548; Armstrong *et al.,* 2014 (0502)). Dr. Stefaniak confirmed these findings:

> [T]he particles can actually dissolve when they're in contact with liquids on the skin, like sweat. So we've actually done a series of studies, using a simulant of sweat, but it had characteristics that very closely matched human sweat. We see in those studies that, in fact, beryllium particles, beryllium oxide, beryllium metal, beryllium alloys, all these sort of what we call insoluble forms actually do in fact dissolve very readily in analog of human sweat. And once beryllium is in an ionic form on the skin, it's actually very easy for it to cross the skin barrier. And that's been shown many, many times in studies that beryllium ions can cross the skin and induce sensitization. (Document ID 1755, Tr. 36–37).

Based on information from various studies demonstrating that poorly soluble particles have the potential to penetrate skin, that skin as a barrier is rarely intact (especially in industrial settings), and that beryllium particles can readily dissolve in sweat and other biological fluids, OSHA finds that dermal exposure to poorly soluble beryllium can cause sensitization (Rossman, *et al.,* 1991, Document ID 1332; Deubner *et al.,* 2001 (1542); Tinkle *et al.,* 2003 (1483); Sutton *et al.,* 2003 (1393); Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539); Document ID 1755, Tr. 36–37).

3. Oral and Gastrointestinal Exposure

According to the WHO Report (2001), gastrointestinal absorption of beryllium can occur by both the inhalation and oral routes of exposure (Document ID 1282). In the case of inhalation, a portion of the inhaled material is transported to the gastrointestinal tract by the mucociliary escalator or by the swallowing of the poorly soluble material deposited in the upper respiratory tract (Schlesinger, 1997, Document ID 1290). Animal studies have shown oral administration of beryllium compounds to result in very limited absorption and storage (as reviewed by U.S. EPA, 1998, Document ID 0661). Oral studies utilizing radio-labeled beryllium chloride in rats, mice, dogs, and monkeys, found the majority of the beryllium was unabsorbed by the gastrointestinal tract and was eliminated in the feces. In most studies, less than 1 percent of the administered radioactivity was absorbed into the bloodstream and subsequently excreted in the urine (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); LeFevre and Joel, 1986 (1464)). Research using soluble beryllium sulfate has shown that as the compound passes into the intestine, which has a higher pH than the stomach (approximate pH of 6 to 8 for the intestine, pH of 1 or 2 for the stomach), the beryllium is precipitated as the poorly soluble phosphate and is not absorbed (Reeves, 1965, Document ID 1430; WHO, 2001 (1282)).

Further studies suggested that beryllium absorbed into the bloodstream is primarily excreted via urine (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); Scott *et al.,* 1950 (1413); Stiefel *et al.,* 1980 (1288)). Unabsorbed beryllium is primarily excreted via the fecal route (Finch *et al.,* 1990, Document ID 1318; Hart *et al.,* 1980 (1493)). Parenteral administration in a variety of animal species demonstrated that beryllium was eliminated at much higher percentages in the urine than in the feces (Crowley *et al.,* 1949, Document ID 1551; Furchner *et al.,* 1973 (1523); Scott *et al.,* 1950 (1413)). A study using percutaneous administration of soluble beryllium nitrate in rats demonstrated that more than 90 percent of the beryllium in the bloodstream was eliminated via urine (WHO, 2001, Document ID 1282). Greater than 99 percent of ingested beryllium chloride was excreted in the feces (Mullen *et al.,* 1972, Document ID 1442). A study of mice, rats, monkeys, and dogs given intravenously dosed with beryllium chloride determined elimination half-times to be between 890 to 1,770 days (2.4 to 4.8 years) (Furchner *et al.,* 1973, Document ID 1523). In a comparison study, baboons and rats were instilled intratracheally with beryllium metal. Mean daily excretion rates were calculated as 4.6×10^{-5} percent of the dose administered in baboons and 3.1×10^{-5} percent in rats (Andre *et al.,* 1987, Document ID 0351).

In summary, animal studies evaluating the absorption, distribution and excretion of beryllium compounds found that, in general, poorly soluble beryllium compounds were not readily absorbed in the gastrointestinal tract and was mostly excreted via feces (Hart *et al.,* 1980, Document ID 1493; Finch *et al.,* 1990 (1318); Mullen *et al.,* 1972 (1442)). Soluble beryllium compounds orally administered were partially cleared via urine; however, some soluble forms are precipitated in the gastrointestinal tract due to different pH values between the intestine and the stomach (Reeves, 1965, Document ID 1430). Intravenous administration of

poorly soluble beryllium compounds were distributed systemically through the lymphatics and stored in the skeleton for potential later release (Furchner *et al.,* 1973, Document ID 1523). Therefore, while intravenous administration can lead to uptake, OSHA does not consider oral and gastrointestinal exposure to be a major route for the uptake of beryllium because poorly soluble beryllium is not readily absorbed in the gastrointestinal tract.

4. Metabolism

Beryllium and its compounds may not be metabolized or biotransformed, but soluble beryllium salts may be converted to less soluble forms in the lung (Reeves and Vorwald, 1967, Document ID 1309). As stated earlier, solubility is an important factor for persistence of beryllium in the lung. Poorly soluble phagocytized beryllium particles can be dissolved into an ionic form by an acidic cellular environment and by myeloperoxidases or macrophage phagolysomal fluids (Leonard and Lauwerys, 1987, Document ID 1293; Lansdown, 1995 (1469); WHO, 2001 (1282); Stefaniak *et al.,* 2006 (1398)). The positive charge of the beryllium ion could potentially make it more biologically reactive because it may allow the beryllium to bind to a peptide or protein and be presented to the T cell receptor or antigen-presenting cell (Fontenot, 2000, Document ID 1531).

5. Conclusion For Particle Characterization and Kinetics and Metabolism of Beryllium

The forms and concentrations of beryllium across the workplace vary substantially based upon location, process, production and work task. Many factors may influence the potency of beryllium including concentration, composition, structure, size, solubility and surface area of the particle.

Studies have demonstrated that beryllium sensitization can occur via the skin or inhalation from soluble or poorly soluble beryllium particles. Beryllium must be presented to a cell in a soluble form for activation of the immune system (NAS, 2008, Document ID 1355), and this will be discussed in more detail in the section to follow. Poorly soluble beryllium can be solubilized via intracellular fluid, lung fluid and sweat to release beryllium ions (Sutton *et al.,* 2003, Document ID 1393; Stefaniak *et al.,* 2011(0537) and 2014(0517)). For beryllium to persist in the lung it needs to be poorly soluble. However, soluble beryllium has been shown to precipitate in the lung to form poorly soluble beryllium (Reeves and Vorwald, 1967, Document ID 1309).

Some animal and epidemiological studies suggest that the form of beryllium may affect the rate of development of BeS and CBD. Beryllium in an inhalable form (either as soluble or poorly soluble particles or mist) can deposit in the respiratory tract and interact with immune cells located along the entire respiratory tract (Scheslinger, 1997, Document ID 1290). Interaction and presentation of beryllium (either in ionic or particulate form) is discussed further in Section V.D.1.

C. Acute Beryllium Diseases

Acute beryllium disease (ABD) is a relatively rapid onset inflammatory reaction resulting from breathing high airborne concentrations of beryllium. It was first reported in workers extracting beryllium oxide (Van Ordstrand *et al.,* 1943, Document ID 1383) and later reported by Eisenbud (1948) and Aub (1949) (as cited in Document ID 1662, p. 2). Since the Atomic Energy Commission's adoption of a maximum permissible peak occupational exposure limit of 25 μg/m^3 for beryllium beginning in 1949, cases of ABD have been much rarer. According to the World Health Organization (2001), ABD is generally associated with exposure to beryllium levels at or above 100 μg/m^3 and may be fatal in 10 percent of cases (Document ID 1282). However, cases of ABD have been reported with beryllium exposures below 100 μg/m^3 (Cummings *et al.,* 2009, Document ID 1550). The Cummings *et al.* (2009) study examined two cases of workers exposed to soluble and poorly soluble beryllium below 100 μg/m^3 using data obtained from company records. Cummings *et al.* (2009) also examined the possibility that an immune-mediated mechanism may exist for ABD as well as CBD and that ABD and CBD are on a pathological continuum since some patients would later develop CBD after recovering from ABD (ACCP, 1965, Document ID 1286; Hall, 1950 (1494); Cummings *et al.,* 2009 (1550)).

ABD involves an inflammatory or immune-mediated reaction that may include the entire respiratory tract, involving the nasal passages, pharynx, bronchial airways and alveoli. Other tissues including skin and conjunctivae may be affected as well. The clinical features of ABD include a nonproductive cough, chest pain, cyanosis, shortness of breath, low-grade fever and a sharp drop in functional parameters of the lungs. Pathological features of ABD include edematous distension, round cell infiltration of the septa, proteinaceous materials, and desquamated alveolar cells in the lung. Monocytes, lymphocytes and plasma cells within the alveoli are also characteristic of the acute disease process (Freiman and Hardy, 1970, Document ID 1527).

Two types of acute beryllium disease have been characterized in the literature: A rapid and severe course of acute fulminating pneumonitis generally developing within 48 to 72 hours of a massive exposure, and a second form that takes several days to develop from exposure to lower concentrations of beryllium (still above the levels set by regulatory and guidance agencies) (Hall, 1950, Document ID 1494; DeNardi *et al.,* 1953 (1545); Newman and Kreiss, 1992 (1440)). Evidence of a dose-response relationship to the concentration of beryllium is limited (Eisenbud *et al.,* 1948, Document ID 0490; Stokinger, 1950 (1484); Sterner and Eisenbud, 1951 (1396)). Recovery from either type of ABD is generally complete after a period of several weeks or months (DeNardi *et al.,* 1953, Document ID 1545). However, deaths have been reported in more severe cases (Freiman and Hardy, 1970, Document ID 1527). According to the BCR, in the United States, approximately 17 percent of ABD patients developed CBD (BCR, 2010). The majority of ABD cases occurred between 1932 and 1970 (Eisenbud, 1982, Document ID 1254; Middleton, 1998 (1445)). ABD is extremely rare in the workplace today due to more stringent exposure controls implemented following occupational and environmental standards set in 1970–1971 (ACGIH, 1971, Document ID 0543; ANSI, 1970 (1303); OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)).

Materion submitted post-hearing comments regarding ABD (Document ID 1662, p. 2; Attachment A, p. 1). Materion contended that only soluble forms of beryllium have been demonstrated to produce ABD at exposures above 100 μg/m^3 because cases of ABD were only found in workers exposed to beryllium during beryllium extraction processes which always contain soluble beryllium (Document ID 1662, pp. 2, 3). Citing communications between Marc Kolanz (Materion) and Dr. Eisenbud, Materion noted that when Mr. Kolanz asked Dr. Eisenbud if he ever ''observed an acute reaction to beryllium that did not involve the beryllium extraction process and exposure to soluble salts of beryllium,'' Dr. Eisenbud responded that ''he did not know of a case that was not either directly associated with

exposure to soluble compounds or where the work task or operation would have been free from exposure to soluble beryllium compounds from adjacent operations.'' (Document ID 1662, p. 3). OSHA acknowledges that workers with ABD may have been exposed to a combination of soluble and poorly soluble beryllium. This alone, however, cannot completely exclude poorly soluble beryllium as a causative or contributing agent of ABD. The WHO (2001) has concluded that both ABD and CBD results from exposure to both soluble and insoluble forms of beryllium. In addition, the European Commission has classified poorly soluble beryllium and beryllium oxide as acute toxicity categories 2 and 3 (Document ID 1669, p. 2).

Additional comments from Materion regarding ABD criticized the study by Cummings *et al.* (2009), stating that it ''incompletely explained the source of the workers exposures, which resulted in the use of a misleading statement that, 'None of the measured air samples exceeded 100 μg/m³ and most were less than 10 μg/m³.' '' (Document ID 1662, p. 3). Materion argues that the Cummings *et al.* study is not valid because workers in that study ''had been involved with high exposures to soluble beryllium salts caused by upsets during the chemical extraction of beryllium.'' (Document ID 1662, pp. 3–4). In response, NIOSH written testimony explained that the measurements in the study ''were collected in areas most likely to be sources of high beryllium exposures in processes, but were not personal breathing zone measurements in the usual sense.'' (Document ID 1725, p. 3). ''Cummings *et al.* (2009) made every effort to overestimate (rather than underestimate) exposure,'' including ''select[ing] the highest time weighted average (TWA) value from the work areas or activities associated with a worker's job and tenure'' and not adjusting for ''potential protective effects of respirators, which were reportedly used for some tasks and during workplace events potentially associated with uncontrolled higher exposures.'' Even so, ''the available TWA data did not exceed 100 μg/m³ even on days with evacuations.'' (Document ID 1725, p. 3). Furthermore, OSHA notes that, the discussion in Cummings *et al.* (2009) stated, ''we cannot rule out the possibility of unusually elevated airborne concentrations of beryllium that went unmeasured.'' (Document ID 1550, p. 5).

In response to Materion's contention that OSHA should eliminate the section on ABD because this disease is no longer a concern today (Document ID 1661, p. 2), OSHA notes that the discussion on ABD is included for thoroughness in review of the health effects caused by exposure to beryllium. As indicated above, the Agency acknowledges that ABD is extremely rare, but not non-existent, in workplaces today due to the more stringent exposure controls implemented since OSHA's inception (OSHA, 1971, see 39 FR 23513).

D. Beryllium Sensitization and Chronic Beryllium Disease

This section provides an overview of the immunology and pathogenesis of BeS and CBD, with particular attention to the role of skin sensitization, particle size, beryllium compound solubility, and genetic variability in individuals' susceptibility to beryllium sensitization and CBD.

Chronic beryllium disease (CBD), formerly known as ''berylliosis'' or ''chronic berylliosis,'' is a granulomatous disorder primarily affecting the lungs. CBD was first described in the literature by Hardy and Tabershaw (1946) as a chronic granulomatous pneumonitis (Document ID 1516). It was proposed as early as 1951 that CBD could be a chronic disease resulting from sensitization to beryllium (Sterner and Eisenbud, 1951, Document ID 1396; Curtis, 1959 (1273); Nishimura, 1966 (1435)). However, for a time, there remained some controversy as to whether CBD was a delayed-onset hypersensitivity disease or a toxicant-induced disease (NAS, 2008, Document ID 1355). Wide acceptance of CBD as a hypersensitivity lung disease did not occur until bronchoscopy studies and bronchoalveolar lavage (BAL) studies were performed demonstrating that BAL cells from CBD patients responded to beryllium challenge (Epstein *et al.,* 1982, Document ID 0436; Rossman *et al.,* 1988 (0476); Saltini *et al.,* 1989 (1351)).

CBD shares many clinical and histopathological features with pulmonary sarcoidosis, a granulomatous lung disease of unknown etiology. These similarities include such debilitating effects as airway obstruction, diminishment of physical capacity associated with reduced lung function, possible depression associated with decreased physical capacity, and decreased life expectancy. Without appropriate information, CBD may be difficult to distinguish from sarcoidosis. It is estimated that up to 6 percent of all patients diagnosed with sarcoidosis may actually have CBD (Fireman *et al.,* 2003, Document ID 1533; Rossman and Kreider, 2003 (1423)). Among patients diagnosed with sarcoidosis in which beryllium exposure can be confirmed, as many as 40 percent may actually have CBD (Muller-Quernheim *et al.,* 2005, Document ID 1262; Cherry *et al.,* 2015 (0463)).

Clinical signs and symptoms of CBD may include, but are not limited to, a simple cough, shortness of breath or dypsnea, fever, weight loss or anorexia, skin lesions, clubbing of fingers, cyanosis, night sweats, cor pulmonale, tachycardia, edema, chest pain and arthralgia. Changes or loss of pulmonary function also occur with CBD such as decrease in vital capacity, reduced diffusing capacity, and restrictive breathing patterns. The signs and symptoms of CBD constitute a continuum of symptoms that are progressive in nature with no clear demarcation between any stages in the disease (Pappas and Newman, 1993, Document ID 1433; Rossman, 1996 (1283); NAS, 2008 (1355)). These symptoms are consistent with the CBD symptoms described during the public hearing by Dr. Kristin Cummings of NIOSH and Dr. Lisa Maier of National Jewish Health (Document ID 1755, Tr. 70–71; 1756, Tr. 105–107).

Besides these listed symptoms from CBD patients, there have been reported cases of CBD that remained asymptomatic (Pappas and Newman, 1993, Document ID 1433; Muller-Querheim, 2005 (1262); NAS, 2008 (1355); NIOSH, 2011 (0544)). Asymptomatic CBD refers to those patients that have physiological changes upon clinical evaluation yet exhibit no outward signs or symptoms (also referred to as subclinical CBD).

Unlike ABD, CBD can result from inhalation exposure to beryllium at levels below the preceding OSHA PEL, can take months to years after initial beryllium exposure before signs and symptoms of CBD occur (Newman 1996, Document ID 1283, 2005 (1437) and 2007 (1335); Henneberger, 2001 (1313); Seidler *et al.,* 2012 (0457); Schuler *et al.,* 2012 (0473)), and may continue to progress following removal from beryllium exposure (Newman, 2005, Document ID 1437; Sawyer *et al.,* 2005 (1415); Seidler *et al.,* 2012 (0457)). Patients with CBD can progress to a chronic obstructive lung disorder resulting in loss of quality of life and the potential for decreased life expectancy (Rossman, *et al.,* 1996, Document ID 1425; Newman *et al.,* 2005 (1437)). The National Academy of Sciences (NAS) report (2008) noted the general lack of published studies on progression of CBD from an early asymptomatic stage to functionally significant lung disease (NAS, 2008, Document ID 1355). The report emphasized that risk factors and

time course for clinical disease have not been fully delineated. However, for people now under surveillance, clinical progression from sensitization and early pathological lesions (*i.e.,* granulomatous inflammation) prior to onset of symptoms to symptomatic disease appears to be slow, although more follow-up is needed (NAS, 2008, Document ID 1355). A study by Newman (1996) emphasized the need for prospective studies to determine the natural history and time course from beryllium sensitization and asymptomatic CBD to full-blown disease (Newman, 1996, Document ID 1283). Drawing from his own clinical experience, Dr. Newman was able to identify the sequence of events for those with symptomatic disease as follows: Initial determination of beryllium sensitization; gradual emergence of chronic inflammation of the lung; pathologic alterations with measurable physiologic changes (*e.g.,* pulmonary function and gas exchange); progression to a more severe lung disease (with extrapulmonary effects such as clubbing and cor pulmonale in some cases); and finally death in some cases (reported between 5.8 to 38 percent) (NAS, 2008, Document ID 1355; Newman, 1996 (1283)).

In contrast to some occupationally related lung diseases, the early detection of chronic beryllium disease may be useful since treatment of this condition can lead not only to regression of the signs and symptoms, but also may prevent further progression of the disease in certain individuals (Marchand-Adam *et al.,* 2008, Document ID 0370; NAS, 2008 (1355)). The management of CBD is based on the hypothesis that suppression of the hypersensitivity reaction (*i.e.,* granulomatous process) will prevent the development of fibrosis. However, once fibrosis has developed, therapy cannot reverse the damage.

A study by Pappas and Newman (1993) observed that patients with known prior beryllium exposure and identified as confirmed positive for beryllium sensitization through the beryllium lymphocyte proliferation test (BeLPT) screening were evaluated for physiological changes in the lung. Pappas and Newman categorized the patients as being either ''clinically identified,'' meaning they had known physiological abnormalities (*e.g.,* abnormal chest radiogram, respiratory symptoms) or ''surveillance-identified,'' meaning they had BeLPT positive results with no reported symptoms, to differentiate state of disease progression. Physiological changes were identified by three factors: (1) Reduced tolerance to exercise; (2) abnormal pulmonary function test during exercise; (3) abnormal arterial blood gases during exercise. Of the patients identified as ''surveillance identified,'' 52 percent had abnormal exercise physiologies while 87 percent of the ''clinically identified'' patients had abnormal physiologies (Pappas and Newman, 1993, Document ID 1433). During the public hearing, Dr. Newman noted that:

> . . . one of the sometimes overlooked points is that in that study . . . the majority of people who were found to have early stage disease already had physiologic impairment. So before the x-ray or the CAT scan could find it the BeLPT had picked it up, we had made a diagnosis of pathology in those people, and their lung function tests—their measures of gas exchange, were already abnormal. Which put them on our watch list for early and more frequent monitoring so that we could observe their worsening and then jump in with treatment at the earliest appropriate time. So there is advantage of having that early diagnosis in terms of the appropriate tracking and appropriate timing of treatment. (Document ID 1756, p. 112).

OSHA was unable to find any controlled studies to determine the optimal treatment for CBD (see Rossman, 1996, Document ID 1425; NAS 2008 (1355); Sood, 2009 (0456)), and none were added to the record during the public comment period. Management of CBD is generally modeled after sarcoidosis treatment. Oral corticosteroid treatment can be initiated in patients with evidence of disease (either by bronchoscopy or other diagnostic measures before progression of disease or after clinical signs of pulmonary deterioration occur). This includes treatment with other anti-inflammatory agents (NAS, 2008. Document ID 1355; Maier *et al.,* 2012 (0461); Salvator *et al.,* 2013 (0459)) as well. It should be noted, however, that treatment with corticosteroids has side-effects of their own that need to be measured against the possibility of progression of disease (Gibson *et al.,* 1996, Document ID 1521; Zaki *et al.,* 1987 (1374)). Alternative treatments such as azathioprine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side effects as well (Pallavicino *et al.,* 2013, Document ID 0630; Freeman, 2012 (0655)).

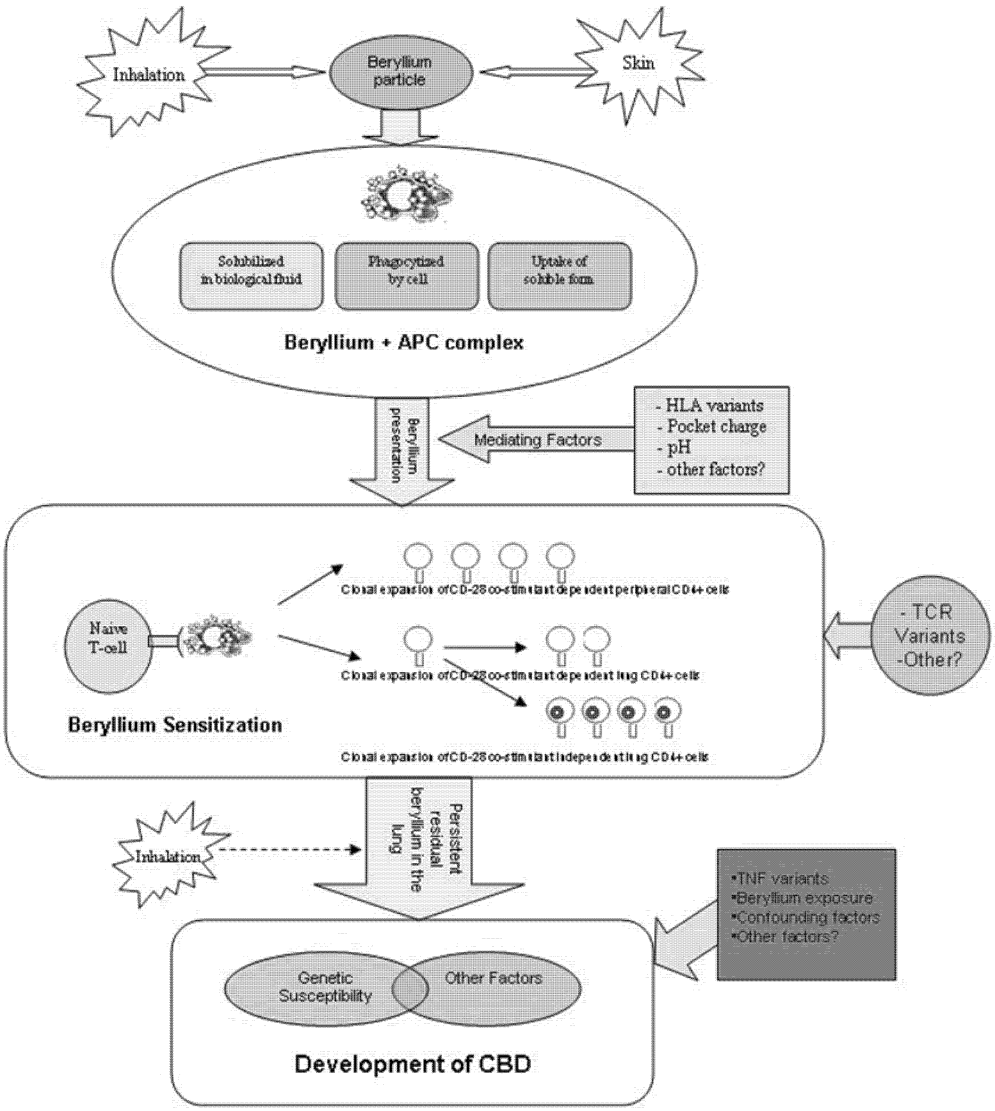
1. Development of Beryllium Sensitization

Sensitization to beryllium is an essential step for worker development of CBD. Sensitization to beryllium can result from inhalation exposure to beryllium (Newman *et al.,* 2005, Document ID 1437; NAS, 2008 (1355)), as well as from skin exposure to beryllium (Curtis, 1951, Document ID 1273; Newman *et al.,* 1996 (1439); Tinkle *et al.,* 2003 (1483); Rossman, *et al.,* 1991, (1332); Deubner *et al.,* 2001 (1542); Tinkle *et al.,* 2003 (1483); Sutton *et al.,* 2003 (1393); Stefaniak *et al.,* 2011 (0537) and 2014 (0517); Duling *et al.,* 2012 (0539); Document ID 1755, Tr. 36–37). Representative Robert C. ''Bobby'' Scott, Ranking Member of Committee on Education and the Workforce, the U.S. House of Representatives, provided comments to the record stating that ''studies have demonstrated that beryllium sensitization, an indicator of immune response to beryllium, can occur from both soluble and poorly soluble beryllium particles.'' (Document ID 1672, p. 3).

Sensitization is currently detected using the BeLPT (a laboratory blood test) described in section V.D.5. Although there may be no clinical symptoms associated with beryllium sensitization, a sensitized worker's immune system has been activated to react to beryllium exposures such that subsequent exposure to beryllium can progress to serious lung disease (Kreiss *et al.,* 1996, Document ID 1477; Newman *et al.,* 1996 (1439); Kreiss *et al.,* 1997 (1360); Kelleher *et al.,* 2001 (1363); Rossman, 2001 (1424); Newman *et al.,* 2005 (1437)). Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of sensitization (NAS, 2008, Document ID 1355). The expert peer reviewers agreed that the scientific evidence supported sensitization as a necessary condition and an early endpoint in the development of CBD (ERG, 2010, Document ID 1270, pp. 19–21). Dr. John Balmes remarked that the ''scientific evidence reviewed in the [Health Effects] document supports consideration of beryllium sensitization as an early endpoint and as a necessary condition in the development of CBD.'' Dr. Patrick Breysee stated that ''there is strong scientific consensus that sensitization is a key first step in the progression of CBD.'' Dr. Terry Gordon stated that ''[a]s discussed in the draft [Health Effects] document, beryllium sensitization should be considered as an early endpoint in the development of CBD.'' Finally, Dr. Milton Rossman agreed ''that sensitization is necessary for someone to develop CBD and should be considered a condition/risk factor for the development of CBD.'' Various factors, including genetic susceptibility, have been shown to influence risk of developing sensitization and CBD (NAS 2008, Document ID 1355) and will be discussed later in this section.

While various mechanisms or pathways may exist for beryllium sensitization, the most plausible mechanisms supported by the best available and most current science are discussed below. Sensitization occurs via the formation of a beryllium-protein complex (an antigen) that causes an immunological response. In some instances, onset of sensitization has been observed in individuals exposed to beryllium for only a few months (Kelleher *et al.,* 2001, Document ID 1363; Henneberger *et al.,* 2001 (1313)). This suggests the possibility that relatively brief, short-term beryllium exposures may be sufficient to trigger the immune hypersensitivity reaction. Several studies (Newman *et al.,* 2001, Document ID 1354; Henneberger *et al.,* 2001 (1313); Rossman, 2001 (1424); Schuler *et al.,* 2005 (0919); Donovan *et al.,* 2007 (0491), Schuler *et al.,* 2012 (0473)) have detected a higher prevalence of sensitization among workers with less than one year of employment compared to some cross-sectional studies which, due to lack of information regarding initial exposure, cannot determine time of sensitization (Kreiss *et al.,* 1996, Document ID 1477; Kreiss *et al.,* 1997 (1360)). While only very limited evidence has described humoral changes in certain patients with CBD (Cianciara *et al.,* 1980, Document ID 1553), clear evidence exists for an immune cell-mediated response, specifically the T-cell (NAS, 2008, Document ID 1355). Figure 2 delineates the major steps required for progression from beryllium contact to sensitization to CBD.

Figure 2 – Schematic of beryllium presentation through to formation of CBD



Beryllium presentation to the immune system is believed to occur either by direct presentation or by antigen processing. It has been postulated that beryllium must be presented to the immune system in an ionic form for cell-mediated immune activation to occur (Kreiss *et al.,* 2007, Document ID 1475). Some soluble forms of beryllium are readily presented, since the soluble beryllium form disassociates into its ionic components. However, for poorly soluble forms, dissolution may need to occur. A study by Harmsen *et al.* (1986) suggested that a sufficient rate of dissolution of small amounts of poorly soluble beryllium compounds might occur in the lungs to allow persistent

low-level beryllium presentation to the immune system (Document ID 1257). Stefaniak *et al.* (2006 and 2012) reported that poorly soluble beryllium particles phagocytized by macrophages were dissolved in phagolysomal fluid (Stefaniak *et al.,* 2006, Document ID 1398; Stefaniak *et al.,* 2012 (0469)) and that the dissolution rate stimulated by phagolysomal fluid was different for various forms of beryllium (Stefaniak *et al.,* 2006, Document ID 1398; Duling *et al.,* 2012 (0539)). Several studies have demonstrated that macrophage uptake of beryllium can induce aberrant apoptotic processes leading to the continued release of beryllium ions which will continually stimulate T-cell activation (Sawyer *et al.,* 2000, Document ID 1417; Sawyer *et al.,* 2004 (1416); Kittle *et al.,* 2002 (0485)). Antigen processing can be mediated by antigen-presenting cells (APC). These may include macrophages, dendritic cells, or other antigen-presenting cells, although this has not been well defined in most studies (NAS, 2008, Document ID 1355).

Because of their strong positive charge, beryllium ions have the ability to haptenate and alter the structure of peptides occupying the antigen-binding cleft of major histocompatibility complex (MHC) class II on antigen-presenting cells (APC). The MHC class II antigen-binding molecule for beryllium is the human leukocyte antigen (HLA) with specific alleles (*e.g.,* HLA–DP, HLA–DR, HLA–DQ) associated with the progression to CBD (NAS, 2008, Document ID 1355; Yucesoy and Johnson, 2011 (0464); Petukh *et al.,* 2014 (0397)). Several studies have also demonstrated that the electrostatic charge of HLA may be a factor in binding beryllium (Snyder *et al.,* 2003, Document ID 0524; Bill *et al.,* 2005 (0499); Dai *et al.,* 2010 (0494)). The strong positive ionic charge of the beryllium ion would have a strong attraction for the negatively charged patches of certain HLA alleles (Snyder *et al.,* 2008, Document ID 0471; Dai *et al.,* 2010 (0494); Petukh *et al.,* 2014 (0397)). Alternatively, beryllium oxide has been demonstrated to bind to the MHC class II receptor in a neutral pH. The six carboxylates in the amino acid sequence of the binding pocket provide a stable bond with the Be-O-Be molecule when the pH of the substrate is neutral (Keizer *et al.,* 2005, Document ID 0455). The direct binding of BeO may eliminate the biological requirement for antigen processing or dissolution of beryllium oxide to activate an immune response.

Once the beryllium-MHC-APC complex is established, the complex binds to a T-cell receptor (TCR) on a naïve T-cell which stimulates the proliferation and accumulation of beryllium-specific $CD4^+$ (cluster of differentiation 4^+) T-cells (Saltini *et al.,* 1989, Document ID 1351 and 1990 (1420); Martin *et al.,* 2011 (0483)) as depicted in Figure 3. Fontenot *et al.* (1999) demonstrated that diversely different variants of TCR were expressed by $CD4^+$ T-cells in peripheral blood cells of CBD patients. However, the $CD4^+$ T-cells from the lung were more homologous in expression of TCR variants in CBD patients, suggesting clonal expansion of a subset of T-cells in the lung (Fontenot *et al.,* 1999, Document ID 0489). This may also indicate a pathogenic potential for subsets of T-cell clones expressing this homologous TCR (NAS, 2008, Document ID 1355). Fontenot *et al.* (2006) (Document ID 0487) reported beryllium self-presentation by HLA–DP expressing BAL $CD4^+$ T-cells. According the NAS report, BAL T-cell self-presentation in the lung granuloma may result in cell death, leading to oligoclonality (only a few clones) of the T-cell population characteristic of CBD (NAS, 2008, Document ID 1355).

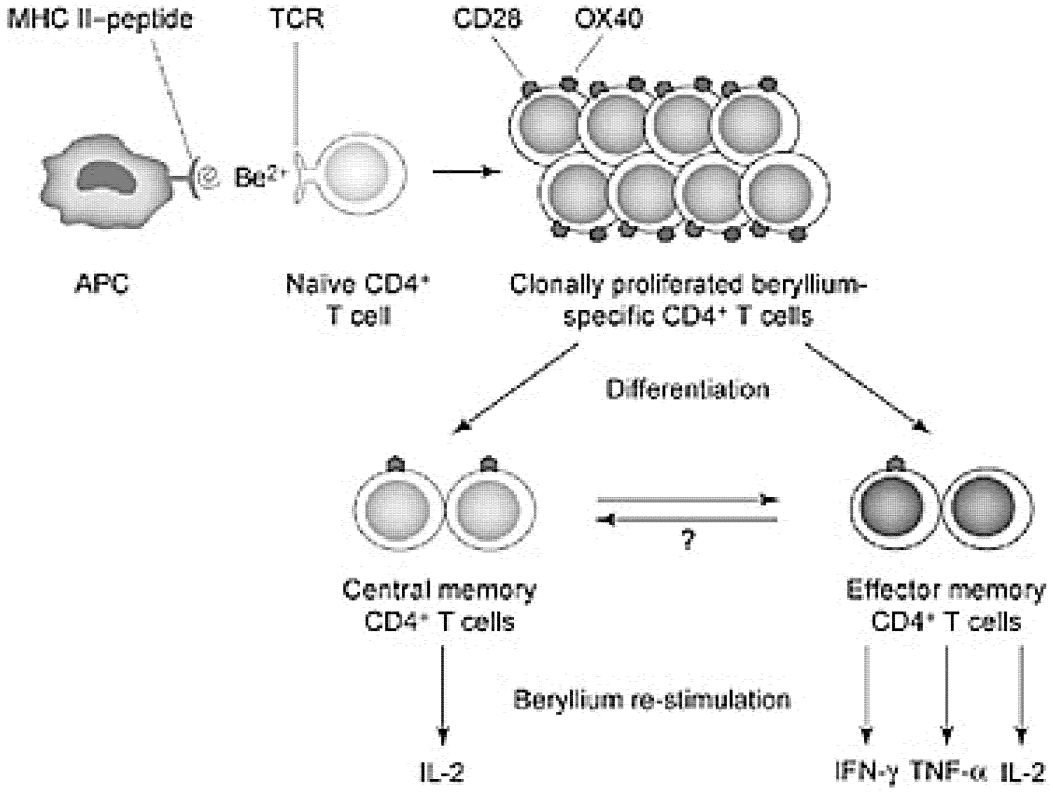


FIGURE 3 - Immune response to beryllium.
Source: Fontenot and Maier 2005. Reprinted with permission; copyright 2005, Trends in Immunology (Document ID 0488).

As CD4+ T-cells proliferate, clonal expansion of various subsets of the CD4+ beryllium specific T-cells occurs (Figure 3). In the peripheral blood, the beryllium-specific CD4+ T cells require co-stimulation with a co-stimulant CD28 (cluster of differentiation 28). During the proliferation and differentiation process CD4+ T-cells secrete pro-inflammatory cytokines that may influence this process (Sawyer *et al.,* 2004, Document ID 1416; Kimber *et al.,* 2011 (0534)).

In summary, OSHA concludes that sensitization is a necessary and early functional change in the immune system that leads to the development of CBD.

2. Development of CBD

The continued presence of residual beryllium in the lung leads to a T-cell maturation process. A large portion of beryllium-specific CD4+ T cells were shown to cease expression of CD28 mRNA and protein, indicating these cells no longer required co-stimulation with the CD28 ligand (Fontenot *et al.,* 2003, Document ID 1529). This change in phenotype correlated with lung inflammation (Fontenot *et al.,* 2003, Document ID 1529). While these CD4+ independent cells continued to secrete cytokines necessary for additional recruitment of inflammatory and immunological cells, they were less proliferative and less susceptible to cell death compared to the CD28 dependent cells (Fontenot *et al.,* 2005, Document ID 1528; Mack *et al.,* 2008 (1460)). These beryllium-specific CD4+ independent cells are considered to be mature memory effector cells (Ndejembi *et al.,* 2006, Document ID 0479; Bian *et al.,* 2005 (0500)). Repeat exposure to beryllium in the lung resulting in a mature population of T cell development independent of co-stimulation by CD28 and development of a population of T effector memory cells (T_{em} cells) may be one of the mechanisms that lead to the more severe reactions observed specifically in the lung (Fontenot *et al.,* 2005, Document ID 1528).

CD4+ T cells created in the sensitization process recognize the beryllium antigen, and respond by proliferating and secreting cytokines and inflammatory mediators, including IL–2, IFN-γ, and TNF-α (Tinkle *et al.,* 1997, Document ID 1387; Tinkle *et al.,* 1997 (1388); Fontenot *et al.,* 2002 (1530)) and MIP–1α and GRO–1 (Hong-Geller, 2006, Document ID 1511). This also results in the accumulation of various types of inflammatory cells including mononuclear cells (mostly CD4+ T cells) in the BAL fluid (Saltini *et al.,* 1989, Document ID 1351, 1990 (1420)).

The development of granulomatous inflammation in the lung of CBD patients has been associated with the accumulation of beryllium responsive CD4+ T_{em} cells in BAL fluid (NAS, 2008, Document ID 1355). The subsequent release of pro-inflammatory cytokines, chemokines and reactive oxygen species by these cells may lead to migration of additional inflammatory/immune cells and the development of a microenvironment that contributes to the development of CBD (Sawyer *et al.,* 2005, Document ID 1415; Tinkle *et al.,* 1996 (0468); Hong-Geller *et al.,* 2006 (1511); NAS, 2008 (1355)).

The cascade of events described above results in the formation of a noncaseating granulomatous lesion. Release of cytokines by the accumulating T cells leads to the formation of granulomatous lesions that are characterized by an outer ring of histiocytes surrounding non-necrotic tissue with embedded multi-nucleated giant cells (Saltini *et al.,* 1989, Document ID 1351, 1990 (1420)).

Over time, the granulomas spread and can lead to lung fibrosis and abnormal

pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000, Document ID 1421). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite or unexplained weight loss, and cor pulmonale have been experienced in certain patients as the disease progresses (Conradi *et al.,* 1971, Document ID 1319; ACCP, 1965 (1286); Kriebel *et al.,* 1988, Document ID 1292; Kriebel *et al.,* 1988 (1473)). While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys (ATSDR, 2002, Document ID 1371).

As previously mentioned, the uptake of beryllium may lead to an aberrant apoptotic process with rerelease of beryllium ions and continual stimulation of beryllium-responsive $CD4^+$ cells in the lung (Sawyer *et al.,* 2000, Document ID 1417; Kittle *et al.,* 2002 (0485); Sawyer *et al.,* 2004 (1416)). Several research studies suggest apoptosis may be one mechanism that enhances inflammatory cell recruitment, cytokine production and inflammation, thus creating a scenario for progressive granulomatous inflammation (Palmer *et al.,* 2008, Document ID 0478; Rana, 2008 (0477)). Macrophages and neutrophils can phagocytize beryllium particles in an attempt to remove the beryllium from the lung (Ding, *et al.,* 2009, Document ID 0492)). Multiple studies (Sawyer *et al.,* 2004, Document ID 1416; Kittle *et al.,* 2002 (0485)) using BAL cells (mostly macrophages and neutrophils) from patients with CBD found that *in vitro* stimulation with beryllium sulfate induced the production of TNF-α (one of many cytokines produced in response to beryllium), and that production of TNF-α might induce apoptosis in CBD and sarcoidosis patients (Bost *et al.,* 1994, Document ID 1299; Dai *et al.,* 1999 (0495)). The stimulation of CBD-derived macrophages by beryllium sulfate resulted in cells becoming apoptotic, as measured by propidium iodide. These results were confirmed in a mouse macrophage cell-line (p388D1) (Sawyer *et al.,* 2000, Document ID 1417). However, other factors, such as genetic factors and duration or level of exposure leading to a continued presence of beryllium in the lung, may influence the development of CBD and are outlined in the following sections V.D.3 and V.D.4.

In summary, the persistent presence of beryllium in the lung of a sensitized individual creates a progressive inflammatory response that can culminate in the granulomatous lung disease, CBD.

3. Genetic and Other Susceptibility Factors

Evidence from a variety of sources indicates genetic susceptibility may play an important role in the development of CBD in certain individuals, especially at levels low enough not to invoke a response in other individuals. Early occupational studies proposed that CBD was an immune reaction based on the high susceptibility of some individuals to become sensitized and progress to CBD and the lack of CBD in others who were exposed to levels several orders of magnitude higher (Sterner and Eisenbud, 1951, Document ID 1396). Recent studies have confirmed genetic susceptibility to CBD involves either, HLA variants, T-cell receptor clonality, tumor necrosis factor (TNF-α) polymorphisms and/or transforming growth factor-beta (TGF-β) polymorphisms (Fontenot *et al.,* 2000, Document ID 1531; Amicosante *et al.,* 2005 (1564); Tinkle *et al.,* 1996 (0468); Gaede *et al.,* 2005 (0486); Van Dyke *et al.,* 2011 (1696); Silveira *et al.,* 2012 (0472)).

Potential sources of variation associated with genetic susceptibility have been investigated. Single Nucleotide Polymorphisms (SNPs) have been studied with regard to genetic variations associated with increased risk of developing CBD. SNPs are the most abundant type of human genetic variation. Polymorphisms in MHC class II and pro-inflammatory genes have been shown to contribute to variations in immune responses contributing to the susceptibility and resistance in many diseases including auto-immunity, beryllium sensitization, and CBD (McClesky *et al.,* 2009, as cited in Document ID 1808, p. 3). Specific SNPs have been evaluated as a factor in the Glu69 variant from the HLA–DPB1 locus (Richeldi *et al.,* 1993, Document ID 1353; Cai *et al.,* 2000 (0445); Saltini *et al.,* 2001 (0448); Silviera *et al.,* 2012 (0472); Dai *et al.,* 2013 (0493)). Other SNPs lacking the Glu69 variant, such as HLA–DRPheβ47, have also been evaluated for an association with CBD (Amicosante *et al.,* 2005, Document ID 1564).

HLA–DPB1 (one of 2 subtypes of HLA–DP) with a glutamic acid at amino position 69 (Glu69) has been shown to confer increased risk of beryllium sensitization and CBD (Richeldi *et al.,* 1993, Document ID 1353; Saltini *et al.,* 2001 (0448); Amicosante *et al.,* 2005 (1564); Van Dyke *et al.,* 2011 (1696); Silveira *et al.,* 2012 (0472)). *In vitro* human research has identified genes coding for specific protein molecules on the surface of the immune cells of sensitized individuals from a cohort of beryllium workers (McCanlies *et al.,* 2004, Document ID 1449). The research identified the HLA–DPB1 (Glu69) allele that place carriers at greater risk of becoming sensitized to beryllium and developing CBD than those not carrying this allele (McCanlies *et al.,* 2004, Document ID 1449). Fontenot *et al.* (2000) demonstrated that beryllium presentation by certain alleles of the class II human leukocyte antigen-DP (HLA–DP [3]) to $CD4^+$ T cells is the mechanism underlying the development of CBD (Document ID 1531). Richeldi *et al.* (1993) reported a strong association between the MHC class II allele HLA–DPB 1 and the development of CBD in beryllium-exposed workers from a Tucson, AZ facility (Document ID 1353). This marker was found in 32 of the 33 workers who developed CBD, but in only 14 of 44 similarly exposed workers without CBD. The more common alleles of the HLA–DPB 1 containing a variant of Glu69 are negatively charged at this site and could directly interact with the positively charged beryllium ion. Additional studies by Amicosante *et al.* (2005) (Document ID 1564) using blood lymphocytes derived from beryllium-exposed workers found a high frequency of this gene in those sensitized to beryllium. In a study of 82 CBD patients (beryllium-exposed workers), Stubbs *et al.* (1996) (Document ID 1394) also found a relationship between the HLA–DP 1 allele and beryllium sensitization. The glutamate-69 allele was present in 86 percent of sensitized subjects, but in only 48 percent of beryllium-exposed, non-sensitized subjects. Some variants of the HLA–DPB1 allele convey higher risk of sensitization and CBD than others. For example, HLA–DPB1*0201 yielded an approximately 3-fold increase in disease outcome relative to controls; HLA–DPB1*1901 yielded an approximately 5-fold increase, and HLA–DPB1*1701 yielded an approximately 10-fold increase (Weston *et al.,* 2005, Document ID 1345; Snyder *et al.,* 2008 (0471)). Specifically, Snyder *et al.* (2008) found that variants of the Glu69 allele with the greatest negative charge may confer greater risk for developing CBD (Document ID 0471). The study by Weston *et al.* (2005) assigned odds ratios for specific alleles on the basis of previous studies discussed above (Document ID 1345). The researchers found a strong

[3] HLA–DP and HLA DPB1 alleles have been associated with genetic susceptibility for developing CBD. HLA–DP has 2 subtypes, HLA–DPA and HLA–DPB. HLA–DBP1 is involved with the Glu69 allele most associated with genetic susceptibility.

correlation (88 percent) between the reported risk of CBD and the predicted surface electrostatic potential and charge of the isotypes of the genes. They were able to conclude that the alleles associated with the most negatively charged proteins carry the greatest risk of developing beryllium sensitization and CBD (Weston *et al.,* 2005, Document ID 1345). This confirms the importance of beryllium charge as a key factor in its ability to induce an immune response.

In contrast, the HLA–DRB1 allele, which lacks Glu69, has also been shown to increase the risk of developing sensitization and CBD (Amicosante *et al.,* 2005, Document ID 1564; Maier *et al.,* 2003 (0484)). Bill *et al.* (2005) found that HLA–DR has a glutamic acid at position 71 of the β chain, functionally equivalent to the Glu69 of HLA–DP (Bill *et al.,* 2005, Document ID 0499). Associations with BeS and CBD have also been reported with the HLA–DQ markers (Amicosante *et al.,* 2005, Document ID 1564; Maier *et al.,* 2003 (0484)). Stubbs *et al.* also found a biased distribution of the MHC class II HLA–DR gene between sensitized and non-sensitized subjects. Neither of these markers was completely specific for CBD, as each study found beryllium sensitization or CBD among individuals without the genetic risk factor. While there remains uncertainty as to which of the MHC class II genes interact directly with the beryllium ion, antibody inhibition data suggest that the HLA–DR gene product may be involved in the presentation of beryllium to T lymphocytes (Amicosante *et al.,* 2002, Document ID 1370). In addition, antibody blocking experiments revealed that anti-HLA–DP strongly reduced proliferation responses and cytokine secretion by BAL CD4 T cells (Chou *et al.,* 2005, Document ID 0497). In the study by Chou (2005), anti-HLA–DR ligand antibodies mainly affected beryllium-induced proliferation responses with little impact on cytokines other than IL–2, thus implying that non-proliferating BAL CD4 T cells may still contribute to inflammation leading to the progression of CBD (Chou *et al.,* 2005, Document ID 0497).

TNF alpha (TNF-α) polymorphisms and TGF beta (TGF-β) polymorphisms have also been shown to confer a genetic susceptibility for developing CBD in certain individuals. TNF-α is a pro-inflammatory cytokine that may be associated with a more progressive form of CBD (NAS, 2008). Beryllium exposure has been shown to upregulate transcription factors AP–1 and NF-κB (Sawyer *et al.,* 2007, as cited in Document ID 1355) inducing an inflammatory response by stimulating production of pro-inflammatory cytokines such as TNF-α by inflammatory cells. Polymorphisms in the 308 position of the TNF-α gene have been demonstrated to increase production of the cytokine and increase severity of disease (Maier *et al.,* 2001, Document ID 1456; Saltini *et al.,* 2001 (0448); Dotti *et al.,* 2004 (1540)). While a study by McCanlies *et al.* (2007) (Document ID 0482) of 886 beryllium workers (including 64 sensitized for beryllium and 92 with CBD) found no relationship between TNF-α polymorphism and sensitization or CBD, the National Academies of Sciences noted that ''discrepancies between past studies showing associations and the more recent studies may be due to misclassification, exposure differences, linkage disequilibrium between HLA–DRB1 and TNF-α genes, or statistical power.'' (NAS, 2008, Document ID 1355).

Other genetic variations have been shown to be associated with increased risk of beryllium sensitization and CBD (NAS, 2008, Document ID 1355). These include TGF-β (Gaede *et al.,* 2005, Document ID 0486), angiotensin-1 converting enzyme (ACE) (Newman *et al.,* 1992, Document ID 1440; Maier *et al.,* 1999 (1458)) and an enzyme involved in glutathione synthesis (glutamate cysteine ligase) (Bekris *et al.,* 2006, as cited in Document ID 1355). McCanlies *et al.* (2010) evaluated the association between polymorphisms in a select group of interleukin genes (IL–1A; IL–1B, IL–1RN, IL–2, IL–9, IL–9R) due to their role in immune and inflammatory processes (Document ID 0481). The study evaluated SNPs in three groups of workers from large beryllium manufacturing facilities in OH and AZ. The investigators found a significant association between variants IL–1A–1142, IL–1A–3769 and IL–1A–4697 and CBD but not between those variants and beryllium sensitization.

In addition to the genetic factors which may contribute to the susceptibility and severity of disease, other factors such as smoking and sex may play a role in the development of CBD (NAS, 2008, Document ID 1355). A recent longitudinal cohort study by Mroz *et al.* (2009) of 229 individuals identified with beryllium sensitization or CBD through workplace medical surveillance found that the prevalence of CBD among ever smokers was significantly lower than among never smokers (38.1 percent versus 49.4 percent, $p = 0.025$). BeS subjects that never smoked were found to be more likely to develop CBD over the course of the study compared to current smokers (12.6 percent versus 6.4 percent, $p = 0.10$). The authors suggested smoking may confer a protective effect against development of lung granulomas as has been demonstrated with hypersensitivity pneumonitis (Mroz *et al.,* 2009, Document ID 1356).

4. Beryllium Sensitization and CBD in the Workforce

Sensitization to beryllium is currently detected in the workforce with the beryllium lymphocyte proliferation test (BeLPT), a laboratory blood test developed in the 1980s, also referred to as the LTT (Lymphocyte Transformation Test) or BeLTT (Beryllium Lymphocyte Transformation Test). In this test, lymphocytes obtained from either bronchoalveolar lavage fluid (the BAL BeLPT) or from peripheral blood (the blood BeLPT) are cultured *in vitro* and exposed to beryllium sulfate to stimulate lymphocyte proliferation. The observation of beryllium-specific proliferation indicates beryllium sensitization. Hereafter, ''BeLPT'' generally refers to the blood BeLPT, which is typically used in screening for beryllium sensitization. This test is described in more detail in subsection D.5.b.

CBD can be detected at an asymptomatic stage by a number of techniques including bronchoalveolar lavage and biopsy (Cordeiro *et al.,* 2007, Document ID 1552; Maier, 2001 (1456)). Bronchoalveolar lavage is a method of ''washing'' the lungs with fluid inserted via a flexible fiberoptic instrument known as a bronchoscope, removing the fluid and analyzing the content for the inclusion of immune cells reactive to beryllium exposure, as described earlier in this section. Fiberoptic bronchoscopy can be used to detect granulomatous lung inflammation prior to the onset of CBD symptoms as well, and has been used in combination with the BeLPT to diagnose pre-symptomatic CBD in a number of recent screening studies of beryllium-exposed workers, which are discussed in the following section detailing diagnostic procedures. Of workers who were found to be sensitized and underwent clinical evaluation, 31 to 49 percent of them were diagnosed with CBD (Kreiss *et al.,* 1993, Document ID 1479; Newman *et al.,* 1996 (1283), 2005 (1437), 2007 (1335); Mroz, 2009 (1356)), although some estimate that with increased surveillance that percentage could be much higher (Newman, 2005, Document ID 1437; Mroz, 2009 (1356)). It has been estimated from ongoing surveillance studies of sensitized individuals with an average follow-up time of 4.5 years that

31 percent of beryllium-sensitized employees were estimated to progress to CBD (Newman *et al.,* 2005, Document ID 1437). The study by Newman *et al.* (2005) was the first longitudinal study to assess the progression from beryllium sensitization to CBD in individuals undergoing clinical evaluation at National Jewish Medical and Research Center from 1988 through 1998. Approximately 50 percent of sensitized individuals (as identified by BeLPT) had CBD at their initial clinical evaluation. The remaining 50 percent, or 76 individuals, without evidence of CBD were monitored at approximately two year intervals for indication of disease progression by pulmonary function testing, chest radiography (with International Labour Organization B reading), fiberoptic bronchoscopy with bronchoalveolar lavage, and transbronchial lung biopsy. Fifty-five of the 76 individuals were monitored with a range of two to five clinical evaluations each. The Newman *et al.* (2005) study found that CBD developed in 31 percent of individuals (17 of the 55) in a period ranging from 1.0 to 9.5 years (average 3.8 years). After an average of 4.8 years (range 1.7 to 11.6 years) the remaining individuals showed no signs of progression to CBD. A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that the sensitization rate in exposed workers increased rapidly over the first 10 years of beryllium exposure and then more gradually in succeeding years. On the other hand, the rate of CBD pathology increased slowly over the first 15 years of exposure and then climbed more steeply following 15 to 30 years of beryllium exposure (Stange *et al.,* 2001, Document ID 1403). The findings from these longitudinal studies of sensitized workers provide evidence of CBD progression over time from asymptomatic to symptomatic disease. One limitation for all these studies is lack of long-term follow-up. Newman suggested that it may be necessary to continue to monitor these workers in order to determine whether all sensitized workers will develop CBD (Newman *et al.,* 2005, Document ID 1437).

CBD has a clinical spectrum ranging from evidence of beryllium sensitization and granulomas in the lung with little symptomatology to loss of lung function and end stage disease, which may result in the need for lung transplantation and decreased life expectancy. Unfortunately, there are very few published clinical studies describing the full range and progression of CBD from the beginning to the end stages and very few of the risk factors for progression of disease have been delineated (NAS, 2008, Document ID 1355). OSHA requested additional information in the NPRM, but no additional studies were added during the public comment period. Clinical management of CBD is modeled after sarcoidosis where oral corticosteroid treatment is initiated in patients who have evidence of progressive lung disease, although progressive lung disease has not been well defined (NAS, 2008, Document ID 1355). In advanced cases of CBD, corticosteroids are the standard treatment (NAS, 2008, Document ID 1355). No comprehensive studies have been published measuring the overall effect of removal of workers from beryllium exposure on sensitization and CBD (NAS, 2008, Document ID 1355) although this has been suggested as part of an overall treatment regime for CBD (Mapel *et al.,* 2002, as cited in Document ID 1850; Sood *et al.,* 2004 (1331); Sood, 2009 (0456); Maier *et al.,* 2012 (0461)). Expert testimony from Dr. Lee Newman and Dr. Lisa Maier agreed that while no studies exist on the efficacy of removal from beryllium exposure, it is medically prudent to reduce beryllium exposure once someone is sensitized (Document ID 1756, Tr. 142). Sood *et al.* reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood *et al.,* 2004, Document ID 1331). However, this was based on anecdotal evidence from six patients with CBD, while this indicates a benefit of removal of patients from exposure, more research is needed to better determine the relationship between exposure duration and disease progression.

Materion commented that sensitization should be defined as a test result indicating an immunological sensitivity to beryllium without identifiable adverse health effects or other signs of illness or disability. It went on to say that, for these reasons, sensitization is not on a pathological continuum with CBD (Document ID 1661, pp. 4–7). Other commenters disagreed. NIOSH addressed whether sensitization should be considered an adverse health effect and said the following in their written hearing testimony:

> Some have questioned whether BeS should be considered an adverse health effect. NIOSH views it as such, since it is a biological change in people exposed to beryllium that is associated with increased risk for developing CBD. BeS refers to the immune system's ability to recognize and react to beryllium. BeS is an antigen-specific cell mediated immunity to beryllium, in which CD4+ T cells recognize a complex composed of beryllium ion, self-peptide, and major histocompatibility complex (MHC) Class II molecule on an antigen-presenting cell [Falta *et al.* (2013); Fontenot *et al.* (2016)]. BeS necessarily precedes CBD. Pathogenesis depends on the immune system's recognition of and reaction to beryllium in the lung, resulting in granulomatous lung disease. BeS can be detected with tests that assess the immune response, such as the beryllium lymphocyte proliferation test (BeLPT), which measures T cell activity in the presence of beryllium salts [Balmes *et al.* (2014)]. Furthermore, after the presence of BeS has been confirmed, periodic medical evaluation at 1–3 year intervals thereafter is required to assess whether BeS has progressed to CBD [Balmes *et al.* (2014)]. Thus, BeS is not just a test result, but an adverse health effect that poses risk of the irreversible lung disease CBD. (Document ID 1725, p. 2)

The American College of Occupational and Environmental Medicine (ACOEM) also commented that the term pathological ''continuum'' should only refer to signs and symptoms associated with CBD because some sensitized workers never develop CBD (Document ID 1685, p. 6). However, Dr. Newman, testifying on behalf of ACOEM, clarified that not all members of the ACOEM task force agreed:

> So I hope I'm reflecting to you the range and variety of outcomes relating to this. My own view is that it's on a continuum. I do want to reflect back that the divided opinion among people on the ACOEM task force was that we should call it a spectrum because not everybody is necessarily lock step into a continuum that goes from sensitization to fatality. (Document ID 1756, Tr. 133).

Lisa Maier, MD of National Jewish Health agreed with Dr. Newman (Document ID 1756, Tr. 133–134). Additionally, Dr. Weissman of NIOSH testified that sensitization is ''a biological change in people exposed to beryllium that is associated with increased risk for developing CBD'' and should be considered an adverse health effect (Document ID 1755, Tr. 13).

OSHA agrees that not every sensitized worker develops CBD, and that other factors such as extent of exposure, particulate characteristics, and genetic susceptibility influence the development and progression of disease. The mechanisms by which beryllium sensitization leads to CBD are described in earlier sections and are supported by numerous studies (Newman *et al.,* 1996a, Document ID 1439; Newman *et al.,* 2005 (1437); Saltini *et al.,* 1989 (1351); Amicosante *et al.,* 2005a (1564); Amicosante *et al.,* 2006 (1465); Fontenot *et al.,* 1999 (0489); Fontenot *et al.,* 2005 (1528)). OSHA concludes that sensitization is an immunological condition that increases one's likelihood

of developing CBD. As such, sensitization is a necessary step along a continuum to clinical lung disease.

5. Human Epidemiological Studies

This section describes the human epidemiological data supporting the mechanistic overview of beryllium-induced disease in workers. It has been divided into reviews of epidemiological studies performed prior to development and implementation of the BeLPT in the late 1980s and after wide use of the BeLPT for screening purposes. Use of the BeLPT has allowed investigators to screen for beryllium sensitization and CBD prior to the onset of clinical symptoms, providing a more sensitive and thorough analysis of the worker population. The discussion of the studies has been further divided by manufacturing processes that may have similar exposure profiles. Table A.1 in the Supplemental Information for the Beryllium Health Effects Section summarizes the prevalence of beryllium sensitization and CBD, range of exposure measurements, and other salient information from the key epidemiological studies (Document ID 1965).

It has been well-established that beryllium exposure, either via inhalation or skin, may lead to beryllium sensitization, or, with inhalation exposure, may lead to the onset and progression of CBD. The available published epidemiological literature discussed below provides strong evidence of beryllium sensitization and CBD in workers exposed to airborne beryllium well below the preceding OSHA PEL of 2 μg/m^3. Several studies demonstrate the prevalence of sensitization and CBD is related to the level of airborne exposure, including a cross-sectional survey of employees at a beryllium ceramics plant in Tucson, AZ (Henneberger *et al.,* 2001, Document ID 1313), case-control studies of workers at the Rocky Flats nuclear weapons facility (Viet *et al.,* 2000, Document ID 1344), and workers from a beryllium machining plant in Cullman, AL (Kelleher *et al.,* 2001, Document ID 1363). The prevalence of beryllium sensitization also may be related to dermal exposure. An increased risk of CBD has been reported in workers with skin lesions, potentially increasing the uptake of beryllium (Curtis, 1951, Document ID 1368; Johnson *et al.,* 2001 (1505); Schuler *et al.,* 2005 (0919)). Three studies describe comprehensive preventive programs, which included expanded respiratory protection, dermal protection, and improved control of beryllium dust migration, that substantially reduced the rate of beryllium sensitization among new hires (Cummings *et al.,* 2007; Thomas *et al.,* 2009 (0590); Bailey *et al.,* 2010 (0676); Schuler *et al.,* 2012(0473)).

Some of the epidemiological studies presented in this section suffer from challenges common to many published epidemiological studies: Limitations in study design (particularly cross-sectional); small sample size; lack of personal and/or short-term exposure data, particularly those published before the late 1990s; and incomplete information regarding specific chemical form and/or particle characterization. Challenges that are specific to beryllium epidemiological studies include: uncertainty regarding the contribution of dermal exposure; use of various BeLPT protocols; a variety of case definitions for determining CBD; and use of various exposure sampling/assessment methods (*e.g.,* daily weighted average (DWA), lapel sampling). Even with these limitations, the epidemiological evidence presented in this section clearly demonstrates that beryllium sensitization and CBD are continuing to occur from present-day exposures below OSHA's preceding PEL of 2 μg/m^3. The available literature also indicates that the rate of beryllium sensitization can be substantially lowered by reducing inhalation exposure and minimizing dermal contact.

a. Studies Conducted Prior to the BeLPT

First reports of CBD came from studies performed by Hardy and Tabershaw (1946) (Document ID 1516). Cases were observed in industrial plants that were refining and manufacturing beryllium metal and beryllium alloys and in plants manufacturing fluorescent light bulbs (NAS, 2008, Document ID 1355). From the late 1940s through the 1960s, clusters of non-occupational CBD cases were identified around beryllium refineries in Ohio and Pennsylvania, and outbreaks in family members of beryllium factory workers were assumed to be from exposure to contaminated clothes (Hardy, 1980, Document ID 1514). It had been established that the risk of disease among beryllium workers was variable and generally rose with the levels of airborne concentrations (Machle *et al.,* 1948, Document ID 1461). And while there was a relationship between air concentrations of beryllium and risk of developing disease both in and surrounding these plants, the disease rates outside the plants were higher than expected and not very different from the rate of CBD within the plants (Eisenbud *et al.,* 1949, Document ID 1284; Lieben and Metzner, 1959 (1343)). There remained considerable uncertainty regarding diagnosis due to lack of well-defined cohorts, modern diagnostic methods, or inadequate follow-up. In fact, many patients with CBD may have been misdiagnosed with sarcoidosis (NAS, 2008, Document ID 1355).

The difficulties in distinguishing lung disease caused by beryllium from other lung diseases led to the establishment of the BCR in 1952 to identify and track cases of ABD and CBD. A uniform diagnostic criterion was introduced in 1959 as a way to delineate CBD from sarcoidosis. Patient entry into the BCR required either: Documented past exposure to beryllium or the presence of beryllium in lung tissue as well as clinical evidence of beryllium disease (Hardy *et al.,* 1967, Document ID 1515); or any three of the six criteria listed below (Hasan and Kazemi, 1974, Document ID 0451). Patients identified using the above criteria were registered and added to the BCR from 1952 through 1983 (Eisenbud and Lisson, 1983, Document ID 1296).

The BCR listed the following criteria for diagnosing CBD (Eisenbud and Lisson, 1983, Document ID 1296):

(1) Establishment of significant beryllium exposure based on sound epidemiologic history;

(2) Objective evidence of lower respiratory tract disease and clinical course consistent with beryllium disease;

(3) Chest X-ray films with radiologic evidence of interstitial fibronodular disease;

(4) Evidence of restrictive or obstructive defect with diminished carbon monoxide diffusing capacity (DL_{CO}) by physiologic studies of lung function;

(5) Pathologic changes consistent with beryllium disease on examination of lung tissue; and

(6) Presence of beryllium in lung tissue or thoracic lymph nodes.

Prevalence of CBD in workers during the time period between the 1940s and 1950s was estimated to be between 1–10% (Eisenbud and Lisson, 1983, Document ID 1296). In a 1969 study, Stoeckle *et al.* presented 60 case histories with a selective literature review utilizing the above criteria except that urinary beryllium was substituted for lung beryllium to demonstrate beryllium exposure. Stoeckle *et al.* (1969) were able to demonstrate corticosteroids as a successful treatment option in one case of confirmed CBD (Document ID 0447). This study also presented a 28 percent mortality rate from complications of CBD at the time of publication. However, even with the improved

methodology for determining CBD based on the BCR criteria, these studies suffered from lack of well-defined cohorts, modern diagnostic techniques or adequate follow-up.

b. Criteria for Beryllium Sensitization and CBD Case Definition Following the Development of the BeLPT

The criteria for diagnosis of CBD have evolved over time as more advanced diagnostic technology, such as the blood BeLPT and BAL BeLPT, has become available. More recent diagnostic criteria have both higher specificity than earlier methods and higher sensitivity, identifying subclinical effects. Recent studies typically use the following criteria (Newman *et al.,* 1989, Document ID 0196; Pappas and Newman, 1993 (1433); Maier *et al.,* 1999 (1458)):

(1) History of beryllium exposure;

(2) Histopathological evidence of non-caseating granulomas or mononuclear cell infiltrates in the absence of infection; and

(3) Positive blood or BAL BeLPT (Newman *et al.,* 1989, Document ID 0196).

The availability of transbronchial lung biopsy facilitates the evaluation of the second criterion, by making histopathological confirmation possible in almost all cases.

A significant component for the identification of CBD is the demonstration of a confirmed abnormal BeLPT result in a blood or BAL sample (Newman, 1996, Document ID 1283). Since the development of the BeLPT in the 1980s, it has been used to screen beryllium-exposed workers for sensitization in a number of studies to be discussed below. The BeLPT is a non-invasive *in vitro* blood test that measures the beryllium antigen-specific T-cell mediated immune response and is the most commonly available diagnostic tool for identifying beryllium sensitization. The BeLPT measures the degree to which beryllium stimulates lymphocyte proliferation under a specific set of conditions, and is interpreted based upon the number of stimulation indices that exceed the normal value. The ''cut-off'' is based on the mean value of the peak stimulation index among controls plus 2 or 3 standard deviations. This methodology was modeled into a statistical method known as the ''least absolute values'' or ''statistical-biological positive'' method and relies on natural log modeling of the median stimulation index values (DOE, 2001, Document ID 0068; Frome, 2003 (0462)). In most applications, two or more stimulation indices that exceed the cut-off constitute an abnormal test.

Early versions of the BeLPT test had high variability, but the use of tritiated thymidine to identify proliferating cells has led to a more reliable test (Mroz *et al.,* 1991, 0435; Rossman *et al.,* 2001 (1424)). In recent years, the peripheral blood test has been found to be as sensitive as the BAL assay, although larger abnormal responses have been observed with the BAL assay (Kreiss *et al.,* 1993, Document ID 1478; Pappas and Newman, 1993 (1433)). False negative results have also been observed with the BAL BeLPT in cigarette smokers who have marked excess of alveolar macrophages in lavage fluid (Kreiss *et al.,* 1993, Document ID 1478). The BeLPT has also been a useful tool in animal studies to identify those species with a beryllium-specific immune response (Haley *et al.,* 1994, Document ID 1364).

Screenings for beryllium sensitization have been conducted using the BeLPT in several occupational surveys and surveillance programs, including nuclear weapons facilities operated by the Department of Energy (Viet *et al.,* 2000, Document ID 1344; Stange *et al.,* 2001 (1403); DOE/HSS Report, 2006 (0664)), a beryllium ceramics plant in Arizona (Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Cummings *et al.,* 2007 (1369)), a beryllium production plant in Ohio (Kreiss *et al.,* 1997, Document ID 1476; Kent *et al.,* 2001 (1112)), a beryllium machining facility in Alabama (Kelleher *et al.,* 2001, Document ID 1363; Madl *et al.,* 2007 (1056)), a beryllium alloy plant (Schuler *et al.,* 2005, Document ID 0473; Thomas *et al.,* 2009 (0590)), and another beryllium processing plant (Rosenman *et al.,* 2005, Document ID 1352) in Pennsylvania. In most of these studies, individuals with an abnormal BeLPT result were retested and were identified as sensitized (*i.e.,* confirmed positive) if the abnormal result was repeated.

In order to investigate the reliability and laboratory variability of the BeLPT, Stange *et al.* (2004, Document ID 1402) studied the BeLPT by splitting blood samples and sending samples to two laboratories simultaneously for BeLPT analysis. Stange *et al.* found the range of agreement on abnormal (positive BeLPT) results was 26.2—61.8 percent depending upon the labs tested (Stange *et al.,* 2004, Document ID 1402). Borak *et al.* (2006) contended that the positive predictive value (PPV) [4] is not high enough to meet the criteria of a good screening tool (Document ID 0498). Middleton *et al.* (2008) used the data from the Stange *et al.* (2004) study to estimate the PPV and determined that the PPV of the BeLPT could be improved from 0.383 to 0.968 when an abnormal BeLPT result is confirmed with a second abnormal result (Middleton *et al.,* 2008, Document ID 0480). In April 2006, the Agency for Toxic Substances and Disease Registry (ATSDR) convened an expert panel of seven physicians and scientists to discuss the BeLPT and to consider what algorithm should be used to interpret BeLPT results to establish beryllium sensitization (Middleton *et al.,* 2008, Document ID 0480). The three criteria proposed by panel members were Criterion A (one abnormal BeLPT result establishes sensitization); Criterion B (one abnormal and one borderline result establish sensitization); and Criterion C (two abnormal results establish sensitization). Using the single-test outcome probabilities developed by Stange *et al.,* the panel convened by ATSDR calculated and compared the sensitivity, specificity, and positive predictive values (PPVs) for each algorithm. The characteristics for each algorithm were as follows:

TABLE 2—CHARACTERISTICS OF BELPT ALGORITHMS (ADAPTED FROM MIDDLETON *et al.,* (2008)

[Adapted from Middleton *et al.,* 2008, Document ID 0480]

	Criterion A (1 abnormal)	Criterion B (1 abnormal + 1 borderline)	Criterion C (2 abnormal)
Sensitivity	68.2%	65.7%	61.2%
Specificity	98.89%	99.92%	99.98%
PPV at 1% prevalence	38.3%	89.3%	96.8%
PPV at 10% prevalence	87.2%	98.9%	99.7%

[4] PPV is the portion of patients with positive test result correctly diagnosed.

TABLE 2—CHARACTERISTICS OF BELPT ALGORITHMS (ADAPTED FROM MIDDLETON *et al.,* (2008)—Continued

[Adapted from Middleton *et al.,* 2008, Document ID 0480]

	Criterion A (1 abnormal)	Criterion B (1 abnormal + 1 borderline)	Criterion C (2 abnormal)
False positives per 10,000	111	8	2

The Middleton *et al.* (2008) study demonstrated that confirmation of BeLPT results, whether as one abnormal and one borderline abnormal or as two abnormals, enhances the test's PPV and protects the persons tested from unnecessary and invasive medical procedures. In populations with a high prevalence of beryllium sensitization (*i.e.,* 10 percent or more), however, a single test may be adequate to predict sensitization (Middleton *et al.,* 2008, Document ID 0480).

Still, there has been criticism regarding the reliability and specificity of the BeLPT as a screening tool and that the BeLPT has not been validated appropriately (Cher *et al.,* 2006, as cited in Document ID 1678; Borak *et al.,* 2006 (0498); Donovan *et al.,* 2007 (0491); Document ID 1678, Attachment 1, p. 6). Even when a confirmational second test is performed, an apparent false positive can occur in people not occupationally exposed to beryllium (NAS, 2008, Document ID 1355). An analysis of survey data from the general workforce and new employees at a beryllium manufacturer was performed to assess the reliability of the BeLPT (Donovan *et al.* 2007, Document ID 0491). Donovan *et al.* analyzed more than 10,000 test results from nearly 2400 participants over a 12-year period. Donovan *et al.* found that approximately 2 percent of new employees had at least one positive BeLPT at the time of hire and 1 percent of new hires with no known occupational exposure were confirmed positive at the time of hire with two BeLPTs. However, this should not be considered unusual because there have been reported incidences of non-occupational and community-based beryllium sensitization (Eisenbud *et al.,* 1949, Document ID 1284; Leiben and Metzner, 1959 (1343); Newman and Kreiss, 1992 (1440); Maier and Rossman, 2008 (0598); NAS, 2008 (1355); Harber *et al.,* 2014 (0415), Harber *et al.,* 2014 (0421)).

Materion objected to OSHA treating ''two or three uninterpretable or borderline abnormal BeLPT test results as confirmation of BeS for the purposes of the standard'' (Document ID 1808, p. 4). In order to address some criticism regarding the PPV of the BeLPT, Middleton *et al.* (2011) conducted another study to evaluate borderline results from BeLPT testing (Document ID 0399). Utilizing the common clinical algorithm with a criterion that accepted one abnormal result and one borderline result as establishing beryllium sensitization resulted in a PPV of 94.4 percent. This study also found that three borderline results resulted in a PPV of 91 percent. Both of these PPVs were based on a population prevalence of 2 percent. This study further demonstrates the value of borderline results in predicting beryllium sensitization using the BeLPT. OSHA finds that multiple, consistent borderline BeLPT results (as found with three borderline results) recognize a change in a person's immune system to beryllium exposure. In addition, a study by Harber *et al.* (2014) reexamined the algorithms to determine sensitization and CBD data using the BioBank data.[5] The study suggested that changing the algorithm could potentially help distinguish sensitization from progression to CBD (Harber *et al.,* 2014, Document ID 0363).

Materion further contended that ''[w]hile some refer to BeLPT testing as a 'gold' standard for BeS, it is hardly 'golden,' as numerous commentators have noted.'' (Document ID 1808, p. 4). NIOSH submitted testimony to OSHA comparing the use of the BeLPT for determining beryllium sensitization to other common medical screening tools such as mammography for breast cancer, tuberculin skin test for latent tuberculosis infection, prostate-specific antigen (PSA) for prostate cancer, and fecal occult blood testing for colon cancer. NIOSH stated that ''[a]lthough there is no gold standard test to identify beryllium sensitization, BeLPT has been estimated to have a sensitivity of 66–86% and a specificity of >99% for sensitization [Middleton *et al.* (2006)]. These values are comparable or superior to those of other common medical screening tests.'' (Document ID 1725, pp. 32–33). In addition, Dr. Maier of National Jewish Health stated during the public hearing that ''medical surveillance should rely on the BeLPT or a similar test if validated in the future, as it detects early and late beryllium health effects. It has been validated in many population-based studies.'' (Document ID 1756, Tr. 103).

Since there are currently no alternatives to the BeLPT in a beryllium sensitization screening program, many programs rely on a second test to confirm a positive result (NAS, 2008). Various expert organizations support the use of the BeLPT (with a second confirmational test) as a screening tool for beryllium sensitization and CBD. The American Thoracic Society (ATS), based on a systematic review of the literature, noted that ''the BeLPT is the cornerstone of medical surveillance'' (Balmes *et al.,* 2014; Document ID 0364, pp. 1–2). The use of the BeLPT in medical surveillance has been endorsed by the National Academies in their review of beryllium-related diseases and disease prevention programs for the U. S. Air Force (NAS, 2008, Document ID 1355). In 2011, NIOSH issued an alert ''Preventing Sensitization and Disease from Beryllium Exposure'' where the BeLPT is recommended as part of a medical screening and surveillance program (NIOSH, 2011, Document ID 0544). OSHA finds that the BeLPT is a useful and reliable test method that has been utilized in numerous studies and validated and improved through multiple studies.

The epidemiological studies presented in this section utilized the BeLPT as either a surveillance tool or a screening tool for determining sensitization status and/or sensitization/CBD prevalence in workers for inclusion in the published studies. Most epidemiological studies have reported rates of sensitization and disease based on a single screening of a working population (''cross-sectional'' or ''population prevalence'' rates). Studies of workers in a beryllium machining plant and a nuclear weapons facility have included follow-up of the population originally screened, resulting in the detection of additional cases of sensitization over several years (Newman *et al.,* 2001, Document ID 1354; Stange *et al.,* 2001 (1403)). Based on the studies above, as well as comments from NIOSH, ATS, and National Jewish Health, OSHA regards

[5] BioBank is a repository of biological specimens and clinical data collected from beryllium-exposed Department of Energy workers and contractors.

the BeLPT as a reliable medical surveillance tool.

c. Beryllium Mining and Extraction

Mining and extraction of beryllium usually involves the two major beryllium minerals, beryl (an aluminosilicate containing up to 4 percent beryllium) and bertrandite (a beryllium silicate hydrate containing generally less than 1 percent beryllium) (WHO, 2001, Document ID 1282). The United States is the world leader in beryllium extraction and also leads the world in production and use of beryllium and its alloys (WHO, 2001, Document ID 1282). Most exposures from mining and extraction come in the form of beryllium ore, beryllium salts, beryllium hydroxide (NAS, 2008, Document ID 1355) or beryllium oxide (Stefaniak *et al.,* 2008, Document ID 1397).

Deubner *et al.* published a study of 75 workers employed at a beryllium mining and extraction facility in Delta, UT (Deubner *et al.,* 2001b, Document ID 1543). Of the 75 workers surveyed for sensitization with the BeLPT, three were identified as sensitized by an abnormal BeLPT result. One of those found to be sensitized was diagnosed with CBD. Exposures at the facility included primarily beryllium ore and salts. General area (GA), breathing zone (BZ), and personal lapel (LP) exposure samples were collected from 1970 to 1999. Jobs involving beryllium hydrolysis and wet-grinding activities had the highest air concentrations, with an annual median GA concentration ranging from 0.1 to 0.4 μg/m^3. Median BZ concentrations were higher than either LP or GA concentrations. The average duration of exposure for beryllium sensitized workers was 21.3 years (27.7 years for the worker with CBD), compared to an average duration for all workers of 14.9 years. However, these exposures were less than either the Elmore, OH, or Tucson, AZ, facilities described below, which also had higher reported rates of BeS and CBD. A study by Stefaniak *et al.* (2008) demonstrated that beryllium was present at the mill in three forms: Mineral, poorly crystalline oxide, and hydroxide (Document ID 1397).

There was no sensitization or CBD among those who worked only at the mine where exposure to beryllium resulted solely from working with bertrandite ore. The authors concluded that the results of this study indicated that beryllium ore and salts may pose less of a hazard than beryllium metal and beryllium hydroxide. These results are consistent with the previously discussed animal studies examining solubility and particle size.

d. Beryllium Metal Processing and Alloy Production

Kreiss *et al.* (1997) conducted a study of workers at a beryllium production facility in Elmore, OH (Document ID 1360). The plant, which opened in 1953 and initially specialized in production of beryllium-copper alloy, later expanded its operations to include beryllium metal, beryllium oxide, and beryllium-aluminum alloy production; beryllium and beryllium alloy machining; and beryllium ceramics production, which was moved to a different factory in the early 1980s. Production operations included a wide variety of jobs and processes, such as work in arc furnaces and furnace rebuilding, alloy melting and casting, beryllium powder processing, and work in the pebble plant. Non-production work included jobs in the analytical laboratory, engineering research and development, maintenance, laundry, production-area management, and office-area administration. While the publication refers to the use of respiratory protection in some areas, such as the pebble plant, the extent of its use across all jobs or time periods was not reported. Use of dermal PPE was not reported.

The authors characterized exposures at the plant using industrial hygiene (IH) samples collected between 1980 and 1993. The exposure samples and the plant's formulas for estimating workers' DWA exposures were used, together with study participants' work histories, to estimate their cumulative and average beryllium exposure levels. Exposure concentrations reflected the high exposures found historically in beryllium production and processing. Short-term BZ measurements had a median of 1.4 μg/m^3, with 18.5 percent of samples exceeding OSHA's preceding permissible ceiling concentration of 5.0 μg/m^3. Particularly high beryllium concentrations were reported in the areas of beryllium powder production, laundry, alloy arc furnace (approximately 40 percent of DWA estimates over 2.0 μg/m^3) and furnace rebuild (28.6 percent of short-term BZ samples over the preceding OSHA permissible ceiling concentration of 5 μg/m^3). LP samples (n = 179), which were available from 1990 to 1992, had a median value of 1 μg/m^3.

Of 655 workers employed at the time of the study, 627 underwent BeLPT screening. Blood samples were divided and split between two labs for analysis, with repeat testing for results that were abnormal or indeterminate. Thirty-one workers had an abnormal blood test result upon initial testing and at least one of two subsequent test results for each of those workers confirmed the worker as sensitized. These workers, together with 19 workers who had an initial abnormal result and one subsequent indeterminate result, were offered clinical evaluation for CBD including the BAL-BeLPT and transbronchial lung biopsy. Nine workers with an initial abnormal test followed by two subsequent normal tests were not clinically evaluated, although four were found to be sensitized upon retesting in 1995. Of 47 workers who proceeded with evaluation for CBD (3 of the 50 initial workers with abnormal results declined to participate), 24 workers were diagnosed with CBD based on evidence of granulomas on lung biopsy (20 workers) or on other findings consistent with CBD (4 workers) (Kreiss *et al.,* 1997, Document ID 1360). After including five workers who had been diagnosed prior to the study, a total of 29 (4.6 percent of the 627 workers who underwent BeLPT screening) workers still employed at the time of the study were found to have CBD. In addition, the plant medical department identified 24 former workers diagnosed with CBD before the study.

Kreiss *et al.* reported that the highest prevalence of sensitization and CBD occurred among workers employed in beryllium metal production, even though the highest airborne total mass concentrations of beryllium were generally among employees operating the beryllium alloy furnaces in a different area of the plant (Kreiss *et al.,* 1997, Document ID 1360). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*i.e.,* particles <10 μm in diameter as defined by the authors) and alveolar-deposited (*i.e.,* particles <1 μm in diameter as defined by the authors) beryllium mass and particle number concentrations, as collected by a general area impactor device, were measured at the beryllium metal production furnaces rather than the beryllium alloy furnaces (Kent *et al.,* 2001, Document ID 1361; McCawley *et al.,* 2001 (1357)). A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The authors concluded that alveolar-deposited particles may be a more relevant exposure metric for predicting the incidence of CBD or sensitization

than the total mass concentration of airborne beryllium.

Bailey *et al.* (2010) (Document ID 0610) evaluated the effectiveness of a workplace preventive program in lowering incidences of sensitization at the beryllium metal, oxide, and alloy production plant studied by Kreiss *et al.* (1997) (Document ID 1360). The preventive program included use of administrative and PPE controls (*e.g.,* improved training, skin protection and other PPE, half-mask or air-purified respirators, medical surveillance, improved housekeeping standards, clean uniforms) as well as engineering and administrative controls (*e.g.,* migration controls, physical separation of administrative offices from production facilities) implemented over the course of five years.

In a cross-sectional/longitudinal hybrid study, Bailey *et al.* compared rates of sensitization in pre-program workers to those hired after the preventive program began. Pre-program workers were surveyed cross-sectionally in 1993–1994, and again in 1999 using the BeLPT to determine sensitization and CBD prevalence rates. The 1999 cross-sectional survey was conducted to determine if improvements in engineering and administrative controls were successful. However, results indicated no improvement in reducing rates of sensitization or CBD.

An enhanced preventive program including particle migration control, respiratory and dermal protection, and process enclosure was implemented in 2000, with continuing improvements made to the program in 2001, 2002–2004, and 2005. Workers hired during this period were longitudinally surveyed for sensitization using the BeLPT. Both the pre-program and program survey of worker sensitization status utilized split-sample testing to verify positive test results using the BeLPT. Of the total 660 workers employed at the production plant, 258 workers participated from the pre-program group while 290 participated from the program group (206 partial program, 84 full program). Prevalence comparisons of the pre-program and program groups (partial and full) were performed by calculating prevalence ratios. A 95 percent confidence interval (95 percent CI) was derived using a cohort study method that accounted for the variance in survey techniques (cross-sectional versus longitudinal) (Bailey *et al.,* 2010). The sensitization prevalence of the pre-program group was 3.8 times higher (95 percent CI, 1.5–9.3) than the program group, 4.0 times higher (95 percent CI, 1.4–11.6) than the partial program subgroup, and 3.3 times higher (95 percent CI, 0.8–13.7) than the full program subgroup indicating that a comprehensive preventive program can reduce, but not eliminate, occurrence of sensitization among non-sensitized workers (Bailey *et al.,* 2010, Document ID 0610).

Rosenman *et al.* (2005) studied a group of several hundred workers who had been employed at a beryllium production and processing facility that operated in eastern Pennsylvania between 1957 and 1978 (Document ID 1352). Of 715 former workers located, 577 were screened for beryllium sensitization with the BLPT and 544 underwent chest radiography to identify cases of beryllium sensitization and CBD. Workers were reported to have exposure to beryllium dust and fume in a variety of chemical forms including beryl ore, beryllium metal, beryllium fluoride, beryllium hydroxide, and beryllium oxide.

Rosenman *et al.* used the plant's DWA formulas to assess workers' full-shift exposure levels, based on IH data collected between 1957–1962 and 1971–1976, to calculate exposure metrics including cumulative, average, and peak for each worker in the study (Document ID 1352). The DWA was calculated based on air monitoring that consisted of GA and short-term task-based BZ samples. Workers' exposures to specific chemical and physical forms of beryllium were assessed, including poorly soluble beryllium (metal and oxide), soluble beryllium (fluoride and hydroxide), mixed soluble and poorly soluble beryllium, beryllium dust (metal, hydroxide, or oxide), fume (fluoride), and mixed dust and fume. Use of respiratory or dermal protection by workers was not reported. Exposures in the plant were high overall. Representative task-based IH samples ranged from 0.9 $\mu g/m^3$ to 84 $\mu g/m^3$ in the 1960s, falling to a range of 0.5–16.7 $\mu g/m^3$ in the 1970s. A large number of workers' mean DWA estimates (25 percent) were above the preceding OSHA PEL of 2.0 $\mu g/m^3$, while most workers had mean DWA exposures between 0.2 and 2.0 $\mu g/m^3$ (74 percent) or below 0.02 $\mu g/m^3$ (1 percent) (Rosenman *et al.,* Table 11; revised erratum April, 2006, Document ID 1352).

Blood samples for the BeLPT were collected from the former workers between 1996 and 2001 and were evaluated at a single laboratory. Individuals with an abnormal test result were offered repeat testing, and were classified as sensitized if the second test was also abnormal. Sixty workers with two positive BeLPTs and 50 additional workers with chest radiography suggestive of disease were offered clinical evaluation, including bronchoscopy with bronchial biopsy and BAL-BeLPT. Seven workers met both criteria. Only 56 (51 percent) of these workers proceeded with clinical evaluation, including 57 percent of those referred on the basis of confirmed abnormal BeLPT and 47 percent of those with abnormal radiographs (Document ID 1352).

Of the 577 workers who were evaluated for CBD, 32 (5.5 percent) with evidence of granulomas were classified as ''definite'' CBD cases (as identified by bronchoscopy). Twelve (2.1 percent) additional workers with positive BAL-BeLPT or confirmed positive BeLPT and radiographic evidence of upper lobe fibrosis were classified as ''probable'' CBD cases. Forty workers (6.9 percent) without upper lobe fibrosis who had confirmed abnormal BeLPT, but who were not biopsied or who underwent biopsy with no evidence of granuloma, were classified as sensitized without disease. It is not clear how many of those 40 workers underwent biopsy. Another 12 (2.1 percent) workers with upper lobe fibrosis and negative or unconfirmed positive BeLPT were classified as ''possible'' CBD cases. Nine additional workers who were diagnosed with CBD before the screening were included in some parts of the authors' analysis (Document ID 1352).

The authors reported a total prevalence of 14.5 percent for CBD (definite and probable) and sensitization. This rate, considerably higher than the overall prevalence of sensitization and disease in several other worker cohorts as described earlier in this section, reflects in part the very high exposures experienced by many workers during the plant's operation in the 1950s, 1960s and 1970s. A total of 115 workers had mean DWAs above the preceding OSHA PEL of 2 $\mu g/m^3$. Of those, seven (6.0 percent) had definite or probable CBD and another 13 (11 percent) were classified as sensitized without disease. The true prevalence of CBD in the group may be higher than reported, due to the low rate of clinical evaluation among sensitized workers (Document ID 1352).

Although most of the workers in this study had high exposures, sensitization and CBD also were observed within the small subgroup of participants believed to have relatively low beryllium exposures. Thirty-three cases of CBD and 24 additional cases of sensitization occurred among 339 workers with mean DWA exposures below OSHA's PEL of 2.0 $\mu g/m^3$ (Rosenman *et al.,* Table 11, erratum 2006, Document ID 1352). Ten cases of sensitization and five cases of

CBD were found among office and clerical workers, who were believed to have low exposures (levels not reported).

Follow-up time for sensitization screening of workers in this study who became sensitized during their employment had a minimum of 20 years to develop CBD prior to screening. In this sense the cohort is especially well suited to compare the exposure patterns of workers with CBD and those sensitized without disease, in contrast to several other studies of workers with only recent beryllium exposures. Rosenman *et al.* characterized and compared the exposures of workers with definite and probable CBD, sensitization only, and no disease or sensitization using chi-squared tests for discrete outcomes and analysis of variance (ANOVA) for continuous variables (cumulative, mean, and peak exposure levels). Exposure-response relationships were further examined with logistic regression analysis, adjusting for potential confounders including smoking, age, and beryllium exposure from outside of the plant. The authors found that cumulative, peak, and duration of exposure were significantly higher for workers with CBD than for sensitized workers without disease ($p < 0.05$), suggesting that the risk of progressing from sensitization to CBD is related to the level or extent of exposure a worker experiences. The risk of developing CBD following sensitization appeared strongly related to exposure to poorly soluble forms of beryllium, which are cleared slowly from the lung and increase beryllium lung burden more rapidly than quickly mobilized soluble forms. Individuals with CBD had higher exposures to poorly soluble beryllium than those classified as sensitized without disease, while exposure to soluble beryllium was higher among sensitized individuals than those with CBD (Document ID 1352).

Cumulative, mean, peak, and duration of exposure were found to be comparable for workers with CBD and workers without sensitization or CBD (''normal'' workers). Cumulative, peak, and duration of exposure were significantly lower for sensitized workers without disease than for normal workers. Rosenman *et al.* suggested that genetic predisposition to sensitization and CBD may have obscured an exposure-response relationship in this study, and plan to control for genetic risk factors in future studies. Exposure misclassification from the 1950s and 1960s may have been another limitation in this study, introducing bias that could have influenced the lack of exposure response. It is also unknown if the 25 percent who died from CBD-related conditions may have had higher exposures (Document ID 1352).

A follow-up was conducted of the cross-sectional study of a population of workers first evaluated by Kreiss *et al.* (1997) (Document ID 1360) and Rosenman *et al.* (2005) (Document ID 1352) by Schuler *et al.* (2012) (Document ID 0473), and in a companion study by Virji *et al.* (2012) (Document ID 0466). Schuler *et al.* evaluated the worker population employed in 1999 with six years or less work tenure in a cross-sectional study. The investigators evaluated the worker population by administering a work history questionnaire with a follow-up examination for sensitization and CBD. A job-exposure matrix (JEM) was combined with work histories to create individual estimates of average, cumulative, and highest-job-related exposure for total, respirable, and sub-micron beryllium mass concentration. Of the 291 eligible workers, 90.7 percent (264) participated in the study. Sensitization prevalence was 9.8 percent (26/264) with CBD prevalence of 2.3 percent (6/264). The investigators found a general pattern of increasing sensitization prevalence as the exposure quartile increased indicating an exposure-response relationship. The investigators found positive associations with both total and respirable mass concentration with sensitization (average and highest job) and CBD (cumulative). Increased sensitization prevalence was observed with metal oxide production alloy melting and casting, and maintenance. CBD was associated with melting and casting. The investigators summarized that both total and respirable mass concentration were relevant predictors of risk (Schuler *et al.,* 2012, Document ID 0473).

In the companion study by Virji *et al.* (2012), the investigators reconstructed historical exposure from 1994 to 1999 utilizing the personal sampling data collected in 1999 as baseline exposure estimates (BEE) (Document ID 0466). The study evaluated techniques for reconstructing historical data to evaluate exposure-response relationships for epidemiological studies. The investigators constructed JEMs using the BEE and estimates of annual changes in exposure for 25 different process areas. The investigators concluded these reconstructed JEMs could be used to evaluate a range of exposure parameters from total, respirable and submicron mass concentration including cumulative, average, and highest exposure.

e. Beryllium Machining Operations

Newman *et al.* (2001) (Document ID 1354) and Kelleher *et al.* (2001) (Document ID 1363) studied a group of 235 workers at a beryllium metal machining plant. Since the plant opened in 1969, its primary operations have been machining and polishing beryllium metal and high-beryllium content composite materials, with occasional machining of beryllium oxide/metal matrix ('E-metal'), and beryllium alloys. Other functions include machining of metals other than beryllium; receipt and inspection of materials; acid etching; final inspection, quality control, and shipping of finished materials; tool making; and engineering, maintenance, administrative, and supervisory functions (Newman *et al.,* 2001, Document ID 1354; Madl *et al.,* 2007 (1056)). Machining operations, including milling, grinding, lapping, deburring, lathing, and electrical discharge machining (EDM) were performed in an open-floor plan production area. Most non-machining jobs were located in a separate, adjacent area; however, non-production employees had access to the machining area.

Engineering and administrative controls, rather than PPE, were primarily used to control beryllium exposures at the plant (Madl *et al.,* 2007, Document ID 1056). Based on interviews with long-standing employees of the plant, Kelleher *et al.* reported that work practices were relatively stable until 1994, when a worker was diagnosed with CBD and a new exposure control program was initiated. Between 1995 and 1999, new engineering and work practice controls were implemented, including removal of pressurized air hoses and discouragement of dry sweeping (1995), enclosure of deburring processes (1996), mandatory uniforms (1997), and installation or updating of local exhaust ventilation (LEV) in EDM, lapping, deburring, and grinding processes (1998) (Madl *et al.,* 2007, Document ID 1056). Throughout the plant's history, respiratory protection was used mainly for ''unusually large, anticipated exposures'' to beryllium (Kelleher *et al.,* 2001, Document ID 1363), and was not routinely used otherwise (Newman *et al.,* 2001, Document ID 1354).

All workers at the plant participated in a beryllium disease surveillance program initiated in 1994, and were screened for beryllium sensitization with the BeLPT beginning in 1995. A BeLPT result was considered abnormal if two or more of six stimulation indices exceeded the normal range (see section

on BeLPT testing above), and was considered borderline if one of the indices exceeded the normal range. A repeat BeLPT was conducted for workers with abnormal or borderline initial results. Workers were identified as beryllium sensitized and referred for a clinical evaluation, including BAL and transbronchial lung biopsy, if the repeat test was abnormal. CBD was diagnosed upon evidence of sensitization with granulomas or mononuclear cell infiltrates in the lung tissue (Newman *et al.,* 2001, Document ID 1354). Following the initial plant-wide screening, plant employees were offered BeLPT testing at two-year intervals. Workers hired after the initial screening were offered a BeLPT within 3 months of their hire date, and at 2-year intervals thereafter (Madl *et al.,* 2007, Document ID 1056).

Kelleher *et al.* performed a nested case-control study of the 235 workers evaluated in Newman *et al.* (2001) to evaluate the relationship between beryllium exposure levels and risk of sensitization and CBD (Kelleher *et al.,* 2001, Document ID 1363). The authors evaluated exposures at the plant using IH samples they had collected between 1996 and 1999, using personal cascade impactors designed to measure the mass of beryllium particles less than 6 μm in diameter, particles less than 1 μm in diameter, and total mass. The great majority of workers' exposures were below the preceding OSHA PEL of 2 μg/m^3. However, a few higher exposure levels were observed in machining jobs including deburring, lathing, lapping, and grinding. Based on a statistical comparison between their samples and historical data provided by the plant, the authors concluded that worker beryllium exposures across all time periods included in the study parameters (1981 to 1984, 1995 to 1997, and 1998 to 1999) could be approximated using the 1996–1999 data. They estimated workers' cumulative and ''lifetime weighted'' (LTW) beryllium exposure based on the exposure samples they collected for each job in 1996–1999 and company records of each worker's job history.

Twenty workers with beryllium sensitization or CBD (cases) were compared to 206 workers (controls) for the case-control analysis from the study evaluating workers originally conducted by Newman *et al.* Of the 20 workers composing the case group, thirteen workers were diagnosed with CBD based on lung biopsy evidence of granulomas and/or mononuclear cell infiltrates (11) or positive BAL results with evidence of lymphocytosis (2). The other seven were evaluated for CBD and found to be sensitized only. Nine of the remaining 215 workers first identified in original study (Newman *et al.,* 2001, Document ID 1354) were excluded due to incomplete job history information, leaving 206 workers in the control group.

Kelleher *et al.*'s analysis included comparisons of the case and control groups' median exposure levels; calculation of odds ratios for workers in high, medium, and low exposure groups; and logistic regression testing of the association of sensitization or CBD with exposure level and other variables. Median cumulative exposures for total mass, particles less than 6 μm in diameter, and particles less than 1 μm in diameter were approximately three times higher among the cases than controls, although the relationships observed were not statistically significant (p values ~ 0.2). No clear difference between cases and controls was observed for the median LTW exposures. Odds ratios with sensitization and CBD as outcomes were elevated in high (upper third) and intermediate exposure groups relative to low (lowest third) exposure groups for both cumulative and LTW exposure, though the results were not statistically significant (p >0.1). In the logistic regression analysis, only machinist work history was a significant predictor of case status in the final model. Quantitative exposure measures were not significant predictors of sensitization or disease risk.

Citing an 11.5 percent prevalence of beryllium sensitization or CBD among machinists as compared with 2.9 percent prevalence among workers with no machinist work history, the authors concluded that the risk of sensitization and CBD is increased among workers who machine beryllium. Although differences between cases and controls in median cumulative exposure did not achieve conventional thresholds for statistical significance, the authors noted that cumulative exposures were consistently higher among cases than controls for all categories of exposure estimates and for all particle sizes, suggesting an effect of cumulative exposure on risk. The levels at which workers developed CBD and sensitization were predominantly below OSHA's preceding PEL of 2 μg/m^3, and no cases of sensitization or CBD were observed among workers with LTW exposure less than 0.02 μg/m^3. Twelve (60 percent) of the 20 sensitized workers had LTW exposures >0.20 μg/m^3.

In 2007, Madl *et al.* published an additional study of 27 workers at the machining plant who were found to be sensitized or diagnosed with CBD between the start of medical surveillance in 1995 and 2005 (Madl *et al.,* 2007, Document ID 1056). As previously described, workers were offered a BeLPT in the initial 1995 screening (or within 3 months of their hire date if hired after 1995) and at 2-year intervals after their first screening. Workers with two positive BeLPTs were identified as sensitized and offered clinical evaluation for CBD, including bronchoscopy with BAL and transbronchial lung biopsy. The criteria for CBD in this study were somewhat stricter than those used in the Newman *et al.* study, requiring evidence of granulomas on lung biopsy or detection of X-ray or pulmonary function changes associated with CBD, in combination with two positive BeLPTs or one positive BAL-BeLPT.

Based on the history of the plant's control efforts and their analysis of historical IH data, Madl *et al.* identified three ''exposure control eras'': A relatively uncontrolled period from 1980–1995; a transitional period from 1996 to 1999; and a relatively well-controlled ''modern'' period from 2000–2005. They found that the engineering and work practice controls instituted in the mid-1990s reduced workers' exposures substantially, with nearly a 15-fold difference in reported exposure levels between the pre-control and the modern period (Madl *et al.,* 2007, Document ID 1056). Madl *et al.* estimated workers' exposures using LP samples collected between 1980 and 2005, including those collected by Kelleher *et al.,* and work histories provided by the plant. As described more fully in the study, they used a variety of approaches to describe individual workers' exposures, including approaches designed to characterize the highest exposures workers were likely to have experienced. Their exposure-response analysis was based primarily on an exposure metric they derived by identifying the year and job of each worker's pre-diagnosis work history with the highest reported exposures. They used the upper 95th percentile of the LP samples collected in that job and year (in some cases supplemented with data from other years) to characterize the worker's upper-level exposures.

Based on their estimates of workers' upper level exposures, Madl *et al.* concluded that sensitized workers or workers with CBD were likely to have been exposed to airborne beryllium levels greater than 0.2 μg/m^3 as an 8-hour TWA at some point in their history of employment in the plant. Madl *et al.* also concluded that most sensitization and CBD cases were likely to have been exposed to levels greater than 0.4 μg/m^3

at some point in their work at the plant. Madl *et al.* did not reconstruct exposures for workers at the plant who were not sensitized and did not develop CBD and therefore could not determine whether non-cases had upper-bound exposures lower than these levels. They found that upper-bound exposure estimates were generally higher for workers with CBD than for those who were sensitized but not diagnosed with CBD at the conclusion of the study (Madl *et al.,* 2007, Document ID 1056). Because CBD is an immunological disease and beryllium sensitization has been shown to occur within a year of exposure for some workers, Madl *et al.* argued that their estimates of workers' short-term upper-bound exposures may better capture the exposure levels that led to sensitization and disease than estimates of long-term cumulative or average exposures such as the LTW exposure measure constructed by Kelleher *et al.* (Madl *et al.,* 2007, Document ID 1056).

f. Beryllium Oxide Ceramics

Kreiss *et al.* (1993) conducted a screening of current and former workers at a plant that manufactured beryllium ceramics from beryllium oxide between 1958 and 1975, and then transitioned to metalizing circuitry onto beryllium ceramics produced elsewhere (Document ID 1478). Of the plant's 1,316 current and 350 retired workers, 505 participated who had not previously been diagnosed with CBD or sarcoidosis, including 377 current and 128 former workers. Although beryllium exposure was not estimated quantitatively in this survey, the authors conducted a questionnaire to assess study participants' exposures qualitatively. Results showed that 55 percent of participants reported working in jobs with exposure to beryllium dust. Close to 25 percent of participants did not know if they had exposure to beryllium, and just over 20 percent believed they had not been exposed.

BeLPT tests were administered to all 505 participants in the 1989–1990 screening period and evaluated at a single lab. Seven workers had confirmed abnormal BeLPT results and were identified as sensitized; these workers were also diagnosed with CBD based on findings of granulomas upon clinical evaluation. Radiograph screening led to clinical evaluation and diagnosis of two additional CBD cases, who were among three participants with initially abnormal BeLPT results that could not be confirmed on repeat testing. In addition, nine workers had been previously diagnosed with CBD, and another five were diagnosed shortly after the screening period, in 1991–1992.

Eight of the 9 CBD cases identified in the screening population were hired before the plant stopped producing beryllium ceramics in 1975, and were among the 216 participants who had reported having been near or exposed to beryllium dust. Particularly high CBD rates of 11.1 to 15.8 percent were found among screening participants who had worked in process development/engineering, dry pressing, and ventilation maintenance jobs believed to have high or uncontrolled dust exposure. One case (0.6 percent) of CBD was diagnosed among the 171 study participants who had been hired after the plant stopped producing beryllium ceramics. Although this worker was hired eight years after the end of ceramics production, he had worked in an area later found to be contaminated with beryllium dust. The authors concluded that the study results suggested an exposure-response relationship between beryllium exposure and CBD, and recommended beryllium exposure control to reduce workers' risk of CBD.

Kreiss *et al.* later published a study of workers at a second ceramics plant located in Tucson, AZ (Kreiss *et al.,* 1996, Document ID 1477), which since 1980 had produced beryllium ceramics from beryllium oxide powder manufactured elsewhere. IH measurements collected between 1981 and 1992, primarily GA or short-term BZ samples and a few (<100) LP samples, were available from the plant. Airborne beryllium exposures were generally low. The majority of area samples were below the analytical detection limit of 0.1 $\mu g/m^3$, while LP and short-term BZ samples had medians of 0.3 $\mu g/m^3$. However, 3.6 percent of short-term BZ samples and 0.7 percent of GA samples exceeded 5.0 $\mu g/m^3$, while LP samples ranged from 0.1 to 1.8 $\mu g/m^3$. Machining jobs had the highest beryllium exposure levels among job tasks, with short-term BZ samples significantly higher for machining jobs than for non-machining jobs (median 0.6 $\mu g/m^3$ vs. 0.3 $\mu g/m^3$, $p = 0.0001$). The authors used DWA formulas provided by the plant to estimate workers' full-shift exposure levels, and to calculate cumulative and average beryllium exposures for each worker in the study. The median cumulative exposure was 591.7 mg-days/m^3 and the median average exposure was 0.35 $\mu g/m^3$ as a DWA.

One hundred thirty-six of the 139 workers employed at the plant at the time of the Kreiss *et al.* (1996) study underwent BeLPT screening and chest radiographs in 1992 (Document ID 1477). Blood samples were split between two laboratories. If one or both test results were abnormal, an additional sample was collected and split between the labs. Seven workers with an abnormal result on two draws were initially identified as sensitized. Those with confirmed abnormal BeLPTs or abnormal chest X-rays were offered clinical evaluation for CBD, including transbronchial lung biopsy and BAL BeLPT. CBD was diagnosed based on observation of granulomas on lung biopsy, in five of the six sensitized workers who accepted evaluation. An eighth case of sensitization and sixth case of CBD were diagnosed in one worker hired in October 1991 whose initial BeLPT was normal, but who was confirmed as sensitized and found to have lung granulomas less than two years later, after sustaining a beryllium-contaminated skin wound. The plant medical department reported 11 additional cases of CBD among former workers (Kreiss *et al.,* 1996, Document ID 1477). The overall prevalence of sensitization in the plant was 5.9 percent, with a 4.4 percent prevalence of CBD.

Kreiss *et al.* (1996) (Document ID 1477) reported that six (75 percent) of the eight sensitized workers were exposed as machinists during or before the period October 1985–March 1988, when measurements were first available for machining jobs. The authors reported that 14.3 percent of machinists were sensitized, compared to 1.2 percent of workers who had never been machinists ($p < 0.01$). Workers' estimated cumulative and average beryllium exposures did not differ significantly for machinists and non-machinists, or for cases and non-cases. As in the previous study of the same ceramics plant published by Kreiss *et al.* in 1993 (Document ID 1478), one case of CBD was diagnosed in a worker who had never been employed in a production job. This worker was employed in office administration, a job with a median DWA of 0.1 $\mu g/m^3$ (range 0.1–0.3 $\mu g/m^3$).

In 1998, Henneberger *et al.* conducted a follow-up cross-sectional survey of 151 employees employed at the beryllium ceramics plant studied by Kreiss *et al.* (1996) (Henneberger *et al.,* 2001, Document ID 1313). All current plant employees were eligible for the study unless they had previously been diagnosed with CBD. The study tracked two sets of workers in presenting prevalence outcomes and exposure characterization. ''Short-term workers'' were those hired since the last plant survey in 1992. ''Long-term workers''

were those hired before 1992 and had a longer history of beryllium exposures. There were 74 short-term and 77 long-term workers in the survey (Henneberger *et al.,* 2001, Document ID 1313).

The authors estimated workers' cumulative, average, and peak beryllium exposures based on the plant's formulas for estimating job-specific DWA exposures, participants' work histories, and area and short-term task-specific BZ samples collected from the start of full production at the plant in 1981 to 1998. The long-term workers, who were hired before the 1992 study was conducted, had generally higher estimated exposures (median—0.39 μg/m^3; mean—14.9 μg/m^3) than the short-term workers, who were hired after 1992 (median—0.28 μg/m^3, mean—6.1 μg/m^3).

Fifteen cases of sensitization were found in the 151 study participants (15/151; 9.9%), including seven among short-term (7/74; 9.5%) and eight among long-term workers (8/77; 10.4%). There were eight cases of CBD (8/151; 5.3%) identified in the study. One sensitized short-term worker developed CBD (1/74; 1.4%). Seven of the eight sensitized long-term workers developed CBD (7/77; 9.1%). The other sensitized long-term worker declined to participate in the clinical evaluation.

Henneberger *et al.* (2001) reported a higher prevalence of sensitization among long-term workers with ''high'' (greater than median) peak exposures compared to long-term workers with ''low'' exposures; however, this relationship was not statistically significant (Document ID 1313). No association was observed for average or cumulative exposures. The authors reported higher (but not statistically significant) prevalence of sensitization among short-term workers with ''high'' (greater than median) average, cumulative, and peak exposures compared to short-term workers with ''low'' exposures of each type.

The cumulative incidence of sensitization and CBD was investigated in a cohort of 136 workers at the beryllium ceramics plant previously studied by the Kreiss and Henneberger groups (Schuler *et al.,* 2008. Document ID 1291). The study cohort consisted of those who participated in the plant-wide BeLPT screening in 1992. Both current and former workers from this group were invited to participate in follow-up BeLPT screenings in 1998, 2000, and 2002–2003. A total of 106 of the 128 non-sensitized individuals in 1992 participated in the 11-year follow-up. Sensitization was defined as a confirmed abnormal BeLPT based on the split blood sample-dual laboratory protocol described earlier. CBD was diagnosed in sensitized individuals based on pathological findings from transbronchial biopsy and BAL fluid analysis. The 11-year crude cumulative incidence of sensitization and CBD was 13 percent (14 of 106) and 8 percent (9 of 106) respectively. The cumulative prevalence was about triple the point prevalences determined in the initial 1992 cross-sectional survey. The corrected cumulative prevalences for those that ever worked in machining were nearly twice that for non-machinists. The data illustrate the value of longitudinal medical screening over time to obtain a more accurate estimate of the occurrence of sensitization and CBD among an exposed working population.

Following the 1998 survey, the company continued efforts to reduce exposures and risk of sensitization and CBD by implementing additional engineering, administrative, and PPE measures (Cummings *et al.,* 2007, Document ID 1369). Respirator use was required in production areas beginning in 1999, and latex gloves were required beginning in 2000. The lapping area was enclosed in 2000, and enclosures were installed for all mechanical presses in 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. The new engineering measures did not appear to substantially reduce airborne beryllium levels in the plant. LP samples collected between 2000 and 2003 had a median of 0.18 μg/m^3 in production, similar to the 1994–1999 samples. However, respiratory protection requirements to control workers' airborne beryllium exposures were instituted prior to the 2000 sample collections, so actual exposure to the production workers may have been lower than the airborne beryllium levels indicate.

To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment. These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 126 workers hired between 2000 and 2004, 93 completed BeLPT testing at hire and at least one additional test at 3 months of employment. One case of sensitization was identified at 24 months of employment (1 percent of 126 workers). This worker had experienced a rash after an incident of dermal exposure to lapping fluid through a gap between his glove and uniform sleeve, indicating that he may have become sensitized via the skin. He was tested again at 48 months of employment, with an abnormal result.

A second worker in the 2000–2004 group had two abnormal BeLPT tests at the time of hire, and a third had one abnormal test at hire and a second abnormal test at 3 months. Both had normal BeLPTs at 6 months, and were not tested thereafter. A fourth worker had one abnormal BeLPT result at the time of hire, a normal result at 3 months, an abnormal result at 6 months, and a normal result at 12 months. Four additional workers had one abnormal result during surveillance, which could not be confirmed upon repeat testing.

Cummings *et al.* (2007) calculated two sensitization rates based on these screening results: (1) A rate using only the sensitized worker identified at 24 months, and (2) a rate including all four workers who had repeated abnormal results (Document ID 1369). They reported a sensitization incidence rate (IR) of 0.7 per 1,000 person-months to 2.7 per 1,000 person-months for the workers hired between 2000 and 2004, using the sum of sensitization-free months of employment among all 93 workers as the denominator.

The authors also estimated an incidence rate (IR) of 5.6 per 1,000 person-months for workers hired between 1993 and the 1998 survey. This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the workers' employment. The denominator in this case was the total months of employment until the 1998 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher than 5.6 per 1,000 person-months. Based on comparison of the IRs, the authors concluded that the addition of respirator use, dermal protection, and particle migration control (housekeeping) improvements appeared to have reduced the risk of sensitization among workers at the plant, even though airborne beryllium levels in some areas of the plant had not changed significantly since the 1998 survey.

g. Copper-Beryllium Alloy Processing and Distribution

Schuler *et al.* (2005) studied a group of 152 workers at a facility who processed copper-beryllium alloys and small quantities of nickel-beryllium alloys and converted semi-finished alloy

strip and wire into finished strip, wire, and rod. Production activities included annealing, drawing, straightening, point and chamfer, rod and wire packing, die grinding, pickling, slitting, and degreasing. Periodically in the plant's history, it also performed salt baths, cadmium plating, welding and deburring. Since the late 1980s, rod and wire production processes have been physically segregated from strip metal production. Production support jobs included mechanical maintenance, quality assurance, shipping and receiving, inspection, and wastewater treatment. Administration was divided into staff primarily working within the plant and personnel who mostly worked in office areas (Schuler, *et al.,* 2005, Document ID 0919). Workers' respirator use was limited, mostly to occasional tasks where high exposures were anticipated.

Following the 1999 diagnosis of a worker with CBD, the company surveyed the workforce, offering all current employees BeLPT testing in 2000 and offering sensitized workers clinical evaluation for CBD, including BAL and transbronchial biopsy. Of the facility's 185 employees, 152 participated in the BeLPT screening. Samples were split between two laboratories, with additional draws and testing for confirmation if conflicting tests resulted in the initial draw. Ten participants (7 percent) had at least two abnormal BeLPT results. The results of nine workers who had abnormal BeLPT results from only one laboratory were not included because the authors believed the laboratory was experiencing technical problems with the test (Schuler *et al.,* 2005, Document ID 0919). CBD was diagnosed in six workers (4 percent) on evidence of pathogenic abnormalities (*e.g.,* granulomas) or evidence of clinical abnormalities consistent with CBD based on pulmonary function testing, pulmonary exercise testing, and/or chest radiography. One worker diagnosed with CBD had been exposed to beryllium during previous work at another copper-beryllium processing facility.

Schuler *et al.* (2005) evaluated airborne beryllium levels at the plant using IH samples collected between 1969 and 2000, including 4,524 GA samples, 650 LP samples and 815 short-duration (3–5 min) high volume (SD–HV) BZ task-specific samples (Document ID 0919). Occupational exposures to airborne beryllium were generally low. Ninety-nine percent of all LP measurements were below the preceding OSHA PEL of 2.0 μg/m³ (8-hr TWA); 93 percent were below the new final OSHA PEL of 0.2 μg/m³ and the median value was 0.02 μg/m³. The SD–HV BZ samples had a median value of 0.44 μg/m³, with 90 percent below the preceding OSHA ceiling limit of 5.0 μg/m³. The highest levels of beryllium exposure were found in rod and wire production, particularly in wire annealing and pickling, the only production job with a median personal sample measurement greater than 0.1 μg/m³ (median 0.12 μg/m³; range 0.01–7.8 μg/m³) (Schuler *et al.,* Table 4). These concentrations were significantly higher than the exposure levels in the strip metal area (median 0.02 μg/m³, range 0.01–0.72 μg/m³), in production support jobs (median 0.02 μg/m³, range <0.01–0.33 μg/m³), plant administration (median 0.02 μg/m³, range <0.01–0.11 μg/m³), and office administration jobs (median 0.01 μg/m³, range <0.01–0.06 μg/m³).

The authors reported that eight of the ten sensitized employees, including all six CBD cases, had worked in both major production areas during their tenure with the plant. The 7 percent prevalence (6 of 81 workers) of CBD among employees who had ever worked in rod and wire was statistically significantly elevated compared with employees who had never worked in rod and wire ($p < 0.05$), while the 6 percent prevalence (6 of 94 workers) among those who had worked in strip metal was not significantly elevated compared to workers who had never worked in strip metal ($p > 0.1$). Based on these results, together with the higher exposure levels reported for the rod and wire production area, Schuler *et al.* (2005) concluded that work in rod and wire was a key risk factor for CBD in this population. Schuler *et al.* also found a high prevalence (13 percent) of sensitization among workers who had been exposed to beryllium for less than a year at the time of the screening, a rate similar to that found by Henneberger *et al.* (2001) among beryllium ceramics workers exposed for one year or less (16 percent) (Henneberger *et al.,* 2001, Document ID 1313). All four workers who were sensitized without disease had been exposed for 5 years or less; conversely, all six of the workers with CBD had first been exposed to beryllium at least five years prior to the screening (Schuler *et al.,* 2005, Table 2, Document ID 0919).

As has been seen in other studies, beryllium sensitization and CBD were found among workers who were typically exposed to low time-weighted average airborne concentrations of beryllium. While jobs in the rod and wire area had the highest exposure levels in the plant, the median personal sample value was only 0.12 μg/m³ as a DWA. However, workers may have occasionally been exposed to higher beryllium levels for short periods during specific tasks. A small fraction of personal samples recorded in rod and wire were above the preceding OSHA PEL of 2.0 μg/m³, and half of workers with sensitization or CBD reported that they had experienced a ''high-exposure incident'' at some point in their work history (Schuler *et al.,* 2005, Document ID 0919). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with the lowest recorded exposures (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³).

After the BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium (Thomas *et al.,* 2009, Document ID 1061). Measures designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000. In 2001, the company installed LEV in die grinding and polishing. LP samples collected between June 2000 and December 2001 show reduced exposures plant-wide. Of 2,211 exposure samples collected, 98 percent were below 0.2 μg/m³, and 59 percent below the limit of detection (LOD), which was either 0.02 μg/m³ or 0.2 μg/m³ depending on the method of sample analysis (Thomas *et al.,* 2009). Median values below 0.03 μg/m³ were reported for all processes except the wire annealing and pickling process. Samples for this process remained somewhat elevated, with a median of 0.1 μg/m³. In January 2002, the plant enclosed the wire annealing and pickling process in a restricted access zone (RAZ), requiring respiratory protection in the RAZ and implementing stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone. While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–2001 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators indicates that actual respiratory exposure was negligible (Thomas *et al.,* 2009, Document ID 1061).

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers. The company screened workers at the time of hire; at intervals of 3, 6, 12, 24, and 48 months;

and at 3-year intervals thereafter. Among 82 workers hired after 1999, three (3.7 percent) cases of sensitization were found. Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process were found to be sensitized within 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was confirmed as sensitized (Thomas *et al.,* 2009, Document ID 1061).

Thomas *et al.* (2009) calculated a sensitization IR of 1.9 per 1,000 person-months for the workers hired after the exposure control program was initiated in 2000 (''program workers''), using the sum of sensitization-free months of employment among all 82 workers as the denominator (Thomas *et al.,* 2009, Document ID 1061). They calculated an estimated IR of 3.8 per 1,000 person-months for 43 workers hired between 1993 and 2000 who had participated in the 2000 BeLPT screening (''legacy workers''). This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the legacy workers' employment. The denominator in this case is the total months of employment until the 2000 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher than 3.8 per 1,000 person-months. Based on comparison of the IRs and the prevalence rates discussed previously, the authors concluded that the combination of dermal protection, respiratory protection, housekeeping improvements and engineering controls implemented beginning in 2000 appeared to have reduced the risk of sensitization among workers at the plant. However, they noted that the small size of the study population and the short follow-up time for the program workers suggested that further research is needed to confirm the program's efficacy (Thomas *et al.,* 2009, Document ID 1061).

Stanton *et al.* (2006) (Document ID 1070) conducted a study of workers in three different copper-beryllium alloy distribution centers in the United States. The distribution centers, consisting of one bulk products center established in 1963 and strip metal centers established in 1968 and 1972, sell products received from beryllium production and finishing facilities and small quantities of copper-beryllium, aluminum-beryllium, and nickel-beryllium alloy materials. Work at distribution centers does not require large-scale heat treatment or manipulation of material typical of beryllium processing and machining plants, but involves final processing steps that can generate airborne beryllium. Slitting, the main production activity at the two strip product distribution centers, generates low levels of airborne beryllium particles, while operations such as tensioning and welding used more frequently at the bulk products center can generate somewhat higher levels. Non-production jobs at all three centers included shipping and receiving, palletizing and wrapping, production-area administrative work, and office-area administrative work.

Stanton *et al.* (2006) estimated workers' beryllium exposures using IH data from company records and job history information collected through interviews conducted by a company occupational health nurse (Document ID 1090). Stanton *et al.* evaluated airborne beryllium levels in various jobs based on 393 full-shift LP samples collected from 1996 to 2004. Airborne beryllium levels at the plant were generally very low, with 54 percent of all samples at or below the LOD, which ranged from 0.02 to 0.1 μg/m^3. The authors reported a median of 0.03 μg/m^3 and an arithmetic mean of 0.05 μg/m^3 for the 393 full-shift LP samples, where samples below the LOD were assigned a value of half the applicable LOD. Median values for specific jobs ranged from 0.01–0.07 μg/m^3 while geometric mean values for specific jobs ranged from 0.02–0.07 μg/m^3. All measurements were below the preceding OSHA PEL of 2.0 μg/m^3 and 97 percent were below the new final OSHA PEL of 0.2 μg/m^3. The study does not report use of respiratory or skin protection.

Eighty-eight of the 100 workers (88 percent) employed at the three centers at the time of the study participated in screening for beryllium sensitization. Blood samples were collected between November 2000 and March 2001 by the company's medical staff. Samples collected from employees of the strip metal centers were split and evaluated at two laboratories, while samples from the bulk product center workers were evaluated at a single laboratory. Participants were considered to be ''sensitized'' to beryllium if two or more BeLPT results, from two laboratories or from repeat testing at the same laboratory, were found to be abnormal. One individual was found to be sensitized and was offered clinical evaluation, including BAL and fiberoptic bronchoscopy. He was found to have lung granulomas and was diagnosed with CBD.

The worker diagnosed with CBD had been employed at a strip metal distribution center from 1978 to 2000 as a shipper and receiver, loading and unloading trucks delivering materials from a beryllium production facility and to the distribution center's customers. Although the LP samples collected for his job between 1996 and 2000 were generally low (n = 35, median 0.01 μg/m^3, range <0.02–0.13 μg/m^3), it is not clear whether these samples adequately characterize his exposure conditions over the course of his work history. He reported that early in his work history, containers of beryllium oxide powder were transported on the trucks he entered. While he did not recall seeing any breaks or leaks in the beryllium oxide containers, some containers were known to have been punctured by forklifts on trailers used by the company during the period of his employment, and could have contaminated trucks he entered. With 22 years of employment at the facility, this worker had begun beryllium-related work earlier and performed it longer than about 90 percent of the study population (Stanton *et al.,* 2006, Document ID 1090).

h. Nuclear Weapons Production Facilities and Cleanup of Former Facilities

Primary exposure from nuclear weapons production facilities comes from beryllium metal and beryllium alloys. A study conducted by Kreiss *et al.* (1989) (Document ID 1480) documented sensitization and CBD among beryllium-exposed workers in the nuclear industry. A company medical department identified 58 workers with beryllium exposure among a work force of 500, of whom 51 (88 percent) participated in the study. Twenty-four workers were involved in research and development (R&D), while the remaining 27 were production workers. The R&D workers had a longer tenure with a mean time from first exposure of 21.2 years, compared to a mean time since first exposure of 5 years among the production workers. Six workers had abnormal BeLPT readings, and four were diagnosed with CBD. This study classified workers as sensitized after one abnormal BeLPT reading, so this resulted in an estimated 11.8 percent prevalence of sensitization.

Kreiss *et al.* (1993) expanded the work of Kreiss *et al.* (1989) (Document ID 1480) by performing a cross-sectional study of 895 current and former beryllium workers in the same nuclear weapons plant (Document ID 1479). Participants were placed in qualitative exposure groups (''no exposure,'' ''minimal exposure,'' ''intermittent

exposure,'' and ''consistent exposure'') based on questionnaire responses. Eighteen workers had abnormal BeLPT test results, with 12 being diagnosed with CBD. Three additional sensitized workers (those with abnormal BeLPT results) developed CBD over the next 2 years. Sensitization occurred in all of the qualitatively defined exposure groups. Individuals who had worked as machinists were statistically overrepresented among beryllium-sensitized cases, compared with non-cases. Cases were more likely than non-cases to report having had a measured overexposure to beryllium ($p = 0.009$), a factor which proved to be a significant predictor of sensitization in logistic regression analyses, as was exposure to beryllium prior to 1970. Beryllium sensitized cases were also significantly more likely to report having had cuts that were delayed in healing ($p = 0.02$). The authors concluded that both individual susceptibility to sensitization and exposure circumstance affect the development of beryllium sensitization and CBD.

In 1991, the Beryllium Health Surveillance Program (BHSP) was established at the Rocky Flats Nuclear Weapons Facility to offer BeLPT screening to current and former employees who may have been exposed to beryllium (Stange *et al.,* 1996, Document ID 0206). Participants received an initial BeLPT and follow-ups at one and three years. Based on histologic evidence of pulmonary granulomas and a positive BAL-BeLPT, Stange *et al.* published a study of 4,397 BHSP participants tested from June 1991 to March 1995, including current employees (42.8 percent) and former employees (57.2 percent). Twenty-nine cases of CBD and 76 cases of sensitization were identified. The sensitization rate for the population was 2.43 percent. Available exposure data included fixed airhead exposure samples collected between 1970 and 1988 (mean concentration 0.016 $\mu g/m^3$) and personal samples collected between 1984 and 1987 (mean concentration 1.04 $\mu g/m^3$). Cases of CBD and sensitization were noted in individuals in all jobs classifications, including those believed to involve minimal exposure to beryllium. The authors recommended ongoing surveillance for workers in all jobs with potential for beryllium exposure.

Stange *et al.* (2001) extended the previous study, evaluating 5,173 participants in the Rocky Flats BHSP who were tested between June 1991 and December 1997 (Document ID 1403). Three-year serial testing was offered to employees who had not been tested for three years or more and did not show beryllium sensitization during the previous study. This resulted in 2,891 employees being tested. Of the 5,173 workers participating in the study, 172 were found to have abnormal BeLPT test results. Ninety-eight (3.33 percent) of the workers were found to be sensitized (confirmed abnormal BeLPT results) in the initial screening, conducted in 1991. Of these workers 74 were diagnosed with CBD, based on a history of beryllium exposure, evidence of non-caseating granulomas or mononuclear cell infiltrates on lung biopsy, and a positive BeLPT or BAL-BeLPT. A follow-up survey of 2,891 workers three years later identified an additional 56 sensitized workers and an additional seven cases of CBD. Sensitization and CBD rates were analyzed with respect to gender, building work locations, and length of employment. Historical employee data included hire date, termination date, leave of absences, and job title changes. Exposure to beryllium was determined by job categories and building or work area codes. In order to determine beryllium exposure for all participants in the study, personal beryllium air monitoring results were used, when available, from employees with the same job title or similar job. However, no quantitative exposure information was presented in the study. The authors conclude that for some individuals, exposure to beryllium at levels below the preceding OSHA PEL appears to cause sensitization and CBD.

Viet *et al.* (2000) conducted a case-control study of the Rocky Flats worker population studied by Stange *et al.* (1996 and 2001, Document ID 0206 and 1403) to examine the relationship between estimated beryllium exposure level and risk of sensitization or CBD. The worker population included 74 beryllium-sensitized workers and 50 workers diagnosed with CBD. Beryllium exposure levels were estimated based on fixed airhead samples from Building 444, the beryllium machine shop, where machine operators were considered to have the highest exposures at the Rocky Flats facility. These fixed air samples were collected away from the breathing zone of the machine operator and likely underestimated exposure. To estimate levels in other locations, these air sample concentrations were used to construct a job exposure matrix that included the determination of the Building 444 exposure estimates for a 30-year period; each subject's work history by job location, task, and time period; and assignment of exposure estimates to each combination of job location, task, and time period as compared to Building 444 machinists. The authors adjusted the levels observed in the machine shop by factors based on interviews with former workers. Workers' estimated mean exposure concentrations ranged from 0.083 $\mu g/m^3$ to 0.622 $\mu g/m^3$. Estimated maximum air concentrations ranged from 0.54 $\mu g/m^3$ to 36.8 $\mu g/m^3$. Cases were matched to controls of the same age, race, gender, and smoking status (Viet *et al.,* 2000, Document ID 1344).

Estimated mean and cumulative exposure levels and duration of employment were found to be significantly higher for CBD cases than for controls. Estimated mean exposure levels were significantly higher for sensitization cases than for controls but no significant difference was observed for estimated cumulative exposure or duration of exposure. Similar results were found using logistic regression analysis, which identified statistically significant relationships between CBD and both cumulative and mean estimated exposure, but did not find significant relationships between estimated exposure levels and sensitization without CBD. Comparing CBD with sensitization cases, Viet *et al.* found that workers with CBD had significantly higher estimated cumulative and mean beryllium exposure levels than workers who were sensitized but did not have CBD.

Johnson *et al.* (2001) conducted a review of personal sampling records and medical surveillance reports at an atomic weapons establishment in Cardiff, United Kingdom (Document ID 1505). The study evaluated airborne samples collected over the 36-year period of operation for the plant. Data included 367,757 area samples and 217,681 personal lapel samples from 194 workers from 1981–1997. The authors estimated that over the 17 years of measurement data analyzed, airborne beryllium concentrations did exceed 2.0 $\mu g/m^3$, but due to the limitations with regard to collection times, it is difficult to assess the full reliability of this estimate. The authors noted that in the entire plant's history, only one case of CBD had been diagnosed. It was also noted that BeLPT had not been routinely conducted among any of the workers at this facility.

Arjomandi *et al.* (2010) (Document ID 1275) conducted a cross-sectional study of workers at a nuclear weapons research and development (R&D) facility to determine the risk of developing CBD in sensitized workers at facilities with exposures much lower than production plants (Document ID 1275). Of the 1,875 current or former workers at the R&D facility, 59 were determined to be

sensitized based on at least two positive BeLPTs (*i.e.,* samples drawn on two separate occasions or on split samples tested in two separate DOE-approved laboratories) for a sensitization rate of 3.1 percent. Workers found to have positive BeLPTs were further evaluated in an Occupational Medicine Clinic between 1999 and 2005. Arjomandi *et al.* (2010) evaluated 50 of the sensitized workers who also had medical and occupational histories, physical examination, chest imaging with high-resolution computed tomography (HRCT) (N = 49), and pulmonary function testing (nine of the 59 workers refused physical examinations so were not included in this study). Forty of the 50 workers chosen for this study underwent bronchoscopy for bronchoalveolar lavage and transbronchial biopsies in additional to the other testing. Five of the 49 workers had CBD at the time of evaluation (based on histology or high-resolution computed tomography); three others had evidence of probable CBD; however, none of these cases were classified as severe at the time of evaluation. The rate of CBD at the time of study among sensitized individuals was 12.5 percent (5/40) for those using pathologic review of lung tissue, and 10.2 percent (5/49) for those using HRCT as a criteria for diagnosis. The rate of CBD among the entire population (5/1875) was 0.3 percent.

The mean duration of employment at the facility was 18 years, and the mean latency period (from first possible exposure) to time of evaluation and diagnosis was 32 years. There was no available exposure monitoring in the breathing zone of workers at the facility, but the authors believed beryllium levels were relatively low (possibly less than 0.1 μg/m^3 for most jobs). There was not an apparent exposure-response relationship for sensitization or CBD. The sensitization prevalence was similar across exposure categories and the CBD prevalence higher among workers with the lower-exposure jobs. The authors concluded that these sensitized workers, who were subjected to an extended duration of low potential beryllium exposures over a long latency period, had a low prevalence of CBD (Arjomandi *et al.,* 2010, Document ID 1275).

i. Aluminum Smelting

Bauxite ore, the primary source of aluminum, contains naturally occurring beryllium. Worker exposure to beryllium can occur at aluminum smelting facilities where aluminum extraction occurs via electrolytic reduction of aluminum oxide into aluminum metal. Characterization of beryllium exposures and sensitization prevalence rates were examined by Taiwo *et al.* (2010) in a study of nine aluminum smelting facilities from four different companies in the U.S., Canada, Italy, and Norway (Document ID 0621).

Of the 3,185 workers determined to be potentially exposed to beryllium, 1,932 (60 percent) agreed to participate in a medical surveillance program between 2000 and 2006. The medical surveillance program included BeLPT analysis, confirmation of an abnormal BeLPT with a second BeLPT, and follow-up of all confirmed positive BeLPT results by a pulmonary physician to evaluate for progression to CBD.

Eight-hour TWA exposures were assessed utilizing 1,345 personal samples collected from the 9 smelters. The personal beryllium samples obtained showed a range of 0.01–13.00 μg/m^3 TWA with an arithmetic mean of 0.25 μg/m^3 and geometric mean of 0.06 μg/m^3. Based on a survey of published studies, the investigators concluded that exposure levels to beryllium observed in aluminum smelters were similar to those seen in other industries that utilize beryllium. Of the 1,932 workers surveyed by BeLPT, nine workers were diagnosed with sensitization (prevalence rate of 0.47 percent, 95% confidence interval = 0.21–0.88 percent) with 2 of these workers diagnosed with probable CBD after additional medical evaluations.

The authors concluded that compared with beryllium-exposed workers in other industries, the rate of sensitization among aluminum smelter workers appears lower. The authors speculated that this lower observed rate could be related to a more soluble form of beryllium found in the aluminum smelting work environment as well as the consistent use of respiratory protection. However, the authors also speculated that the low participation rate of 60 percent may have underestimated the sensitization rate in this worker population.

A study by Nilsen *et al.* (2010) also found a low rate of sensitization among aluminum workers in Norway. Three-hundred sixty-two workers and thirty-one control individuals were tested for beryllium sensitization based on the BeLPT. The results found that one (0.28%) of the smelter workers had been sensitized. No borderline results were reported. The exposures estimated in this plant were 0.1 μg/m^3 to 0.31 μg/m^3 (Nilsen *et al.,* 2010, Document ID 0460).

6. Animal Models of CBD

This section reviews the relevant animal studies supporting the biological mechanisms outlined above. In order for an animal model to be useful for investigating the mechanisms underlying the development of CBD, the model should include: The demonstration of a beryllium-specific immune response; the formation of immune granulomas following inhalation exposure to beryllium; and progression of disease as observed in human disease. While exposure to beryllium has been shown to cause chronic granulomatous inflammation of the lung in animal studies using a variety of species, most of the granulomatous lesions were not immune-induced reactions (which would predominantly consist of T-cells or lymphocytes), but were foreign-body-induced reactions, which predominantly consist of macrophages and monocytes, with only a small numbers of lymphocytes. Although no single model has completely mimicked the disease process as it progresses in humans, animal studies have been useful in providing biological plausibility for the role of immunological alterations and lung inflammation and in clarifying certain specific mechanistic aspects of beryllium disease, such as sensitization and CBD. However, there is no dependable animal model that mimics all facets of the human response, and studies thus far have been limited by single dose experiments, too few animals, or abbreviated observation periods. Therefore, the utility of this data is limited. The following is a discussion of the most relevant animal studies regarding the mechanisms of sensitization and CBD development in humans. Table A.2 in the Supplemental Information for the Beryllium Health Effects Section summarizes species, route, chemical form of beryllium, dose levels, and pathological findings of the key studies (Document ID 1965).

Harmsen *et al.* performed a study to assess whether the beagle dog could provide an adequate model for the study of beryllium-induced lung diseases (Harmsen *et al.,* 1986, Document ID 1257). One group of dogs served as an air inhalation control group and four other groups received high (approximately 50 μg/kg) and low (approximately 20 μg/kg) doses of beryllium oxide calcined at 500 °C or 1,000 °C, administered as aerosols in a single exposure.[6]

[6] As discussed above, calcining temperature affects the solubility and SSA of beryllium particles. Those particles calcined at higher temperatures (*e.g.,* 1,000 °C) are less soluble and have lower SSA than particles calcined at lower temperatures (*e.g.,* 500 °C). Solubility and SSA are

Continued

BAL content was collected at 30, 60, 90, 180, and 210 days after exposure, and lavage fluid and cellular content was evaluated for neutrophilic and lymphocytic infiltration. In addition, BAL cells were evaluated at the 210 day period to determine activation potential by phytohemagglutinin (PHA) or beryllium sulfate as mitogen. BAL neutrophils were significantly elevated only at 30 days with exposure to either dose of 500 °C beryllium oxide. BAL lymphocytes were significantly elevated at all time points of the high dose of beryllium oxide. No significant effect of 1,000 °C beryllium oxide exposure on mitogenic response of any lymphocytes was seen. In contrast, peripheral blood lymphocytes from the 500 °C beryllium oxide exposed groups were significantly stimulated by beryllium sulfate compared with the phytohemagglutinin exposed cells. Only the BAL lymphocytes from animals exposed to the 500 °C beryllium oxide responded to stimulation by either PHA or beryllium sulfate.

In a series of studies, Haley *et al.* also found that the beagle dog models certain aspects of human CBD (Haley *et al.,* 1989, 1991 and 1992; Document ID 1366, 1315, 1365. Briefly, dogs were exposed by inhalation to a single exposure to beryllium aerosol generated from beryllium oxide calcined at 500 °C or 1,000 °C for initial lung burdens of 17 or 50 µg beryllium/kg body weight (Haley *et al.,* 1989, Document ID 1366; 1991 (1315)). The dogs were monitored for lung pathologic effects, particle clearance, and immune sensitization of peripheral blood leukocytes. Lung retention was higher in the 1,000 °C treated beryllium oxide group (Haley *et al.,* 1989, Document ID 1366).

Haley *et al.* (1989) described the bronchoalveolar lavage (BAL) and histopathological changes in dogs exposed as described above. One group of dogs underwent BAL for lung lymphocyte analysis at 3, 6, 7, 11, 15, 18, and 22 months post exposure. The investigators found an increase in the percentage and numbers of lymphocytes in BAL fluid at 3 months post-exposure in dogs exposed to either dose of beryllium oxide calcined at 500 °C and 1,000 °C. Positive BeLPT results were observed with BAL lymphocytes only in the group with a high initial lung burden of the material calcined at 500 °C at 3 and 6 month post exposure. Another group underwent histopathological examination at days 8, 32, 64, 180, and 365 (Haley *et al.,* 1989, Document ID 1366; 1991 (1315)). Histopathologic examination revealed peribronchiolar and perivascular lymphocytic histiocytic inflammation, peaking at 64 days after beryllium oxide exposure. Lymphocytes were initially well differentiated, but progressed to lymphoblastic cells and aggregated in lymphofollicular nodules or microgranulomas over time. Although there was considerable inter-animal variation, lesions were generally more severe in the dogs exposed to material calcined at 500 °C. The investigators observed granulomatous lesions and lung lymphocyte responses consistent with those observed in humans with CBD, including perivascular and peribronchiolar infiltrates of lymphocytes and macrophages, progressing to microgranulomas with areas of granulomatous pneumonia and interstitial fibrosis. However, lesions declined in severity after 64 days post-exposure. The lesions found in dog lungs closely resembled those found in humans with CBD: Severe granulomas, lymphoblast transformation, increased pulmonary lymphocyte concentrations and variation in beryllium sensitivity. It was concluded that the canine model for CBD may provide insight into this disease.

In a follow-up experiment, control dogs and those exposed to beryllium oxide calcined at 500 °C were allowed to rest for 2.5 years, and then re-exposed to filtered air (controls) or beryllium oxide calcined at 500 °C (cases) for an initial lung burden target of 50 µg beryllium oxide/kg body weight (Haley *et al.,* 1992, Document ID 1365). Immune responses of blood and BAL lymphocytes, as well as lung lesions in dogs sacrificed 210 days post-exposure, were compared with results following the initial exposure. The severity of lung lesions was comparable under both conditions, suggesting that a 2.5-year interval was sufficient to prevent cumulative pathologic effects in beagle dogs.

In a comparison study of dogs and monkeys, Conradi *et al.* (1971) exposed animals via inhalation to an average aerosol to either 0, 3,300 or 4,380 µg/m^3 of beryllium as beryllium oxide calcined at 1,400 °C for 30 minutes, once per month for 3 months (Document ID 1319). Conradi *et al.* found no changes in the histological or ultrastructure of the lung of animals exposed to beryllium versus control animals. This was in contrast to previous findings reported in other studies cited by Conradi *et al.* The investigators speculated that the differences may be due in part to calcination temperature or follow-up time after initial exposure. The findings from Haley *et al.* (1989, Document ID 1366; 1991 (1915); and 1992 (1365)) as well as Harmsen *et al.* (1986, Document ID 1257) suggest that the beagle model for sensitization of CBD is more closely related to the human response that other species such as the monkey (and those reviewed in Table A2 of the Supplemental Information for the Beryllium Health Effects Section).

A 1994 study by Haley *et al.* comparing the potential toxicity of beryllium oxide versus beryllium metal showed that instillation of both beryllium oxide and beryllium metal induced an immune response in monkeys. Briefly, male cynomolgus monkeys were exposed to either beryllium metal or beryllium oxide calcined at 500 °C via intrabronchiolar instillation as a saline suspension. Lymphocyte counts in BAL fluid were observed through bronchoalveolar lavage at 14, 30, 60, 90, and 120 days post exposure, and were found to be significantly increased in monkeys exposed to beryllium metal on post-exposure days 14, 30, 60, and 90, and in monkeys exposed to beryllium oxide on post-exposure day 30 and 60. Histological examination of lung tissue revealed that monkeys exposed to beryllium metal developed interstitial fibrosis, Type II cell hyperplasia with increased lymphocytes infiltration, and lymphocytic mantles accumulating around alveolar macrophages. Similar but much less severe lesions were observed in beryllium-oxide-exposed monkeys. Only monkeys exposed to beryllium metal had positive BAL BeLPT results (Haley *et al.,* 1994, Document ID 1364).

As discussed earlier in this Health Effects section, at the cellular level, beryllium dissolution may be necessary in order for either a dendritic cell or a macrophage to present beryllium as an antigen to induce the cell-mediated CBD immune reactions (NAS, 2008, Document ID 1355). Several studies have shown that low-fired beryllium oxide, which is predominantly made up of poorly crystallized small particles, is more immunologically reactive than beryllium oxide calcined at higher firing temperatures that result in less reactivity due to increasing crystal size (Stefaniak *et al.,* 2006, Document ID 1398). As discussed previously, Haley *et al.* (1989, Document ID 1366) found more severe lung lesions and a stronger immune response in beagle dogs receiving a single inhalation exposure to beryllium oxide calcined at 500 °C than in dogs receiving an equivalent initial lung burden of beryllium oxide calcined at 1,000 °C. Haley *et al.* found that beryllium oxide calcined at 1,000 °C

factors in determining the toxic potential of beryllium compounds or materials.

elicited little local pulmonary immune response, whereas the much more soluble beryllium oxide calcined at 500 °C produced a beryllium-specific, cell-mediated immune response in dogs (Haley *et al.,* 1989, Document ID 1366 and 1991 (1315)).

In a later study, beryllium metal appeared to induce a greater toxic response than beryllium oxide following intrabronchiolar instillation in cynomolgus monkeys, as evidenced by more severe lung lesions, a larger effect on BAL lymphocyte counts, and a positive response in the BeLPT with BAL lymphocytes only after exposure to beryllium metal (Haley *et al.,* 1994, Document ID 1364). A study by Mueller and Adolphson (1979) observed that an oxide layer can develop on beryllium-metal surfaces after exposure to air (Mueller and Adolphson, 1979, Document ID 1260). According to the NAS report, Harmesen *et al* (1994) suggested that the presence of beryllium metal could lead to persistent exposures of small amounts beryllium oxide sufficient for presentation to the immune system (NAS, 2008, Document ID 1355).

Genetic studies in humans led to the creation of an animal model containing different human HLA–DP alleles inserted into FVB/N mice for mechanistic studies of CBD. Three strains of genetically engineered mice (transgenic mice) were created that conferred different risks for developing CBD based on human studies (Weston *et al.,* 2005, Document ID 1345; Snyder *et al.,* 2008 (0471)): (1) The HLA–DPB1*0401 transgenic strain, where the transgene codes for lysine residue at the 69th position of the B-chain conferred low risk of CBD; (2) the HLA–DPB1*0201 mice, where the transgene codes for glutamic acid residue at the 69th position of the B-chain conferred medium risk of CBD; and (3) the HLA–DPB1*1701 mice, where the transgene codes for glutamic acid at the 69th position of the B-chain but coded for a more negatively charged protein to confer higher risk of CBD (Tarantino-Hutchinson *et al.,* 2009, Document ID 0536).

In order to validate the transgenic model, Tarantino-Hutchison *et al.* challenged the transgenic mice along with seven different inbred mouse strains to determine the susceptibility and sensitivity to beryllium exposure. Mice were dermally exposed with either saline or beryllium, then challenged with either saline or beryllium (as beryllium sulfate) using the MEST protocol (mouse ear-swelling test). The authors determined that the high risk HLA–DPB1*1701 transgenic strain responded 4 times greater (as measured via ear swelling) than control mice and at least 2 times greater than other strains of mice. The findings correspond to epidemiological study results reporting an enhanced CBD odds ratio for the HLA–DPB1*1701 in humans (Weston *et al.,* 2005, Document ID 1345; Snyder *et al.,* 2008 (0471)). Transgenic mice with the genes corresponding to the low and medium odds ratio study did not respond significantly over the control group. The authors concluded that while HLA–DPB1*1701 is important to beryllium sensitization and progression to CBD, other genetic and environmental factors contribute to the disease process as well.

7. Beryllium Sensitization and CBD Conclusions

There is substantial evidence that skin and inhalation exposure to beryllium may lead to sensitization (section V.D.1) and that inhalation exposure, or skin exposure coupled with inhalation exposure, may lead to the onset and progression of CBD (section V.D.2). These conclusions are supported by extensive human studies (section V.D.5). While all facets of the biological mechanism for this complex disease have yet to be fully elucidated, many of the key events in the disease sequence have been identified and described in the earlier sections (sections V.D.1–5). Sensitization is considered to be a necessary first step to the onset of CBD (NAS, 2008, Document ID 1355; ERG, 2010 (1270)). Sensitization is the process by which the immune system recognizes beryllium as a foreign substance and responds in a manner that may lead to development of CBD. It has been documented that a substantial proportion of sensitized workers exposed to airborne beryllium can progress to CBD (Rosenman *et al.,* 2005, Document ID 1352; NAS, 2008 (1355); Mroz *et al.,* 2009 (1356)). Animal studies, particularly in dogs and monkeys, have provided supporting evidence for T cell lymphocyte proliferation in the development of granulomatous lung lesions after exposure to beryllium (Harmsen *et al.,* 1986, Document ID 1257; Haley *et al.,* 1989 (1366), 1992 (1365), 1994 (1364)). The animal studies have also provided important insights into the roles of chemical form, genetic susceptibility, and residual lung burden in the development of beryllium lung disease (Harmsen *et al.,* 1986, Document ID 1257; Haley *et al.,* 1992 (1365); Tarantino-Hutchison *et al.,* 2009 (0536)). The evidence supports sensitization as an early functional change that allows the immune system to recognize and adversely react to beryllium. As such, OSHA regards beryllium sensitization as a necessary first step along a continuum that can culminate in clinical lung disease.

The epidemiological evidence presented in section V.D.5 demonstrates that sensitization and CBD are continuing to occur from exposures below OSHA's preceding PEL. The prevalence of sensitization among beryllium-exposed workers, as measured by the BeLPT and reported in 16 surveys of occupationally exposed cohorts reviewed by the Agency, ranged from 0.3 to 14.5 percent (Deubner *et al.,* 2001, Document ID 1543; Kreiss *et al.,* 1997 (1360); Rosenman *et al.,* 2005 (1352); Schuler *et al.,* 2012 (0473); Bailey *et al.,* 2010 (0676); Newman *et al.,* 2001 (1354); OSHA, 2014 (1589); Kreiss *et al.,* 1996 (1477); Henneberger *et al.,* 2001 (0589); Cummings *et al.,* 2007 (1369); Schuler *et al.,* 2005 (0919); Thomas *et al.,* 2009 (1061); Kreiss *et al.,* 1989 (1480); Arjomandi *et al.,* 2010 (1275); Taiwo *et al.,* 2011 (0621); Nilson *et al.,* 2010 (0460)). The lower prevalence estimates (0.3 to 3.7 percent) were from facilities known to have implemented respiratory protection programs and have lower personal exposures (Cummings *et al.,* 2007, Document ID 1369; Thomas *et al.,* 2009 (1061); Bailey *et al.,* 2010 (0676); Taiwo et al, 2011 (0621), Nilson *et al.,* 2010 (0460); Arjomandi *et al.,* 2010 (1275)). Thirteen of the surveys also evaluated workers for CBD and reported prevalences of CBD ranging from 0.1 to 7.8 percent. The cohort studies cover workers across many different industries and processes as discussed in section V.D.5. Several studies show that incidence of sensitization among workers can be reduced by reducing inhalation exposure and that minimizing skin exposure may serve to further reduce sensitization (Cummings *et al.,* 2007, Document ID 1369; Thomas *et al.,* 2009 (1061); Bailey *et al.,* 2010 (0676)). The risk assessment further discusses the effectiveness of interventions to reduce beryllium exposures and the risk of sensitization and CBD (see section VI of this preamble, Risk Assessment).

Longitudinal studies of sensitized workers found early signs of asymptomatic CBD that can progress to clinical disease in some individuals. One study found that 31 percent of beryllium-exposed sensitized employees progressed to CBD with an average follow-up time of 3.8 years (Newman, 2005, Document ID 1437). However, Newman (2005) went on to suggest that if follow-up times were much longer, the rate of progression from

sensitization to CBD could be much higher. Mroz *et al.* (2009) (Document ID 1356) conducted a longitudinal study between 1982 and 2002 in which they followed 171 cases of CBD and 229 cases of sensitization initially evaluated through workforce medical surveillance by National Jewish Health. All study subjects had abnormal BeLPTs upon study entry and were then clinically evaluated and treated for CBD. Over the 20-year study period, 22 sensitized individuals went on to develop CBD which was an incidence of 8.8 percent (*i.e.,* 22 cases out of 251 sensitized, calculated by adding those 22 cases to the 229 initially classified as sensitized). The findings from this study indicated that the average span of time from initial beryllium exposure to CBD diagnosis for those 22 workers was 24 years (Mroz *et al.,* 2009, Document ID 1356).

A study of sensitized workers believed to have been exposed to low levels of airborne beryllium metal (*e.g.,* 0.01 μg/m^3 or less) at a nuclear weapons research and development facility were clinically evaluated between 1999 and 2005 (Arjomandi *et al.*, 2010, Document ID 1275). Five of 49 sensitized workers (10.2 percent incidence) were found to have pathology consistent with CBD. The CBD was asymptomatic and had not progressed to clinical disease. The mean duration of employment among workers in the study was 18 years with mean latency of 32 years to time of CBD diagnosis (Arjomandi *et al.*, 2010, Document ID 1275). This suggests that some sensitized individuals can develop CBD even from low levels of beryllium exposure. Another study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that sensitization rate among exposed workers was highest over the first 10 years of beryllium exposure while onset of CBD pathology was greatest following 15 to 30 years of exposure (Stange *et al.,* 2001, Document ID 1403). This indicates length of exposure may play a role in further development of the disease. OSHA concludes from the study evidence that the persistent presence of beryllium in the lungs of sensitized workers can lead to a progression of CBD over time from an asymptomatic stage to serious clinical disease.

E. Beryllium Lung Cancer Section

Beryllium exposure is associated with a variety of adverse health effects, including lung cancer. The potential for beryllium and its compounds to cause cancer has been previously assessed by various other agencies (EPA, ATSDR, NAS, NIEHS, and NIOSH), with each agency identifying beryllium as a potential carcinogen. In addition, IARC did an extensive evaluation in 1993 (Document ID 1342) and reevaluation in April 2009 (IARC, 2012, Document ID 0650). In brief, IARC determined beryllium and its compounds to be carcinogenic to humans (Group 1 category), while EPA considers beryllium to be a probable human carcinogen (EPA, 1998, Document ID 0661), and the National Toxicology Program (NTP) classifies beryllium and its compounds as known carcinogens (NTP, 2014, Document ID 0389). OSHA has conducted an independent evaluation of the carcinogenic potential of beryllium and these compounds. The following is a summary of the studies used to support the Agency's finding that beryllium and its compounds are human carcinogens.

1. Genotoxicity Studies

Genotoxicity can be an important indicator for screening the potential of a material to induce cancer and an important mechanism leading to tumor formation and carcinogenesis. In a review conducted by the National Academy of Science, beryllium and its compounds have tested positively in nearly 50 percent of the genotoxicity studies conducted without exogenous metabolic activity. However, they were found to be non-genotoxic in most bacterial assays (NAS, 2008, Document ID 1355).

Non-mammalian test systems (generally bacterial assays) are often used to identify genotoxicity of a compound. In bacteria studies evaluating beryllium sulfate for mutagenicity, all studies performed utilizing the Ames assay (Simmon, 1979, Document ID 0434; Dunkel *et al.,* 1981 (0432); Arlauskas *et al.,* 1985 (0454); Ashby *et al.,* 1990 (0437)) and other bacterial assays (E. coli *pol A* (Rosenkranz and Poirer, 1979, Document ID 1426); E. coli WP2 *uvrA* (Dunkel *et al.,* 1981, Document ID 0432), as well as those utilizing *Saccharomyces cerevisiae* (Simmon, 1979, Document ID 0434)) were reported as negative, with the exception of results reported for Bacillus *subtilis rec* assay (Kada *et al.,* 1980, Document ID 0433; Kanematsu *et al.,* 1980 (1503)). Beryllium nitrate was also reported as negative in the Ames assay (Tso and Fung, 1981, Document ID 0446; Kuroda *et al.,* 1991 (1471)) but positive in a Bacillus *subtilis rec* assay (Kuroda *et al.,* 1991, Document ID 1471). In addition, beryllium chloride was reported as negative using the Ames assay (Ogawa *et al.,* 1987, as cited in Document ID 1341, p. 112; Kuroda *et al.,* 1991 (1471)) and other bacterial assays (E. coli WP2 *uvrA* (Rossman *et al.,* 1984, Document ID 0431), as well as the Bacillus *subtilis rec* assay (Nishioka, 1975, Document ID 0449)) and failed to induce SOS DNA repair in E. coli (Rossman *et al.,* 1984, Document ID 0431). Positive results for beryllium chloride were reported for Bacillus *subtilis rec* assay using spores (Kuroda *et al.,* 1991, Document ID 1471) as well as increased mutations in the *lacI* gene of E. coli KMBL 3835 (Zakour and Glickman, 1984, Document ID 1373). Beryllium oxide was reported to be negative in the Ames assay and Bacillus *subtilis rec* assays (Kuroda *et al.,* 1991, Document ID 1471; EPA, 1998 (0661)).

Mutations using *in vitro* mammalian systems were also evaluated. Beryllium chloride induced mutations in V79 and CHO cultured cells (Miyaki *et al.,* 1979, Document ID 0450; Hsie *et al.,* 1978 (0427); Vegni-Talluri and Guiggiani, 1967 (1382)), and beryllium sulfate induced clastogenic alterations, producing breakage or disrupting chromosomes in mammalian cells (Brooks *et al.,* 1989, Document ID 0233; Larramendy *et al.,* 1981 (1468); Gordon and Bowser, 2003 (1520)). However, beryllium sulfate did not induce unscheduled DNA synthesis in primary rat hepatocytes and was not mutagenic when injected intraperitoneally in adult mice in a host-mediated assay using *Salmonella typhimurium* (Williams *et al.,* 1982). Positive results were found for beryllium chloride when evaluating the *hprt* gene in Chinese hamster lung V79 cells (Miyaki *et al.,* 1979, Document ID 0450).

Data from *in vivo* genotoxicity testing of beryllium are limited. Beryllium metal was found to induce methylation of the p16 gene in the lung tumors of rats exposed to beryllium metal (Swafford *et al.,* 1997, Document ID 1392) (described in more detail in section V.E.3). A study by Nickell-Brady *et al.,* (1994) found that beryllium sulfate (1.4 and 2.3 g/kg, 50 percent and 80 percent of median lethal dose) administered by gavage did not induce micronuclei in the bone marrow of CBA mice. However, a marked depression of red blood cell production was suggestive of bone marrow toxicity, which was evident 24 hours after dosing. No mutations were seen in *p53* or *c-raf-1* and only weak mutations were detected in *K-ras* in lung carcinomas from F344/N rats given a single nose-only exposure to beryllium metal (described in more detail in section V. E. 3) (Nickell-Brady *et al.,* 1994, Document ID 1312). On the other hand, beryllium chloride evaluated in a mouse model indicated increased DNA strand breaks and the formation of micronuclei

in bone marrow (Attia *et al.,* 2013, Document ID 0501).

In summary, genetic mutations have been observed in mammalian systems (*in vitro* and *in vivo*) with beryllium chloride, beryllium sulfate, and beryllium metal in a number of studies (Miyaki *et al.,* 1979, Document ID 0450; Hsie *et al.,* 1978 (0427); Vegni-Talluri and Guiggiani, 1967 (1382); Brooks *et al.,* 1989 (0233); Larramendy *et al.,* 1981 (1468); Miyaki *et al.,* 1979 (0450); Swafford *et al.,* 1997 (1392); Attia *et al.,* 2013 (0501); EPA, 1998 (0661); Gordon and Bowser, 2003 (1520)). However, most studies utilizing non-mammalian test systems (either with or without metabolic activity) have found that beryllium chloride, beryllium nitrate, beryllium sulfate, and beryllium oxide did not induce gene mutations, with the exception of Kada *et al.* (1980, Document ID 0433) (Kanematsu *et al.,*1980, Document ID 1503; Kuroda *et al.,* 1991 (1471)).

2. Human Epidemiological Studies

This section describes the human epidemiological data supporting the mechanistic overview of beryllium-induced lung cancer in workers. It has been divided into reviews of epidemiological studies by industry and beryllium form. The epidemiological studies utilizing data from the BCR, in general, focus on workers mainly exposed to soluble forms of beryllium. Those studies evaluating the epidemiological evidence by industry or process are, in general, focused on exposures to poorly soluble or mixed (soluble and poorly soluble) compounds. Table A.3 in the Supplemental Information for the Beryllium Health Effects Section summarizes the important features and characteristics of each study discussed herein (Document ID 1965).

a. Beryllium Case Registry (BCR)

Two studies evaluated participants in the BCR (Infante *et al.,* 1980, Document ID 1507; Steenland and Ward, 1991 (1400)). Infante *et al.* (1980) evaluated the mortality patterns of white male participants in the BCR diagnosed with non-neoplastic respiratory symptoms of beryllium disease. Of the 421 cases evaluated, 7 of the participants had died of lung cancer. Six of the deaths occurred more than 15 years after initial beryllium exposure. The duration of exposure for 5 of the 7 participants with lung cancer was less than 1 year, with the time since initial exposure ranging from 12 to 29 years. One of the participants was exposed for 4 years with a 26-year interval since the initial exposure. Exposure duration for one participant diagnosed with pulmonary fibrosis could not be determined; however, it had been 32 years since the initial exposure. Based on BCR records, the participants were classified as being in the acute respiratory group (*i.e.,* those diagnosed with acute respiratory illness at the time of entry in the registry) or the chronic respiratory group (*i.e.,* those diagnosed with pulmonary fibrosis or some other chronic lung condition at the time of entry into the BCR). The 7 participants with lung cancer were in the BCR because of diagnoses of acute respiratory illness. For only one of those individuals was initial beryllium exposure less than 15 years prior. Only 1 of the 6 (with greater than 15 years since initial exposure to beryllium) had been diagnosed with chronic respiratory disease. The study did not report exposure concentrations or smoking habits. The authors concluded that the results from this cohort agreed with previous animal studies and with epidemiological studies demonstrating an increased risk of lung cancer in workers exposed to beryllium.

Steenland and Ward (1991) (Document ID 1400) extended the work of Infante *et al.* (1980) (Document ID 1507) to include females and to include 13 additional years of follow-up. At the time of entry in the BCR, 93 percent of the women in the study, but only 50 percent of the men, had been diagnosed with CBD. In addition, 61 percent of the women had worked in the fluorescent tube industry and 50 percent of the men had worked in the basic manufacturing industry with confirmed beryllium exposure. A total of 22 males and 6 females died of lung cancer. Of the 28 total deaths from lung cancer, 17 had been exposed to beryllium for less than 4 years and 11 had been exposed for greater than 4 years. The study did not report exposure concentrations. Survey data collected in 1965 provided information on smoking habits for 223 cohort members (32 percent), on the basis of which the authors suggested that the rate of smoking among workers in the cohort may have been lower than U.S. rates. The authors concluded that there was evidence of increased risk of lung cancer in workers exposed to beryllium and then diagnosed with beryllium disease (ABD and CBD).

b. Beryllium Manufacturing and/or Processing Plants (Extraction, Fabrication, and Processing)

Several epidemiological cohort studies have reported excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1960s.

Bayliss *et al.* (1971) (Document ID 1285) performed a nested cohort study of 7,948 former workers from the beryllium processing industry who were employed from 1942–1967. Information for the workers was collected from the personnel files of participating companies. Of the 7,948 employees, a cause of death was known for 753 male workers. The number of observed lung cancer deaths was 36 compared to 34.06 expected for a standardized mortality ratio (SMR) of 1.06. When evaluated by the number of years of employment, 24 of the 36 men were employed for less than 1 year in the industry (SMR = 1.24), 8 were employed for 1 to 5 years (SMR 1.40), and 4 were employed for more than 5 years (SMR = 0.54). Half of the workers who died from lung cancer began employment in the beryllium production industry prior to 1947. When grouped by job classification, over two thirds of the workers with lung cancer were in production-related jobs while the rest were classified as office workers. The authors concluded that while the lung cancer mortality rates were the highest of all other mortality rates, the SMR for lung cancer was still within range of the expected based on death rates in the United States. The limitations of this study included the lack of information regarding exposure concentrations, smoking habits, and the age and race of the participants.

Mancuso (1970, Document ID 1453; 1979, (0529); 1980 (1452)) and Mancuso and El-Attar (1969) (Document ID 1455) performed a series of occupational cohort studies on a group of workers (primarily white males) employed in the beryllium manufacturing industry during 1937–1948. The cohort identified in Mancuso and El-Attar (1969) was a study of 3,685 workers (primarily white males) while Mancuso (1970, 1976, 1980) continued the study follow-up with 3266 workers due to several limitations in identifying specific causes for mortality as identified in Mancuso and El-Attar (1969). The beryllium production facilities were located in Ohio and Pennsylvania and the records for the employees, including periods of employment, were obtained from the Social Security Administration. These studies did not include analyses of mortality by job title or exposure category (exposure data was taken from a study by Zielinsky *et al.,* 1961 (as cited in Mancuso, 1970)). In addition, there were no exposure concentrations estimated or adjustments for smoking. The estimated duration of employment ranged from less than 1 year to greater than 5 years. In the most recent study (Mancuso, 1980), employees from the

viscose rayon industry served as a comparison population. There was a significant excess of lung cancer deaths based on the total number of 80 observed lung cancer mortalities at the end of 1976 compared to an expected number of 57.06 based on the comparison population resulting in an SMR of 1.40 ($p < 0.01$) (Mancuso, 1980). There was a statistically significant excess in lung cancer deaths for the shortest duration of employment (<12 months, $p < 0.05$) and the longest duration of employment (>49 months, $p < 0.01$). Based on the results of this study, the author concluded that the ability of beryllium to induce cancer in workers does not require continuous exposure and that it is reasonable to assume that the amount of exposure required to produce lung cancer can occur within a few months of initial exposure regardless of the length of employment.

Wagoner *et al.* (1980) (Document ID 1379) expanded the work of Mancuso (1970, Document ID 1453; 1979 (0529); 1980 (1452)) using a cohort of 3,055 white males from the beryllium extraction, processing, and fabrication facility located in Reading, Pennsylvania. The men included in the study worked at the facility sometime between 1942 and 1968, and were followed through 1976. The study accounted for length of employment. Other factors accounted for included age, smoking history, and regional lung cancer mortality. Forty-seven members of the cohort died of lung cancer compared to an expected 34.29 based on U.S. white male lung cancer mortality rates ($p < .05$). The results of this cohort showed an excess risk of lung cancer in beryllium-exposed workers at each duration of employment (<5 years and ≥5 years), with a statistically significant excess noted at <5 years of employment and a ≥25-year interval since the beginning of employment ($p < 0.05$). The study was criticized by two epidemiologists (MacMahon, 1978, Document ID 0107; Roth, 1983 (0538)), by a CDC Review Committee appointed to evaluate the study (as cited in Document ID 0067), and by one of the study's coauthors (Bayliss, 1980, Document ID 0105) for inadequate discussion of possible alternative explanations of excess lung cancer in the cohort. The specific issues identified include the use of 1965–1967 U.S. white male lung cancer mortality rates to generate expected numbers of lung cancers in the period 1968–1975 (which may underestimate the expected number of lung cancer deaths for the cohort) and inadequate adjustment for smoking.

One occupational nested case-control study evaluated lung cancer mortality in a cohort of 3,569 male workers employed at a beryllium alloy production plant in Reading, PA, from 1940 to 1969 and followed through 1992 (Sanderson *et al.,* 2001, Document ID 1250). There were a total of 142 known lung cancer cases and 710 controls. For each lung cancer death, 5 age- and race-matched controls were selected by incidence density sampling. Confounding effects of smoking were evaluated. Job history and historical air measurements at the plant were used to estimate job-specific beryllium exposures from the 1930s to 1990s. Calendar-time-specific beryllium exposure estimates were made for every job and used to estimate workers' cumulative, average, and maximum exposures. Because of the long period of time required for the onset of lung cancer, an ''exposure lag'' was employed to discount recent exposures less likely to contribute to the disease.

The largest and most comprehensive study investigated the mortality experience of 9,225 workers employed in 7 different beryllium processing plants over a 30-year period (Ward *et al.,* 1992, Document ID 1378). The workers at the two oldest facilities (*i.e.,* Lorain, OH, and Reading, PA) were found to have significant excess lung cancer mortality relative to the U.S. population. The workers at these two plants were believed to have the highest exposure levels to beryllium. Ward *et al.* (1992) performed a retrospective mortality cohort study of 9,225 male workers employed at seven beryllium processing facilities, including the Ohio and Pennsylvania facilities studied by Mancuso and El-Attar (1969) (Document ID 1455), Mancuso (1970, Document ID 1453; 1979 (0529); 1980 (1452)), and Wagoner *et al.* (1980) (Document ID 1379). The men were employed for no less than 2 days between January 1940 and December 1969. Medical records were followed through 1988. At the end of the study 61.1 percent of the cohort was known to be living and 35.1 percent was known to be deceased. The duration of employment ranged from 1 year or less to greater than 10 years with the largest percentage of the cohort (49.7 percent) employed for less than one year, followed by 1 to 5 years of employment (23.4 percent), greater than 10 years (19.1 percent), and 5 to 10 years (7.9 percent). Of the 3,240 deaths, 280 observed deaths were caused by lung cancer compared to 221.5 expected deaths, yielding a statistically significant SMR of 1.26 ($p < 0.01$). Information on the smoking habits of 15.9 percent of the cohort members, obtained from a 1968 Public Health Service survey conducted at four of the plants, was used to calculate a smoking-adjusted SMR of 1.12, which was not statistically significant. The number of deaths from lung cancer was also examined by decade of hire. The authors reported a relationship between earlier decades of hire and increased lung cancer risk.

A different analysis of the lung cancer mortality in this cohort using various local reference populations and alternate adjustments for smoking generally found smaller, non-significant rates of excess mortality among the beryllium-exposed employees (Levy *et al.,* 2002, Document ID 1463). Both cohort studies (Levy *et al.,* 2002, Document ID 1463; Ward *et al.,* 1992 (1378)) are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with different levels and durations of beryllium exposure. The majority of employees at the Lorain, OH, and Reading, PA, facilities were employed for a relatively short period of less than one year.

Levy *et al.* (2002) (Document ID 1463) questioned the results of Ward *et al.* (1992) (Document ID 1378) and performed a reanalysis of the Ward *et al.* data. The Levy *et al.* reanalysis differed from the Ward *et al.* analysis in the following significant ways. First, Levy *et al.* (2002) (Document ID 1463) examined two alternative adjustments for smoking, which were based on (1) a different analysis of the American Cancer Society (ACS) data used by Ward *et al.* (1992) (Document ID 1378) for their smoking adjustment, or (2) results from a smoking/lung cancer study of veterans. Second, Levy *et al.* (2002) also examined the impact of computing different reference rates derived from information about the lung cancer rates in the cities in which most of the workers at two of the plants lived (Document ID 1463). Finally, Levy *et al.* (2002) considered a meta-analytical approach to combining the results across beryllium facilities (Document ID 1463). For all of the alternatives Levy *et al.* (2002) (Document ID 1463) considered, except the meta-analysis, the facility-specific and combined SMRs derived were lower than those reported by Ward *et al.* (1992) (Document ID 1378). Only the SMR for the Lorain, OH, facility remained statistically significantly elevated in some reanalyses. The SMR obtained when combining over the plants was not statistically significant in eight of the nine approaches they examined, leading

Levy *et al.* (2002) (Document ID 1463) to conclude that there was little evidence of statistically significant elevated SMRs in those plants. This study was not included in the synthesis of epidemiological studies assessed by IARC due to several methodological limitations (IARC, 2012, Document ID 0650).

The EPA Integrated Risk Information System (IRIS), IARC, and California EPA Office of Environmental Health Hazard Assessment (OEHHA) all based their cancer assessments on the Ward *et al.* 1992 study, with supporting data concerning exposure concentrations from Eisenbud and Lisson (1983) (Document ID 1296) and NIOSH (1972) (Document ID 0560), who estimated that the lower-bound estimate of the median exposure concentration exceeded 100 μg/m^3 and found that concentrations in excess of 1,000 μg/m^3 were common. The IRIS cancer risk assessment recalculated expected lung cancers based on U.S. white male lung cancer rates (including the period 1968–1975) and used an alternative adjustment for smoking. In addition, one individual with lung cancer, who had not worked at the plant, was removed from the cohort. After these adjustments were made, an elevated rate of lung cancer was still observed in the overall cohort (46 cases vs. 41.9 expected cases). However, based on duration of employment or interval since beginning of employment, neither the total cohort nor any of the subgroups had a statistically significant increase in lung cancer deaths (EPA, 1987, Document ID 1295). Based on its evaluation of this and other epidemiological studies, the EPA characterized the human carcinogenicity data then available as ''limited'' but ''suggestive of a causal relationship between beryllium exposure and an increased risk of lung cancer'' (EPA, 1998, Document ID 0237). The EPA report includes quantitative estimates of risk that were derived using the information presented in Wagoner *et al.* (1980), the expected lung cancers recalculated by the EPA, and bounds on presumed exposure levels.

Sanderson *et al.* (2001) (Document ID 1419) estimated the cumulative, average, and maximum beryllium exposure concentration for the 142 known lung cancer cases to be 46.06 ± 9.3μg/m^3-days, 22.8 ± 3.4 μg/m^3, and 32.4 ± 13.8 μg/m^3, respectively. The lung cancer mortality rate was 1.22 (95 percent CI = 1.03 − 1.43). Exposure estimates were lagged by 10 and 20 years in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer. In the 10- and 20-year lagged exposures the geometric mean tenures and cumulative exposures of the lung cancer mortality cases were higher than the controls. In addition, the geometric mean and maximum exposures of the workers were significantly higher than controls when the exposure estimates were lagged 10 and 20 years ($p < 0.01$).

Results of a conditional logistic regression analysis indicated that there was an increased risk of lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years (Sanderson *et al.,* 2001, Document ID 1419). There was also a lack of evidence that confounding factors such as smoking affected the results of the regression analysis. The authors noted that there was considerable uncertainty in the estimation of exposure in the 1940s and 1950s and the shape of the dose-response curve for lung cancer (Sanderson *et al.,* 2001, Document ID 1419). Another analysis of the study data using a different statistical method did not find a significantly greater relative risk of lung cancer with increasing beryllium exposures (Levy *et al.,* 2007). The average beryllium air levels for the lung cancer cases were estimated to be an order of magnitude above the preceding 8-hour OSHA TWA PEL (2 μg/m^3) and roughly two orders of magnitude higher than the typical air levels in workplaces where beryllium sensitization and pathological evidence of CBD have been observed. IARC evaluated this reanalysis in 2012 and found the study introduced a downward bias into risk estimates (IARC, 2012, Document ID 0650). NIOSH comments in the rulemaking docket support IARC's finding (citing Schubauer-Berigan *et al.,* 2007; Hein *et al.,* 2009, 2011; Langholz and Richardson 2009; Wacholder 2009) (Document ID 1671, Attachment 1, p. 10).

Schubauer-Berigan *et al.* (2008) (Document ID 1350) reanalyzed data from the Sanderson *et al.* (2001) nested case-control study of 142 lung cancer cases in the Reading, PA, beryllium processing plant. This dataset was reanalyzed using conditional (stratified by case age) logistic regression. Independent adjustments were made for potential confounders of birth year and hire age. Average and cumulative exposures were analyzed using the values reported in the original study. The objective of the reanalysis was to correct for the known differences in smoking rates by birth year. In addition, the authors evaluated the effects of age at hire to determine differences observed by Sanderson *et al.* in 2001 (Document ID 1419). The effect of birth cohort adjustment on lung cancer rates in beryllium-exposed workers was evaluated by adjusting in a multivariable model for indicator variables for the birth cohort quartiles.

Unadjusted analyses showed little evidence of lung cancer risk associated with beryllium occupational exposure using cumulative exposure until a 20-year lag was used. Adjusting for either birth cohort or hire age attenuated the risk for lung cancer associated with cumulative exposure. Using a 10- or 20-year lag in workers born after 1900 also showed little evidence of lung cancer risk, while those born prior to 1900 did show a slight elevation in risk. Unlagged and lagged analysis for average exposure showed an increase in lung cancer risk associated with occupational exposure to beryllium. The finding was consistent for either workers adjusted or unadjusted for birth cohort or hire age. Using a 10-year lag for average exposure showed a significant effect by birth cohort.

Schubauer-Berigan *et al.* stated that the reanalysis indicated that differences in the hire ages among cases and controls, first noted by Deubner *et al.* (2001) (Document ID 0109) and Levy *et al.* (2007) (Document ID 1462), were primarily due to the fact that birth years were earlier among controls than among cases, resulting from much lower baseline risk of lung cancer for men born prior to 1900 (Schubauer-Berigan *et al.,* 2008, Document ID 1350). The authors went on to state that the reanalysis of the previous NIOSH case-control study suggested the relationship observed previously between cumulative beryllium exposure and lung cancer was greatly attenuated by birth cohort adjustment.

Hollins *et al.* (2009) (Document ID 1512) re-examined the weight of evidence of beryllium as a lung carcinogen in a recent publication. Citing more than 50 relevant papers, the authors noted the methodological shortcomings examined above, including lack of well-characterized historical occupational exposures and inadequacy of the availability of smoking history for workers. They concluded that the increase in potential risk of lung cancer was observed among those exposed to very high levels of beryllium and that beryllium's carcinogenic potential in humans at these very high exposure levels was not relevant to today's industrial settings. IARC performed a similar re-evaluation in 2009 (IARC, 2012, Document ID 0650) and found that the weight of evidence for beryllium lung carcinogenicity, including the animal studies described below, still warranted a Group I classification, and that

beryllium should be considered carcinogenic to humans.

Schubauer-Berigan *et al.* (2011) (Document ID 1266) extended their analysis from a previous study estimating associations between mortality risk and beryllium exposure to include workers at 7 beryllium processing plants. The study followed the mortality incidences of 9,199 workers from 1940 through 2005 at the 7 beryllium plants. JEMs were developed for three plants in the cohort: The Reading plant, the Hazleton plant, and the Elmore plant. The last is described in Couch *et al.* 2010. Including these JEMs substantially improved the evidence base for evaluating the carcinogenicity of beryllium, and this change represents more than an update of the beryllium cohort. Standardized mortality ratios (SMRs) were estimated based on U.S. population comparisons for lung, nervous system and urinary tract cancers, chronic obstructive pulmonary disease (COPD), chronic kidney disease, and categories containing chronic beryllium disease (CBD) and cor pulmonale. Associations with maximum and cumulative exposure were calculated for a subset of the workers.

Overall mortality in the cohort compared with the U.S. population was elevated for lung cancer (SMR 1.17; 95% CI 1.08 to 1.28), COPD (SMR 1.23; 95% CI 1.13 to 1.32), and the categories containing CBD (SMR 7.80; 95% CI 6.26 to 9.60) and cor pulmonale (SMR 1.17; 95% CI 1.08 to 1.26) (Schubauer-Berigan *et al.,* 2011, Document ID 1266). Mortality rates for most diseases of interest increased with time since hire. For the category including CBD, rates were substantially elevated compared to the U.S. population across all exposure groups. Workers whose maximum beryllium exposure was ≥10 μg/m^3 had higher rates of lung cancer, urinary tract cancer, COPD and the category containing cor pulmonale than workers with lower exposure. These studies showed strong associations for cumulative exposure (when short-term workers were excluded), maximum exposure, or both. Significant positive trends with cumulative exposure were observed for nervous system cancers ($p = 0.0006$) and, when short-term workers were excluded, lung cancer ($p = 0.01$), urinary tract cancer ($p = 0.003$), and COPD ($p < 0.0001$).

The authors concluded that the findings from this reanalysis reaffirmed that lung cancer and CBD are related to beryllium exposure. The authors went on to suggest that beryllium exposures may be associated with nervous system and urinary tract cancers and that cigarette smoking and other lung carcinogens were unlikely to explain the increased incidences in these cancers. The study corrected an error that was discovered in the indirect smoking adjustment initially conducted by Ward *et al.,* concluding that cigarette smoking rates did not differ between the cohort and the general U.S. population. No association was found between cigarette smoking and either cumulative or maximum beryllium exposure, making it very unlikely that smoking was a substantial confounder in this study (Schubauer-Berigan *et al.,* 2011, Document ID 1266).

A study by Boffetta *et al.* (2014, Document ID 0403) and an abstract by Boffetta *et al.,* (2015, Document ID 1661, Attachment 1) were submitted by Materion for Agency consideration (Document ID 1661, p. 3). Briefly, Boffetta *et al.* investigated lung cancer and other diseases in a cohort of 4,950 workers in four beryllium manufacturing facilities. Based on available process information from the facilities, the cohort of workers included only those working with poorly soluble beryllium. Workers having potential for soluble beryllium exposure were excluded from the study. Boffetta *et al.* reported a slight increase in lung cancer rates among workers hired prior to 1960, but the increase was reported as not statistically significant. Bofetta *et al.* (2014) indicated that ''[t]his study confirmed the lack of an increase in mortality from lung cancer and nonmalignant respiratory diseases related to [poorly] soluble beryllium compounds'' (Document ID 0403, p. 587). OSHA disagrees, and a more detailed analysis of the Boffetta *et al.* (2014, Document ID 0403) study is provided in the Risk Assessment section (VI) of this preamble. The Boffetta *et al.* (2015, Document ID 1661, Attachment 1) study cited by Materion was an abstract to the 48th annual Society of Epidemiological Research conference and does not provide sufficient information for OSHA to consider.

To summarize, most of the epidemiological studies reviewed in this section show an elevated lung cancer rate in beryllium-exposed workers compared to control groups. While exposure data was incomplete in many studies inferences can be made based on industry profiles. Specifically, studies reviewing excess lung cancer in workers registered in the BCR found an elevated lung cancer rate in those patients identified as having acute beryllium disease (ABD). ABD patients are most closely associated with exposure to soluble forms of beryllium (Infante *et al.,* 1980, Document ID 1507; Steenland and Ward, 1991 (1348)). Industry profiles in processing and extraction indicate that most exposures would be due to poorly soluble forms of beryllium. Excess lung cancer rates were observed in workers in industries associated with extraction and processing (Schubauer-Berigan *et al.,* 2008, Document ID 1350; Schubauer-Berigan *et al.* 2011 (1266, 1815 Attachment 105); Ward *et al.,* 1992 (1378); Hollins *et al.,* 2009 (1512); Sanderson *et al.,* 2001 (1419); Mancuso *et al.,* 1980 (1452); Wagoner *et al.,* 1980 (1379)). During the public comment period NIOSH noted that:

> . . . in Table 1 of Ward *et al.* (1992), all three of these beryllium plants were engaged in operations associated with both soluble and [poorly soluble] forms of beryllium. Industrial hygienists from NIOSH [Sanderson *et al.* (2001); Couch *et al.* (2011)] and elsewhere [Chen (2001); Rosenman *et al.* (2005)] created job-exposure matrices (JEMs), which estimated the form of beryllium exposure (soluble, consisting of beryllium salts; [poorly soluble], consisting of beryllium metal, alloys, or beryllium oxide; and mixed forms) associated with each job, department and year combination at each plant. Unpublished evaluations of these JEM estimates linked to the employee work histories in the NIOSH risk assessment study [Schubauer-Berigan *et al.,* 2011b, Document ID 0521] show that the vast majority of beryllium work-time at all three of these facilities was due to either [poorly] soluble or mixed chemical forms. In fact, [poorly] soluble beryllium was the largest single contributor to work-time (for beryllium exposure of known solubility class) at the three facilities across most time periods . . . . Therefore, the strong and consistent exposure-response pattern that was observed in the published NIOSH studies was very likely associated with exposure to [poorly] soluble as well as soluble forms of beryllium. (Document ID 1725, p. 9)

Taken collectively, the Agency finds that the epidemiological data presented in the reviewed studies provides sufficient evidence to demonstrate carcinogenicity in humans of both soluble and poorly soluble forms of beryllium.

3. Animal Cancer Studies

This section reviews the animal literature used to support the findings for beryllium-induced lung cancer. Early animal studies revealed that some beryllium compounds are carcinogenic when inhaled (ATSDR, 2002, Document ID 1371). Lung tumors have been induced via inhalation and intratracheal administration of beryllium to rats and monkeys, and osteosarcomas have been induced via intravenous and intramedullary (inside the bone) injection of beryllium in rabbits and mice. In addition to lung cancer,

osteosarcomas have been produced in mice and rabbits exposed to various beryllium salts by intravenous injection or implantation into the bone (NTP, 1999, Document ID 1341: IARC, 2012 (0650)). While not completely understood, experimental studies in animals (*in vitro and in vivo*) have found that a number of mechanisms are likely involved in beryllium-induced carcinogenicity, including chronic inflammation, genotoxicity, mitogenicity, oxidative stress, and epigenetic changes.

In an inhalation study assessing the potential tumorigenicity of beryllium, Schepers *et al.* (1957) (Document ID 0458) exposed 115 albino Sherman and Wistar rats (male and female) via inhalation to 0.0357 mg beryllium/m^3 (1 γ beryllium/ft^3) [7] as an aqueous aerosol of beryllium sulfate for 44 hours/week for 6 months, and observed the rats for 18 months after exposure. Three to four control rats were killed every two months for comparison purposes. Seventy-six lung neoplasms,[8] including adenomas, squamous-cell carcinomas, acinous adenocarcinomas, papillary adenocarcinomas, and alveolar-cell adenocarcinomas, were observed in 52 of the rats exposed to the beryllium sulfate aerosol. Adenocarcinomas were the most numerous. Pulmonary metastases tended to localize in areas with foam cell clustering and granulomatosis. No neoplasia was observed in any of the control rats. The incidence of lung tumors in exposed rats is presented in the following Table 3:

TABLE 3—NEOPLASM ANALYSIS, BASED ON SCHEPERS ET AL. (1957)

Neoplasm	Number	Metastases
Adenoma	18	0
Squamous carcinoma	5	1
Acinous adenocarcinoma	24	2
Papillary adenocarcinoma	11	1
Alveolar-cell adenocarcinoma	7	0
Mucigenous tumor	7	1
Endothelioma	1	0
Retesarcoma	3	3

TABLE 3—NEOPLASM ANALYSIS, BASED ON SCHEPERS ET AL. (1957)—Continued

Neoplasm	Number	Metastases
Total	76	8

Schepers (1962) (Document ID 1414) reviewed 38 existing beryllium studies that evaluated seven beryllium compounds and seven mammalian species. Beryllium sulfate, beryllium fluoride, beryllium phosphate, beryllium alloy ($BeZnMnSiO_4$), and beryllium oxide were proven to be carcinogenic. Ten varieties of tumors were observed, with adenocarcinoma being the most common variety.

In another study, Vorwald and Reeves (1959) (Document ID 1482) exposed Sherman albino rats via the inhalation route to aerosols of 0.006 mg beryllium/m^3 as beryllium oxide and 0.0547 mg beryllium/m^3 as beryllium sulfate for 6 hours/day, 5 days/week for an unspecified duration. Lung tumors (single or multifocal) were observed in the animals sacrificed following 9 months of daily inhalation exposure. The histologic pattern of the cancer was primarily adenomatous; however, epidermoid and squamous cell cancers were also observed. Infiltrative, vascular, and lymphogenous extensions often developed with secondary metastatic growth in the tracheobronchial lymph nodes, the mediastinal connective tissue, the parietal pleura, and the diaphragm.

In the first of two articles, Reeves *et al.* (1967) investigated the carcinogenic process in lungs resulting from chronic (up to 72 weeks) beryllium sulfate inhalation (Document ID 1310). One hundred fifty male and female Sprague Dawley C.D. strain rats were exposed to beryllium sulfate aerosol at a mean atmospheric concentration of 34.25 μg beryllium/m^3 (with an average particle diameter of 0.12 μm). Prior to initial exposure and again during the 67–68 and 75–76 weeks of life, the animals received prophylactic treatments of tetracycline-HCl to combat recurrent pulmonary infections.

The animals entered the exposure chamber at 6 weeks of age and were exposed 7 hours per day/5 days per week for up to 2,400 hours of total exposure time. An equal number of unexposed controls were held in a separate chamber. Three male and three female rats were sacrificed monthly during the 72-week exposure period. Mortality due to respiratory or other infections did not appear until 55 weeks of age, and 87 percent of all animals survived until their scheduled sacrifices.

Average lung weight towards the end of exposure was 4.25 times normal with progressively increasing differences between control and exposed animals. The increase in lung weight was accompanied by notable changes in tissue texture with two distinct pathological processes—inflammatory and proliferative. The inflammatory response was characterized by marked accumulation of histiocytic elements forming clusters of macrophages in the alveolar spaces. The proliferative response progressed from early epithelial hyperplasia of the alveolar surfaces, through metaplasia (after 20–22 weeks of exposure), anaplasia (cellular dedifferentiation) (after 32–40 weeks of exposure), and finally to lung tumors.

Although the initial proliferative response occurred early in the exposure period, tumor development required considerable time. Tumors were first identified after nine months of beryllium sulfate exposure, with rapidly increasing rates of incidence until tumors were observed in 100 percent of exposed animals by 13 months. The 9-to-13-month interval is consistent with earlier studies. The tumors showed a high degree of local invasiveness. No tumors were observed in control rats. All 56 tumors studied appeared to be alveolar adenocarcinomas and 3 were ''fast-growing'' tumors that reached a very large size comparatively early. About one-third of the tumors showed small foci where the histologic pattern differed. Most of the early tumor foci appeared to be alveolar rather than bronchiolar, which is consistent with the expected pathogenesis, since permanent deposition of beryllium was more likely on the alveolar epithelium rather than on the bronchiolar epithelium. Female rats appeared to have an increased susceptibility to beryllium exposure. Not only did they have a higher mortality (control males [n = 8], exposed males [n = 9] versus control females [n = 4], exposed females [n = 17]) and body weight loss than male rats, but the three ''fast-growing'' tumors occurred in females.

In the second article, Reeves *et al.* (1967) (Document ID 1309) described the rate of accumulation and clearance of beryllium sulfate aerosol from the same experiment (Reeves *et al.,* 1967) (Document ID 1310). At the time of the monthly sacrifice, beryllium assays were performed on the lungs, tracheobronchial lymph nodes, and blood of the exposed rats. The pulmonary beryllium levels of rats showed a rate of accumulation which

[7] Schepers *et al.* (1957) reported concentrations in γ Be/ft^3; however, γ/ft^3 is no longer a common unit. Therefore, the concentration was converted to mg/m^3.

[8] While a total of 89 tumors were observed or palpated at the time of autopsy in the $BeSO_4$-exposed animals, only 76 tumors are listed as histologically neoplastic. Only the new growths identified in single midcoronal sections of both lungs were recorded.

decreased during continuing exposure and reached a plateau (defined as equilibrium between deposition and clearance) of about 13.5 µg beryllium for males and 9 µg beryllium for females in whole lungs after approximately 36 weeks. Females were notably less efficient than males in utilizing the lymphatic route as a method of clearance, resulting in slower removal of pulmonary beryllium deposits, lower accumulation of the inhaled material in the tracheobronchial lymph nodes, and higher morbidity and mortality.

There was no apparent correlation between the extent and severity of pulmonary pathology and total lung load. However, when the beryllium content of the excised tumors was compared with that of surrounding nonmalignant pulmonary tissues, the former showed a notable decrease (0.50 ± 0.35 µg beryllium/gram versus 1.50 ± 0.55 µg beryllium/gram). This was believed to be largely a result of the dilution factor operating in the rapidly growing tumor tissue. However, other factors, such as lack of continued local deposition due to impaired respiratory function and enhanced clearance due to high vascularity of the tumor, may also have played a role. The portion of inhaled beryllium retained in the lungs for a longer duration, which is in the range of one-half of the original pulmonary load, may have significance for pulmonary carcinogenesis. This pulmonary beryllium burden becomes localized in the cell nuclei and may be an important factor in eliciting the carcinogenic response associated with beryllium inhalation.

Groth *et al.* (1980) (Document ID 1316) conducted a series of experiments to assess the carcinogenic effects of beryllium, beryllium hydroxide, and various beryllium alloys. For the beryllium metal/alloys experiment, 12 groups of 3-month-old female Wistar rats (35 rats/group) were used. All rats in each group received a single intratracheal injection of either 2.5 or 0.5 mg of one of the beryllium metals or beryllium alloys as described in Table 3 below. These materials were suspended in 0.4 cc of isotonic saline followed by 0.2 cc of saline. Forty control rats were injected with 0.6 cc of saline. The geometric mean particle sizes varied from 1 to 2 µm. Rats were sacrificed and autopsied at various intervals ranging from 1 to 18 months post-injection.

TABLE 4—SUMMARY OF BERYLLIUM DOSE, BASED ON GROTH ET AL. (1980)

[Document ID 1316]

Form of Be	Percent Be	Percent other compounds	Total Number rats autopsied	Compound dose(mg)	Be dose(mg)
Be metal	100	None	16	2.5	2.5
			21	0.5	0.5
Passivated Be metal	99	0.26% Chromium	26	2.5	2.5
			20	0.5	0.5
BeAl alloy	62	38% Aluminum	24	2.5	1.55
			21	0.5	0.3
BeCu alloy	4	96% Copper	28	2.5	0.1
			24	0.5	0.02
BeCuCo alloy	2.4	0.4% Cobalt	33	2.5	0.06
		96% Copper	30	0.5	0.012
BeNi alloy	2.2	97.8% Nickel	28	2.5	0.056
			27	0.5	0.011

Lung tumors were observed only in rats exposed to beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. Passivation refers to the process of removing iron contamination from the surface of beryllium metal. As discussed, metal alloys may have a different toxicity than beryllium alone. Rats exposed to 100 percent beryllium exhibited relatively high mortality rates, especially in the groups where lung tumors were observed. Nodules varying from 1 to 10 mm in diameter were also observed in the lungs of rats exposed to beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These nodules were suspected of being malignant.

To test this hypothesis, transplantation experiments involving the suspicious nodules were conducted in nine rats. Seven of the nine suspected tumors grew upon transplantation. All transplanted tumor types metastasized to the lungs of their hosts. Lung tumors were observed in rats injected with both the high and low doses of beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. No lung tumors were observed in rats injected with the other compounds. Of a total of 32 lung tumors detected, most were adenocarcinomas and adenomas; however, two epidermoid carcinomas and at least one poorly differentiated carcinoma were observed. Bronchiolar alveolar cell tumors were frequently observed in rats injected with beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. All stages of cuboidal, columnar, and squamous cell metaplasia were observed on the alveolar walls in the lungs of rats injected with beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These lesions were generally reduced in size and number or absent from the lungs of animals injected with the other alloys (BeCu, BeCuCo, BeNi).

The extent of alveolar metaplasia could be correlated with the incidence of lung cancer. The incidences of lung tumors in the rats that received 2.5 mg of beryllium metal, and 2.5 and 0.5 mg of passivated beryllium metal, were significantly different ($p \leq 0.008$) from controls. When autopsies were performed at the 16-to-19-month interval, the incidence (2/6) of lung tumors in rats exposed to 2.5 mg of beryllium-aluminum alloy was statistically significant ($p = 0.004$) when compared to the lung tumor incidence (0/84) in rats exposed to BeCu, BeNi, and BeCuCo alloys, which contained much lower concentrations of Be (Groth *et al.,* 1980, Document ID 1316).

Finch *et al.* (1998b) (Document ID 1367) investigated the carcinogenic effects of inhaled beryllium on heterozygous TSG-p53 knockout (*p53* $^{+/-}$) mice and wild-type (*p53*+/+) mice. Knockout mice can be valuable tools in determining the role played by specific genes in the toxicity of a material of interest, in this case beryllium. Equal numbers of approximately 10-week-old male and female mice were used for this study. Two exposure groups were used to provide dose-response information on lung carcinogenicity. The maximum initial lung burden (ILB) target of 60 µg

beryllium was based on previous acute inhalation exposure studies in mice. The lower exposure target level of 15 µg was selected to provide a lung burden significantly less than the high-level group, but high enough to yield carcinogenic responses. Mice were exposed in groups to beryllium metal or to filtered air (controls) via nose-only inhalation. The specific exposure parameters are presented in Table 4 below. Mice were sacrificed 7 days post exposure for ILB analysis, and either at 6 months post exposure (n = 4–5 mice per group per gender) or when 10 percent or less of the original population remained (19 months post exposure for *p53* $^{+/-}$ knockout and 22.5 months post exposure for *p53*+/+ wild-type mice). The sacrifice time was extended in the study because a significant number of lung tumors were not observed at 6 months post exposure.

TABLE 5—SUMMARY OF ANIMAL DATA, BASED ON FINCH ET AL. (1998)

[Document ID 1367]

Mouse strain	Mean exposure concentration (µg Be/L)	Target beryllium lung burden (µg)	Number of mice	Mean daily exposure duration (minutes)	Mean ILB (µg)	Number of mice with 1 or more lung tumors/total number examined
Knockout (*p53* $^{+/-}$)	34	15	30	112 (single)	NA	0/29
	36	60	30	139	NA	4/28
Wild-type (*p53* $^{+/+}$)	34	15	6	112 (single)	12 ± 4	NA
	36	60	36	139	54 ± 6	0/28
Knockout (*p53* $^{+/-}$)	NA (air)	Control	30	60–180 (single)	NA	0/30

Lung burdens of beryllium measured in wild-type mice at 7 days post exposure were approximately 70–90 percent of target levels. No exposure-related effects on body weight were observed in mice; however, lung weights and lung-to-body-weight ratios were somewhat elevated in 60 µg target ILB *p53* $^{+/-}$ knockout mice compared to controls ($0.05 < p < 0.10$). In general, *p53*+/+ wild-type mice survived longer than *p53* $^{+/-}$ knockout mice and beryllium exposure tended to decrease survival time in both groups. The incidence of beryllium-induced lung tumors was marginally higher in the 60 µg target ILB *p53* $^{+/-}$ knockout mice compared to 60 µg target ILB *p53*+/+ wild-type mice ($p = 0.056$). The incidence of lung tumors in the 60 µg target ILB *p53* $^{+/-}$ knockout mice was also significantly higher than controls (p = 0.048). No tumors developed in the control mice, 15 µg target ILB *p53* $^{+/-}$ knockout mice, or 60 µg target ILB *p53*+/+ wild-type mice throughout the length of the study. Most lung tumors in beryllium-exposed mice were squamous cell carcinomas, three of four of which were poorly circumscribed and all of which were associated with at least some degree of granulomatous pneumonia. The study results suggest that having an inactivated *p53* allele is associated with lung tumor progression in *p53* $^{+/-}$ knockout mice. This is based on the significant difference seen in the incidence of beryllium-induced lung neoplasms for the *p53* $^{+/-}$ knockout mice compared with the *p53* $^{+/+}$ wild-type mice. The authors conclude that since there was a relatively late onset of tumors in the beryllium-exposed *p53* $^{+/-}$ knockout mice, a 6-month bioassay in this mouse strain might not be an appropriate model for lung carcinogenesis (Finch *et al.,* 1998, Document ID 1367).

During the public comment period Materion submitted correspondence from Dr. Finch speculating on the reason for the less-robust lung cancer response observed in mice (versus that observed in rats) (Document ID 1807, Attachment 11, p. 1). Materion contended that this was support for their assertion of evidence that ''directly contradicts the claims that beryllium metal causes cancer in animals'' (Document ID 1807, p. 6). OSHA reviewed this correspondence and disagrees with Materion's assertion. While Dr. Finch did suggest that the mouse lung cancer response was less robust, it was still present. Dr. Finch went on to suggest that while the rat has a more profound neutrophilic response (typical of a ''foreign body response), the mouse has a lung response more typical of humans (neutrophilic and lymphocytic) (Document ID 1807, Attachment 11, p. 1).

Nickell-Brady *et al.* (1994) investigated the development of lung tumors in 12-week-old F344/N rats after a single nose-only inhalation exposure to beryllium aerosol, and evaluated whether beryllium lung tumor induction involves alterations in the K-*ras, p53,* and c-*raf*-1 genes (Document ID 1312). Four groups of rats (30 males and 30 females per group) were exposed to different mass concentrations of beryllium (Group 1: 500 mg/m^3 for 8 min; Group 2: 410 mg/m^3 for 30 min; Group 3: 830 mg/m^3 for 48 min; Group 4: 980 mg/m^3 for 39 min). The beryllium mass median aerodynamic diameter was 1.4 µm ($\sigma_g = 1.9$). The mean beryllium lung burdens for each exposure group were 40, 110, 360, and 430 µg, respectively.

To examine genetic alterations, DNA isolation and sequencing techniques (PCR amplification and direct DNA sequence analysis) were performed on wild-type rat lung tissue (*i.e.,* control samples) along with two mouse lung tumor cell lines containing known K-*ras* mutations, 12 carcinomas induced by beryllium (*i.e.,* experimental samples), and 12 other formalin-fixed specimens. Tumors appeared in beryllium-exposed rats by 14 months, and 64 percent of exposed rats developed lung tumors during their lifetime. Lungs frequently contained multiple tumor sites, with some of the tumors greater than 1 cm. A total of 24 tumors were observed. Most of the tumors (n = 22) were adenocarcinomas exhibiting a papillary pattern characterized by cuboidal or columnar cells, although a few had a tubular or solid pattern. Fewer than 10 percent of the tumors were adenosquamous (n = 1) or squamous cell (n = 1) carcinomas.

No transforming mutations of the K-*ras* gene (codons 12, 13, or 61) were detected by direct sequence analysis in any of the lung tumors induced by beryllium. However, using a more sensitive sequencing technique (PCR enrichment restriction fragment length polymorphism (RFLP) analysis) resulted in the detection of K-*ras* codon 12 GGT to GTT transversions in 2 of 12 beryllium-induced adenocarcinomas. No *p53* or c-*raf*-1 alterations were observed in any of the tumors induced by beryllium exposure (*i.e.,* no differences observed between beryllium-exposed and control rat tissues). The authors note that the results suggest that

activation of the K-*ras* proto-oncogene is both a rare and late event, possibly caused by genomic instability during the progression of beryllium-induced rat pulmonary adenocarcinomas. It is unlikely that the K-*ras* gene plays a role in the carcinogenicity of beryllium. The results also indicate that *p53* mutation is unlikely to play a role in tumor development in rats exposed to beryllium.

Belinsky *et al.* (1997) reviewed the findings by Nickell-Brady *et al.* (1994) (Document ID 1312) to further examine the role of the K-*ras* and *p53* genes in lung tumors induced in the F344 rat by non-mutagenic (non-genotoxic) exposures to beryllium. Their findings are discussed along with the results of other genomic studies that look at carcinogenic agents that are either similarly non-mutagenic or, in other cases, mutagenic. The authors concluded that the identification of non-*ras* transforming genes in rat lung tumors induced by non-mutagenic exposures, such as beryllium, as well as mutagenic exposures will help define some of the mechanisms underlying cancer induction by different types of DNA damage.

The inactivation of the *p16* INK4a(*p16*) gene is a contributing factor in disrupting control of the normal cell cycle and may be an important mechanism of action in beryllium-induced lung tumors. Swafford *et al.* (1997) investigated the aberrant methylation and subsequent inactivation of the *p16* gene in primary lung tumors induced in F344/N rats exposed to known carcinogens via inhalation (Document ID 1392). The research involved a total of 18 primary lung tumors that developed after exposing rats to five agents, one of which was beryllium. In this study, only one of the 18 lung tumors was induced by beryllium exposure; the majority of the other tumors were induced by radiation (x-rays or plutonium-239 oxide). The authors hypothesized that if *p16* inactivation plays a central role in development of non-small-cell lung cancer, then the frequency of gene inactivation in primary tumors should parallel that observed in the corresponding cell lines. To test the hypothesis, a rat model for lung cancer was used to determine the frequency and mechanism for inactivation of *p16* in matched primary lung tumors and derived cell lines. The methylation-specific PCR (MSP) method was used to detect methylation of *p16* alleles. The results showed that the presence of aberrant *p16* methylation in cell lines was strongly correlated with absent or low expression of the gene. The findings also demonstrated that aberrant *p16* CpG island methylation, an important mechanism in gene silencing leading to the loss of *p16* expression, originates in primary tumors.

Building on the rat model for lung cancer and associated findings from Swafford *et al.* (1997) (Document ID 1392), Belinsky *et al.* (2002) (Document ID 1300) conducted experiments in 12-week-old F344/N rats (male and female) to determine whether beryllium-induced lung tumors involve inactivation of the *p16* gene and estrogen receptor α (ER) gene. Rats received a single nose-only inhalation exposure to beryllium aerosol at four different exposure levels. The mean lung burdens measured in each exposure group were 40, 110, 360, and 430 μg. The methylation status of the *p16* and ER genes was determined by MSP. A total of 20 tumors detected in beryllium-exposed rats were available for analysis of gene-specific promoter methylation. Three tumors were classified as squamous cell carcinomas and the others were determined to be adenocarcinomas. Methylated *p16* was present in 80 percent (16/20), and methylated ER was present in one-half (10/20), of the lung tumors induced by exposure to beryllium. Additionally, both genes were methylated in 40 percent of the tumors. The authors noted that four tumors from beryllium-exposed rats appeared to be partially methylated at the *p16* locus. Bisulfite sequencing of exon 1 of the ER gene was conducted on normal lung DNA and DNA from three methylated, beryllium-induced tumors to determine the density of methylation within amplified regions of exon 1 (referred to as CpG sites). Two of the three methylated, beryllium-induced lung tumors showed extensive methylation, with more than 80 percent of all CpG sites methylated.

The overall findings of this study suggest that inactivation of the *p16* and ER genes by promoter hypermethylation are likely to contribute to the development of lung tumors in beryllium-exposed rats. The results showed a correlation between changes in *p16* methylation and loss of gene transcription. The authors hypothesize that the mechanism of action for beryllium-induced *p16* gene inactivation in lung tumors may be inflammatory mediators that result in oxidative stress. The oxidative stress damages DNA directly through free radicals or indirectly through the formation of 8-hydroxyguanosine DNA adducts, resulting primarily in a single-strand DNA break.

Wagner *et al.* (1969) (Document ID 1481) studied the development of pulmonary tumors after intermittent daily chronic inhalation exposure to beryllium ores in three groups of male squirrel monkeys. One group was exposed to bertrandite ore, a second to beryl ore, and the third served as unexposed controls. Each of these three exposure groups contained 12 monkeys. Monkeys from each group were sacrificed after 6, 12, or 23 months of exposure. The 12-month sacrificed monkeys (n = 4 for bertrandite and control groups; n = 2 for beryl group) were replaced by a separate replacement group to maintain a total animal population approximating the original numbers and to provide a source of confirming data for biologic responses that might arise following the ore exposures. Animals were exposed to bertrandite and beryl ore concentrations of 15 mg/m^3, corresponding to 210 μg beryllium/m^3 and 620 μg beryllium/m^3 in each exposure chamber, respectively. The parent ores were reduced to particles with geometric mean diameters of 0.27 μm (± 2.4) for bertrandite and 0.64 μm (± 2.5) for beryl. Animals were exposed for approximately 6 hours/day, 5 days/week. The histological changes in the lungs of monkeys exposed to bertrandite and beryl ore exhibited a similar pattern. The changes generally consisted of aggregates of dust-laden macrophages, lymphocytes, and plasma cells near respiratory bronchioles and small blood vessels. There were, however, no consistent or significant pulmonary lesions or tumors observed in monkeys exposed to either of the beryllium ores. This is in contrast to the findings in rats exposed to beryl ore and to a lesser extent bertrandite, where atypical cell proliferation and tumors were frequently observed in the lungs. The authors hypothesized that the rats' greater susceptibility may be attributed to the spontaneous lung disease characteristic of rats, which might have interfered with lung clearance.

As previously described, Conradi *et al.* (1971) investigated changes in the lungs of monkeys and dogs two years after intermittent inhalation exposure to beryllium oxide calcined at 1,400 °C (Document ID 1319). Five adult male and female monkeys (*Macaca irus*) weighing between 3 and 5.75 kg were used in the study. The study included two control monkeys. Beryllium concentrations in the atmosphere of whole-body exposed monkeys varied between 3.30 and 4.38 mg/m^3. Thirty-minute exposures occurred once a month for three months, with beryllium oxide concentrations increasing at each exposure interval. Lung tissue was investigated using electron microscopy

and morphometric methods. Beryllium content in portions of the lungs of five monkeys was measured two years following exposure by emission spectrography. The reported concentrations in monkeys (82.5, 143.0, and 112.7 μg beryllium per 100 gm of wet tissue in the upper lobe, lower lobe, and combined lobes, respectively) were higher than those in dogs. No neoplastic or granulomatous lesions were observed in the lungs of any exposed animals and there was no evidence of chronic proliferative lung changes after two years.

To summarize, animal studies show that multiple forms of beryllium, when inhaled or instilled in the respiratory tract of rats, mice, and monkeys, lead to increased incidence of lung tumors. Animal studies have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation and tumor formation at levels below overload conditions (Groth *et al.,* 1980, Document ID 1316; Finch *et al.,* 1998 (1367); Nickel-Brady *et al.,* 1994 (1312)). The animal studies support the human epidemiological evidence and contributed to the findings of the NTP, IARC, and others that beryllium and beryllium-containing material should be regarded as known human carcinogens. The beryllium compounds found to be carcinogenic in animals include both soluble beryllium compounds, such as beryllium sulfate and beryllium hydroxide, as well as poorly soluble beryllium compounds, such as beryllium oxide and beryllium metal. The doses that produce tumors in experimental animal are fairly large and also lead to chronic pulmonary inflammation. The exact tumorigenic mechanism for beryllium is unclear and a number of mechanisms are likely involved, including chronic inflammation, genotoxicity, mitogenicity, oxidative stress, and epigenetic changes.

4. In Vitro Studies

The exact mechanism by which beryllium induces pulmonary neoplasms in animals remains unknown (NAS 2008, Document ID 1355). Keshava *et al.* (2001) performed studies to determine the carcinogenic potential of beryllium sulfate in cultured mammalian cells (Document ID 1362). Joseph *et al.* (2001) investigated differential gene expression to understand the possible mechanisms of beryllium-induced cell transformation and tumorigenesis (Document ID 1490). Both investigations used cell transformation assays to study the cellular/molecular mechanisms of beryllium carcinogenesis and assess carcinogenicity. Cell lines were derived from tumors developed in nude mice injected subcutaneously with non-transformed BALB/c-3T3 cells that were morphologically transformed *in vitro* with 50–200 μg beryllium sulfate/ml for 72 hours. The non-transformed cells were used as controls.

Keshava *et al.* (2001) found that beryllium sulfate is capable of inducing morphological cell transformation in mammalian cells and that transformed cells are potentially tumorigenic (Document ID 1362). A dose-dependent increase (9–41 fold) in transformation frequency was noted. Using differential polymerase chain reaction (PCR), gene amplification was investigated in six proto-oncogenes (K-*ras,* c-*myc,* c-fos, c-*jun,* c-*sis, erb-B2*) and one tumor suppressor gene (*p53*). Gene amplification was found in c-*jun* and K-*ras.* None of the other genes tested showed amplification. Additionally, Western blot analysis showed no change in gene expression or protein level in any of the genes examined. Genomic instability in both the non-transformed and transformed cell lines was evaluated using random amplified polymorphic DNA fingerprinting (RAPD analysis). Using different primers, 5 of the 10 transformed cell lines showed genomic instability when compared to the non-transformed BALB/c-3T3 cells. The results indicate that beryllium sulfate-induced cell transformation might, in part, involve gene amplification of K-*ras* and c-*jun* and that some transformed cells possess neoplastic potential resulting from genomic instability.

Using the Atlas mouse 1.2 cDNA expression microarrays, Joseph *et al.* (2001) studied the expression profiles of 1,176 genes belonging to several different functional categories after beryllium sulfate exposure in a mouse cell line (Document ID 1490). Compared to the control cells, expression of 18 genes belonging to two functional groups (nine cancer-related genes and nine DNA synthesis, repair, and recombination genes) was found to be consistently and reproducibly different (at least 2-fold) in the tumor cells. Differential gene expression profile was confirmed using reverse transcription-PCR with primers specific to the differentially expressed genes. Two of the differentially expressed genes (c-*fos* and c-*jun*) were used as model genes to demonstrate that the beryllium-induced transcriptional activation of these genes was dependent on pathways of protein kinase C and mitogen-activated protein kinase and independent of reactive oxygen species in the control cells. These results indicate that beryllium-induced cell transformation and tumorigenesis are associated with up-regulated expression of the cancer-related genes (such as c-*fos,* c-*jun,* c-*myc,* and R-*ras*) and down-regulated expression of genes involved in DNA synthesis, repair, and recombination (such as *MCM4, MCM5, PMS2, Rad23,* and DNA *ligase I*).

In summary, *in vitro* studies have been used to evaluate the neoplastic potential of beryllium compounds and the possible underlying mechanisms. Both Keshava *et al.* (2001) (Document ID 1362) and Joseph *et al.* (2001) (Document ID 1490) have found that beryllium sulfate induced a number of onco-genes (c-*fos,* c-*jun,* c-*myc,* and R-*ras*) and down-regulated genes responses for normal cellular function and repair (including those involved in DNA synthesis, repair, and recombination).

5. Lung Cancer Conclusions

OSHA has determined that substantial evidence in the record indicates that beryllium compounds should be regarded as occupational lung carcinogens. Many well-respected scientific organizations, including IARC, NTP, EPA, NIOSH, and ACGIH, have reached similar conclusions with respect to the carcinogenicity of beryllium.

While some evidence exists for direct-acting genotoxicity as a possible mechanism for beryllium carcinogenesis, the weight of evidence suggests that an indirect mechanism, such as inflammation or other epigenetic changes, may be responsible for most tumorigenic activity of beryllium in animals and humans (IARC, 2012, Document ID 0650). Inflammation has been postulated to be a key contributor to many different forms of cancer (Jackson *et al.,* 2006; Pikarsky *et al.,* 2004; Greten *et al.,* 2004; Leek, 2002). In fact, chronic inflammation may be a primary factor in the development of up to one-third of all cancers (Ames *et al.,* 1990; NCI, 2010).

In addition to a T-cell-mediated immunological response, beryllium has been demonstrated to produce an inflammatory response in animal models similar to the response produced by other particles (Reeves *et al.,* 1967, Document ID 1309; Swafford *et al.,* 1997 (1392); Wagner *et al.,* 1969 (1481)), possibly contributing to its carcinogenic potential. Studies conducted in rats have demonstrated that chronic inhalation of materials similar in solubility to beryllium results in increased pulmonary inflammation,

fibrosis, epithelial hyperplasia, and, in some cases, pulmonary adenomas and carcinomas (Heinrich *et al.,* 1995, Document ID 1513; NTP, 1993 (1333); Lee *et al.,* 1985 (1466); Warheit *et al.,* 1996 (1377)). This response is generally referred to as an ''overload'' response and is specific to particles of low solubility with a low order of toxicity, which are non-mutagenic and non-genotoxic (*i.e.,* poorly soluble particles like titanium dioxide and non-asbestiform talc); this response is observed only in rats (Carter *et al.,* 2006, Document ID 1556). ''Overload'' is described in ECETOC (2013) as inhalation of high concentrations of low solubility particles resulting in lung burdens that impair particle clearance mechanisms (ECETOC, 2013 as cited in Document ID 1807, Attachment 10, p. 3 (pdf p. 87)). Substantial data indicate that tumor formation in rats after exposure to some poorly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity (or lack thereof) of the particle itself. Because these specific particles (*i.e.,* titanium dioxide and non-asbestiform talc) exhibit no cytotoxicity or genotoxicity, they are considered to be biologically inert (ECETOC, 2013; see Document ID 1807, Attachment 10, p. 3 (pdf p. 87)). Animal studies, as summarized above, have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation below an overload scenario. NIOSH submitted comments describing the findings from a low-dose study of beryllium metal among male and female F344 rats (Document ID 1960, p. 11). The study by Finch *et al.* (2000) indicated lung tumor rates of 4, 4, 12, 50, 61, and 91 percent in animals with beryllium metal lung burdens of 0, 0.3, 1, 3, 10, and 50 µg respectively (Finch *et al.,* 2000 as cited in Document ID 1960, p. 11). NIOSH noted the lung burden levels were much lower than those from previous studies, such as a 1998 Finch *et al.* study with initial lung burdens of 15 and 60 µg (Document ID 1960, p. 11). Based on evidence from mammalian studies of the mutagenicity and genotoxicity of beryllium (as described in above in section V.E.1) and the evidence of tumorigenicity at lung burden levels well below overload, OSHA concludes that beryllium particles are not poorly soluble particles like titanium dioxide and non-asbestiform talc.

It has been hypothesized that the recruitment of neutrophils during the inflammatory response and subsequent release of oxidants from these cells play an important role in the pathogenesis of rat lung tumors (Borm *et al.,* 2004, Document ID 1559; Carter and Driscoll, 2001 (1557); Carter *et al.,* 2006 (1556); Johnston *et al.,* 2000 (1504); Knaapen *et al.,* 2004 (1499); Mossman, 2000 (1444)). This is one potential carcinogenic pathway for beryllium particles. Inflammatory mediators, acting at levels below overload doses as characterized in many of the studies summarized above, have been shown to play a significant role in the recruitment of cells responsible for the release of reactive oxygen and hydrogen species. These species have been determined to be highly mutagenic as well as mitogenic, inducing a proliferative response (Ferriola and Nettesheim, 1994, Document ID 0452; Coussens and Werb, 2002 (0496)). The resultant effect is an environment rich for neoplastic transformations and the progression of fibrosis and tumor formation. This is consistent with findings from the National Cancer Institute, which has estimated that one-third of all cancers may be due to chronic inflammation (NCI, 2010, Document ID 0532). However, an inflammation-driven contribution to the neoplastic transformation does not imply no risk at levels below inflammatory response; rather, the overall weight of evidence suggests a mechanism of an indirect carcinogen at levels where inflammation is seen. While tumorigenesis secondary to inflammation is one reasonable mode of action, other plausible modes of action independent of inflammation (*e.g.,* epigenetic, mitogenic, reactive oxygen mediated, indirect genotoxicity, etc.) may also contribute to the lung cancer associated with beryllium exposure. As summarized above, animal studies have consistently demonstrated beryllium exposure resulting in chronic pulmonary inflammation below overload conditions in multiple species (Groth *et al.,* 1980, Document ID 1316; Finch *et al.,* 1998 (1367); Nickel-Brady *et al.,* 1994 (1312)). While OSHA recognizes chronic inflammation as one potential pathway to carcinogencity the Agency finds that other carcinogenic pathways such as genotoxicity and epigenetic changes may also contribute to beryllium-induced carcinogenesis.

During the public comment period OSHA received several comments on the carcinogenicity of beryllium. The NFFS agreed with OSHA that ''the science is quite clear in linking these soluble Beryllium compounds'' to lung cancer (Document ID 1678, p. 6). It also, however, contended that there is considerable scientific dispute regarding the carcinogenicity of beryllium metal (*i.e.,* poorly soluble beryllium), citing findings by the EU's REACH Beryllium Commission (later clarified as the EU Beryllium Science and Technology Association) (Document ID 1785, p. 1; Document ID 1814) and a study by Strupp and Furnes (2010) (Document ID 1678, pp. 6–7, and Attachment 1). Materion, similarly, commented that ''[a] report conclusion during the recent review of the European Cancer Directive for the European Commission stated regarding beryllium: 'There was little evidence for any important health impact from current or recent past exposures in the EU' '' (Document ID 1958, p. 4).

The contentions of both Materion and NFFS regarding scientific findings from the EU is directly contradicted by the document submitted to the docket by the European Commission on Health, Safety and Hygiene at Work, discussed above. This document states that the European Chemicals Agency (ECHA) has determined that all forms of beryllium (soluble and poorly soluble) are carcinogenic (Category 1B) with the exception of aluminum beryllium silicates (which have not been allocated a classification) (Document ID 1692, pp. 2–3).

OSHA also disagrees with NFFS's other contention that there is a scientific dispute regarding the carcinogenicity of poorly soluble forms of beryllium. In coming to the conclusion that all forms of beryllium and beryllium compounds are carcinogenic, OSHA independently evaluated the scientific literature, including the findings of authoritative entities such as NIOSH, NTP, EPA, and IARC (see section V.E). The evidence from human, animal, and mechanistic studies together demonstrates that both soluble and poorly soluble beryllium compounds are carcinogenic (see sections V.E.2, V.E.3, V.E.4). The well-respected scientific bodies mentioned above came to the same conclusion: That both soluble and poorly soluble beryllium compounds are carcinogenic to humans.

As supporting documentation the NFFS submitted an ''expert statement'' by Strupp and Furnes (2010), which reviews the toxicological and epidemiological information regarding beryllium carcinogenicity. Based on select information in the scientific literature on lung cancer, the Strupp and Furnes (2010) study concluded that there was insufficient evidence in humans and animals to conclude that insoluble (poorly soluble) beryllium was carcinogenic (Document ID 1678, Attachment 1, pp. 21–23). Strupp and Furnes (2010) asserted that this was based on criteria established under

Annex VI of Directive 67/548/EEC which establishes criteria for classification and labelling of hazardous substances under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA reviewed the Strupp and Furnes (2010) ''expert statement'' submitted by NFFS and found it to be unpersuasive. Its review of the epidemiological evidence mischaracterized the findings from the NIOSH cohort and the nested case-control studies (Ward *et al.,* 1992; Sanderson *et al.,* 2001; Schubauer-Berigan *et al.,* 2008) and misunderstood the methods commonly used to analyze occupational cohort studies (Document ID 1725, pp. 27–28).

The Strupp and Furnes statement also did not include the more recent studies by Schubauer-Berigan *et al.* (2011, Document ID 1815, Attachment 105, 2011 (0626)), which demonstrated elevated rates for lung cancer (SMR 1.17; 95% CI 1.08 to 1.28) in a study of 7 beryllium processing plants. In addition, Strupp and Furnes did not consider expert criticism from IARC on the studies by Levy *et al.* (2007) and Deubner *et al.,* (2007), which formed the basis of their findings. NIOSH submitted comments that stated:

> The Strupp (2011b) review of the epidemiological evidence for lung carcinogenicity of beryllium contained fundamental mischaracterizations of the findings of the NIOSH cohort and nested case-control studies (Ward *et al.* 1992; Sanderson *et al.* 2001; Schubauer-Berigan *et al.* 2008), as well as an apparent misunderstanding of the methods commonly used to analyze occupational cohort studies (Document ID 1960, Attachment 2, p. 10).

As further noted by NIOSH:

> Strupp's epidemiology summary mentions two papers that were critical of the Sanderson *et al.* (2001) nested case-control study. The first of these, Levy *et al.* (2007a), was a re-analysis that incorporated a nonstandard method of selecting control subjects and the second, Deubner *et al.* (2007), was a simulation study designed to evaluate Sanderson's study design. Both of these papers have themselves been criticized for using faulty methods (Schubauer-Berigan *et al.* 2007; Kriebel, 2008; Langholz and Richardson, 2008); however, Strupp's coverage of this is incomplete. (Document ID 1960, Attachment 2, Appendix, p. 19).

NIOSH went on to state that while the Sanderson *et al.* (2001) used standard accepted methods for selecting the control group, the Deubner *et al.* (2007) study limited control group eligibility and failed to adequately match control and case groups (Document ID 1960, Attachment 2, Appendix, pp. 19–20). NIOSH noted that an independent analysis published by Langholz and Richardson (2009) and Hein *et al.,* (2009) (as cited in Document ID 1960, Attachment 2, Appendix, p. 20) found that Levy *et al.'s* method of eliminating controls from the study had the effect of ''always produc[ing] downwardly biased effect estimates and for many scenarios the bias was substantial.'' (Document ID 1960, Attachment 2, Appendix, p. 20). NIOSH went on to cite numerous errors in the studies cited by Strupp (2011) (Document ID 1794, 1795).[9] OSHA finds NIOSH's criticisms of the Strupp (2011) studies as well as their criticism of studies by Levy *et al.,* 2007 and Deubner *et al.,* 2007 to be reliable and credible.

The Strupp and Furnes (2010) statement provided insufficient information on the extraction of beryllium metal for OSHA to fully evaluate the merit of the studies regarding potential genotoxicity of poorly soluble beryllium (Document ID 1678, Attachment 1, pp. 18–20). In addition, Strupp and Furnes did not consider the peer-reviewed published studies evaluating the genotoxicity of beryllium metal (see section V.E.1 and V.E.2).

In coming to the conclusion that the evidence is insufficient for classification under GHS, Strupp and Furnes failed to consider the full weight of evidence in their evaluation using the criteria set forth under Annex VI of Directive 67/548/EEC which establishes criteria for classification and labelling of hazardous substances under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (Document ID 1678, attachment 1, pp. 21–23). Thus, the Agency concludes that the Strupp and Furnes statement does not constitute the best available scientific evidence for the evaluation of whether poorly soluble forms of beryllium cause cancer.

Materion also submitted comments indicating there is an ongoing scientific debate regarding the relevance of the rat lung tumor response to humans with respect to poorly soluble beryllium compounds (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)), Materion contended that the increased lung cancer risk in beryllium-exposed animals is due to a particle overload phenomenon, in which lung clearance of beryllium particles initiates a non-specific neutrophilic response that results in intrapulmonary lung tumors. The materials cited by Materion as supportive of its argument—Obedorster (1995), a 2009 working paper to the UN Subcommittee on the Globally Harmonized System of Classification and Labelling of Chemicals (citing ILSI (2000) as supporting evidence for poorly soluble particles), Snipes (1996), the Health Risk Assessment Guidance for Metals, ICMM (2007), and ECETOC (2013)—discuss the inhalation of high exposure levels of poorly soluble particles in rats and the relevance of these studies to the human carcinogenic response (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)). Using particles such as titanium dioxide, carbon black, non-asbestiform talc, coal dust, and diesel soot as models, ILSI (2000) and ECETOC (2013) describe studies that have demonstrated that chronic inhalation of poorly soluble particles can result in pulmonary inflammation, fibrosis, epithelial cell hyperplasia, and adenomas and carcinomas in rats at exposure levels that exceed lung clearance mechanisms (the ''overload'' phenomenon) (ILSI (2000)[10], p. 2, as cited in Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)).

However, these expert reports indicate that the ''overload'' phenomenon caused by biologically inert particles (poorly soluble particles of low cytotoxicity for which there is no evidence of genotoxicity) is relevant only to the rat species. (Document ID 1807, Attachment 10, pp. 1–3 (pdf pp. 85–87)). OSHA finds that this model is not in keeping with the data presented for beryllium for several reasons. First, beryllium has been shown to be a ''biologically active'' particle due to its ability to induce an immune response in multiple species including humans, has been shown to be genotoxic in certain mammalian test systems, and induces epigenetic changes (*e.g.* DNA methylation) (as described in detail in sections V. D. 6, V.E.1, V.E.3 and V.E.4). Second, beryllium has been shown to produce lung tumors after inhalation or instillation in several animal species, including rats, mice, and monkeys (Finch *et al.,* 1998, Document ID 1367; Schepers *et al.,* 1957 (0458) and 1962 (1414); Wagner *et al.,* 1969 (1481); Belinsky *et al.,* 2002 (1300); Groth *et al.,*

[9] Strupp and Furnes was the background information for the Strupp (2011) publications (Document ID, Attachment 2, Appendix, p. 20).

[10] It is important to note that the ILSI report states that in interpreting data from rat studies alone, ''in the absence of mechanistic data to the contrary it must be assumed that the rat model can identify potential hazards to humans'' (ILSI, 2000, p. 2, as cited in Document ID 1807, Attachment 10, p. 1 (pdf p. 85)). The report by Oberdorster has similar language to the ILSI report (see Document ID 1807, Attachment 10, pp. 1, 3 (pdf pp. 85, 87). It should also be noted that the working paper to the UN Subcommittee on the Globally Harmonized System of Classification and Labelling of Chemicals, which cited ILSI (2000), was not adopted and has not been included in any revision to the GHS (*http://www.unece.org/fileadmin/DAM/trans/doc/2009/ac10c4/ST-SG-AC10-C4-34e.pdf*).

1980 (1316); Vorwald and Reeves, 1957 (1482); Nickell-Brady *et al.,* 1994 (1312); Swafford *et al.,* 1997 (1392); IARC, 2012 (1355)). In addition, poorly soluble beryllium has been demonstrated to produce chronic inflammation at levels below overload (Groth *et al.,* 1980, Document ID 1316; Nickell-Brady *et al.,* 1994 (1312); Finch *et al.,* 1998 (1367); Finch *et al.,* 2000 (as cited in Document ID 1960, p. 11)).

In addition, IARC and NAS performed an extensive review of the available animal studies and their findings were supportive of the OSHA findings of carcinogenicity (IARC, 2012, Document ID 0650; NAS, 2008 (1355)). OSHA performed an independent evaluation as outlined in section V.E.3 and found sufficient evidence of tumor formation in multiple species (rats, mice, and monkeys) after inhalation at levels below overload conditions. The Agency has found evidence supporting the hypothesis that multiple mechanisms may be at work in the development of cancer in experimental animals and humans and cannot dismiss the roles of inflammation (neutrophilic and T-cell mediated), genotoxicity, and epigenetic factors (see section V.E.1, V.E. 3, V.E.4). After evaluating the best scientific evidence available from epidemiological and animal studies (see section V.E) OSHA concludes the weight of evidence supports a mechanistic finding that both soluble and poorly soluble forms of beryllium and beryllium-containing compounds are carcinogenic.

F. Other Health Effects

Past studies on other health effects have been thoroughly reviewed by several scientific organizations (NTP, 1999, Document ID 1341; EPA, 1998 (0661); ATSDR, 2002 (1371); WHO, 2001 (1282); HSDB, 2010 (0533)). These studies include summaries of animal studies, *in vitro* studies, and human epidemiological studies associated with cardiovascular, hematological, hepatic, renal, endocrine, reproductive, ocular and mucosal, and developmental effects. High-dose exposures to beryllium have been shown to have an adverse effect upon a variety of organs and tissues in the body, particularly the liver. The adverse systemic effects on humans mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)). (OSHA, 1971, see 39 FR 23513; ACGIH, 1971 (0543); ANSI, 1970 (1303)) and EPA, 1973 (38 FR 8820) and therefore are less relevant today than in the past. The available data is fairly limited. The hepatic, cardiovascular, renal, and ocular and mucosal effects are briefly summarized below. Health effects in other organ systems listed above were only observed in animal studies at very high exposure levels and are, therefore, not discussed here. During the public comment period OSHA received comments suggesting that OSHA add dermal effects to this section. Therefore, dermal effects have been added, below, and are also discussed in the section on kinetics and metabolism (section V.B.2).

1. Hepatic Effects

Beryllium has been shown to accumulate in the liver and a correlation has been demonstrated between beryllium content and hepatic damage. Different compounds have been shown to distribute differently within the hepatic tissues. For example, in one study, beryllium phosphate accumulated almost exclusively within sinusoidal (Kupffer) cells of the liver, while beryllium sulfate was found mainly in parenchymal cells. Conversely, beryllium sulphosalicylic acid complexes were rapidly excreted (Skilleter and Paine, 1979, Document ID 1410).

According to a few autopsies, beryllium-laden livers had central necrosis, mild focal necrosis and inflammation, as well as, occasionally, beryllium granuloma (Sprince *et al.,* 1975, Document ID 1405).

2. Cardiovascular Effects

Severe cases of CBD can result in cor pulmonale, which is hypertrophy of the right heart ventricle. In a case history study of 17 individuals exposed to beryllium in a plant that manufactured fluorescent lamps, autopsies revealed right atrial and ventricular hypertrophy (Hardy and Tabershaw, 1946, Document ID 1516). It is not likely that these cardiac effects were due to direct toxicity to the heart, but rather were a response to impaired lung function. However, an increase in deaths due to heart disease or ischemic heart disease was found in workers at a beryllium manufacturing facility (Ward *et al.,* 1992, Document ID 1378). Additionally, a study by Schubauer-Berigan *et al.* (2011) found an increase in mortality due to cor pulmonale in a follow-up study of workers at seven beryllium processing plants who were exposed to beryllium levels near the preceding OSHA PEL of 2.0 μg/m^3 (Schubauer-Berigan *et al.,* 2011, Document ID 1266).

Animal studies performed in monkeys indicate heart enlargement after acute inhalation exposure to 13 mg beryllium/m^3 as beryllium hydrogen phosphate, 0.184 mg beryllium/m^3 as beryllium fluoride, or 0.198 mg beryllium/m^3 as beryllium sulfate (Schepers, 1957, Document ID 0458). Decreased arterial oxygen tension was observed in dogs exposed to 30 mg beryllium/m^3 as beryllium oxide for 15 days (HSDB, 2010, Document ID 0533), 3.6 mg beryllium/m^3 as beryllium oxide for 40 days (Hall *et al.,* 1950, Document ID 1494), and 0.04 mg beryllium/m^3 as beryllium sulfate for 100 days (Stokinger *et al.,* 1950, Document ID 1484). These are thought to be indirect effects on the heart due to pulmonary fibrosis and toxicity, which can increase arterial pressure and restrict blood flow.

3. Renal Effects

Renal or kidney stones have been found in severe cases of CBD that resulted from high levels of beryllium exposure. Renal stones containing beryllium occurred in about 10 percent of patients affected by high exposures (Barnett *et al.,* 1961, Document ID 0453). The ATSDR reported that 10 percent of the CBD cases found in the BCR reported kidney stones. In addition, an excess of calcium in the blood and urine was frequently found in patients with CBD (ATSDR, 2002, Document ID 1371).

4. Ocular and Mucosal Effects

Soluble and poorly soluble beryllium compounds have been shown to cause ocular irritation in humans (VanOrdstrand *et al.,* 1945, Document ID 1383; De Nardi *et al.,* 1953 (1545); Nishimura, 1966 (1435); Epstein, 1991 (0526); NIOSH, 1994 (1261). In addition, soluble and poorly soluble beryllium has been shown to induce acute conjunctivitis with corneal maculae and diffuse erythema (HSDB, 2010, Document ID 0533).

The mucosa (mucosal membrane) is the moist lining of certain tissues/organs including the eyes, nose, mouth, lungs, and the urinary and digestive tracts. Soluble beryllium salts have been shown to be directly irritating to mucous membranes (HSDB, 2010, Document ID 0533).

5. Dermal Effects

Several commenters suggested OSHA add dermal effects to this Health Effects section. National Jewish Health noted that rash and granulomatous reactions of the skin still occur in occupational settings (Document ID 1664, p. 5). The National Supplemental Screening Program also recommended including skin conditions such as dermatitis and nodules (Document ID 1677, p. 3). The American Thoracic Society also recommended including ''beryllium sensitization, CBD, and skin disease as the major adverse health effects

associated with exposure to beryllium at or below 0.1 μg/m³ and acute beryllium disease at higher exposures based on the currently available epidemiologic and experimental studies'' (Document ID 1688, p. 2). OSHA agrees and has included dermal effects in this section of the final preamble.

As summarized in Epstein (1991), skin exposure to soluble beryllium compounds (mainly beryllium fluoride but also beryllium metal which may contain beryllium fluoride) resulted in irritant dermatitis with inflammation, and local edema. Beryllium oxide, beryllium alloys and nearly pure beryllium metal did not produce such responses in the skin of workers (Epstein, 1991, Document ID 0526). Skin lacerations or abrasions contaminated with soluble beryllium can lead to skin ulcerations (Epstein, 1991, Document ID 0526). Soluble and poorly soluble beryllium-compounds that penetrate the skin as a result of abrasions or cuts have been shown to result in chronic ulcerations and skin granulomas (VanOrdstrand *et al.,* 1945, Document ID 1383; Lederer and Savage, 1954 (1467)). However, ulcerating granulomatous formation of the skin is generally associated with poorly soluble forms of beryllium (Epstein, 1991, Document ID 0526). Beryllium, beryllium oxide and other soluble and poorly soluble forms of beryllium have been classified as a skin irritant (category 2) in accordance with the EU Classification, Labelling and Packaging Regulation (Document ID 1669, p. 2). Contact dermatitis (skin hypersensitivity) was observed in some individuals exposed via skin to soluble forms of beryllium, especially individuals with a dermal irritant response (Epstein, 1991, Document ID 0526). Contact allergy has been observed in workers exposed to beryllium chloride (Document ID 0522).

G. Summary of Conclusions Regarding Health Effects

Through careful analysis of the best available scientific information outlined in this section, OSHA has determined that beryllium and beryllium-containing compounds can cause sensitization, CBD, and lung cancer. The Agency has determined through its review and evaluation of the studies outlined in section V.A.2 of this health effects section that skin and inhalation exposure to beryllium can lead to sensitization; and inhalation exposure, or skin exposure coupled with inhalation, can cause onset and progression of CBD. In addition, the Agency's review and evaluation of the studies outlined in section V.E. of this health effects section led to a finding that inhalation exposure to beryllium and beryllium-containing materials can cause lung cancer.

1. OSHA's Evaluation of the Evidence Finds That Beryllium Causes Sensitization Below the Preceding PEL and Sensitization is a Precursor to CBD

Through the biological and immunological processes outlined in section V.B. of the Health Effects, the Agency has concluded that the scientific evidence supports the following mechanisms for the development of sensitization and CBD.

- Inhaled beryllium and beryllium-containing materials able to be retained and solubilized in the lungs have the ability to initiate sensitization and facilitate CBD development (section V.B.5). Genetic susceptibility may play a role in the development of sensitization and progression to CBD in certain individuals.
- Beryllium compounds that dissolve in biological fluids, such as sweat, can penetrate intact skin and initiate sensitization (section V.A.2; V.B). Phagosomal fluid and lung fluid have the capacity to dissolve beryllium compounds in the lung (section V.A.2a).
- Sensitization occurs through a T-cell mediated process with both soluble and poorly soluble beryllium and beryllium-containing compounds through direct antigen presentation or through further antigen processing in the skin or lung. T-cell mediated responses, such as sensitization, are generally regarded as long-lasting (*e.g.,* not transient or readily reversible) immune conditions (section V.D.1).
- Beryllium sensitization and CBD are adverse events along a pathological continuum in the disease process with sensitization being the necessary first step in the progression to CBD (section V.D).
- Particle characteristics such as size, solubility, surface area, and other properties may play a role in the rate of development of beryllium sensitization and CBD. However, there is currently not sufficient information to delineate the biological role these characteristics may play.
- Animal studies have provided supporting evidence for T-cell proliferation in the development of granulomatous lung lesions after beryllium exposure (sections V.D.2; V.D.6).
- Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of beryllium sensitization (section V.D.1). While no clinical symptoms are associated with sensitization, a sensitized worker is at risk of developing CBD when inhalation exposure to beryllium has occurred. Epidemiological evidence that covers a wide variety of beryllium compounds and industrial processes demonstrates that sensitization and CBD are continuing to occur at present-day exposures below OSHA's preceding PEL (sections V.D.4; V.D.5 and section VI of this preamble).
- OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from its earliest asymptomatic stage following sensitization through to full-blown CBD and death (section V.D.7).
- Genetic variabilities appear to enhance risk for developing sensitization and CBD in some groups (section V.D.3).

In addition, epidemiological studies outlined in section V.D.5 have demonstrated that efforts to reduce exposures have succeeded in reducing the frequency of sensitization and CBD.

2. OSHA's Evaluation of the Evidence Has Determined Beryllium To Be a Human Carcinogen

OSHA conducted an evaluation of the available scientific information regarding the carcinogenic potential of beryllium and beryllium-containing compounds (section V.E). Based on the weight of evidence and plausible mechanistic information obtained from *in vitro* and *in vivo* animal studies as well as clinical and epidemiological investigations, the Agency has determined that beryllium and beryllium-containing materials are properly regarded as human carcinogens. This information is in accordance with findings from IARC, NTP, EPA, NIOSH, and ACGIH (section V.E). Key points from this analysis are summarized briefly here.

- Epidemiological cohort studies have reported statistically significant excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1970s (section V.E.2).
- Significant positive associations were found between lung cancer mortality and both average and cumulative beryllium exposures when appropriately adjusted for birth cohort and short-term work status (section V.E.2).
- Studies in which large amounts of different beryllium compounds were inhaled or instilled in the respiratory tracts in multiple species of laboratory animals resulted in an increased

incidence of lung tumors (section V.E.3).

- Authoritative scientific organizations, such as the IARC, NTP, and EPA, have classified beryllium as a known or probable human carcinogen (section V.E).

While OSHA has determined there is sufficient evidence of beryllium carcinogenicity, the Agency acknowledges that the exact tumorigenic mechanism for beryllium has yet to be determined. A number of mechanisms are likely involved, including chronic inflammation, genotoxicity, mitogenicity, oxidative stress, and epigenetic changes (section V.E.3).

- Studies of beryllium-exposed animals have consistently demonstrated chronic pulmonary inflammation after exposure (section V.E.3). Substantial data indicate that tumor formation in certain animals after inhalation exposure to poorly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity of the particles (section V.E.5).
- A review conducted by the NAS (2008) (Document ID 1355) found that beryllium and beryllium-containing compounds tested positive for genotoxicity in nearly 50 percent of studies without exogenous metabolic activity, suggesting a possible direct-acting mechanism may exist (section V.E.1) as well as the potential for epigenetic changes (section V.E.4).

Other health effects are discussed in sections F of the Health Effects Section and include hepatic, cardiovascular, renal, ocular, and mucosal effects. The adverse systemic effects from human exposures mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1973 (ACGIH, 1971, Document ID 0543; ANSI, 1970 (1303); OSHA, 1971, see 39 FR 23513; EPA, 1973 (38 FR 8820)) and therefore are less relevant.

VI. Risk Assessment

To promulgate a standard that regulates workplace exposure to toxic materials or harmful physical agents, OSHA must first determine that the standard reduces a ''significant risk'' of ''material impairment.'' Section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b). The first part of this requirement, ''significant risk,'' refers to the likelihood of harm, whereas the second part, ''material impairment,'' refers to the severity of the consequences of exposure. Section II, Pertinent Legal Authority, of this preamble addresses the statutory bases for these requirements and how they have been construed by the Supreme Court and federal courts of appeals.

It is OSHA's practice to evaluate risk to workers and determine the significance of that risk based on the best available evidence. Using that evidence, OSHA identifies material health impairments associated with potentially hazardous occupational exposures, assesses whether exposed workers' risks are significant, and determines whether a new or revised rule will substantially reduce these risks. As discussed in Section II, Pertinent Legal Authority, when determining whether a significant risk exists OSHA considers whether there is a risk of at least one-in-a-thousand of developing amaterial health impairment from a working lifetime of exposure at the prevailing OSHA standard (referred to as the ''preceding standard'' or ''preceding TWA PEL'' in this preamble). For this purpose, OSHA generally assumes that a term of 45 years constitutes a working life. The Supreme Court has found that OSHA is not required to support its finding of significant risk with scientific certainty, but may instead rely on a body of reputable scientific thought and may make conservative assumptions (*i.e.,* err on the side of protecting the worker) in its interpretation of the evidence (see Section II, Pertinent Legal Authority).

For single-substance standards governed by section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5), OSHA sets a permissible exposure limit (PEL) based on its risk assessment as well as feasibility considerations. These health and risk determinations are made in the context of a rulemaking record in which the body of evidence used to establish material impairment, assess risks, and identify affected worker population, as well as the Agency's preliminary risk assessment, are placed in a public rulemaking record and subject to public comment. Final determinations regarding the standard, including final determinations of material impairment and risk, are thus based on consideration of the entire rulemaking record.

OSHA's approach for the risk assessment for beryllium incorporates both: (1) A review of the literature on populations of workers exposed to beryllium at and below the preceding time-weighted average permissible exposure limit (TWA PEL) of 2 μg/m^3; and (2) OSHA's own analysis of a data set of beryllium-exposed machinists. The Preliminary Risk Assessment included in the NPRM evaluated risk at several alternate TWA PELs that the Agency was considering (1 μg/m^3, 0.5 μg/m^3, 0.2 μg/m^3, and 0.1 μg/m^3), as well as OSHA's preceding TWA PEL of 2 μg/m^3. OSHA's risk assessment relied on available epidemiological studies to evaluate the risk of sensitization and CBD for workers exposed to beryllium at and below the preceding TWA PEL and the effectiveness of exposure control programs in reducing risk. OSHA also conducted a statistical analysis of the exposure-response relationship for sensitization and CBD at the preceding PEL and alternate PELs the Agency was considering. For this analysis, OSHA used data provided by National Jewish Health (NJH), a leading medical center specializing in the research and treatment of CBD, on a population of workers employed at a beryllium machining plant in Cullman, AL. The review of the epidemiological studies and OSHA's own analysis both show significant risk of sensitization and CBD among workers exposed at and below the preceding TWA PEL of 2 μg/m^3. They also show substantial reduction in risk where employers implemented a combination of controls, including stringent control of airborne beryllium levels and additional measures, such as respirators and dermal personal protective equipment (PPE) to further protect workers against dermal contact and airborne beryllium exposure.

To evaluate lung cancer risk, OSHA relied on a quantitative risk assessment published in 2011 by Schubauer-Berigan *et al.* (Document ID 1265). Schubauer-Berigan *et al.* found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure; the authors predicted significant risk of lung cancer at the preceding TWA PEL, and substantial reductions in risk at the alternate PELs OSHA considered in the proposed rule, including the final TWA PEL of 0.2 μg/m^3 (Schubauer-Berigan *et al.,* 2011).

OSHA requested input on the preliminary risk assessment presented in the NPRM, and received comments from a variety of public health experts and organizations, unions, industrial organizations, individual employers, and private citizens. While many comments supported OSHA's general approach to the risk assessment and the conclusions of the risk assessment, some commenters raised specific concerns with OSHA's analytical methods or recommended additional studies for OSHA's consideration. Comments about the risk assessment as a whole are reviewed here, while comments on specific aspects of the risk assessment are addressed in the relevant sections throughout the remainder of

this chapter and in the background document, Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization (OSHA, 2016), which can be found in the rulemaking docket (docket number OSHA–H005C–2006–0870) at *www.regulations.gov.* Following OSHA's review of all the comments submitted on the preliminary risk assessment, and its incorporation of suggested changes to the risk assessment, where appropriate, the Agency reaffirms its conclusion that workers' risk of material impairment of health from beryllium exposure at the preceding PEL of 2 μg/m³ is significant, and is substantially reduced but still significant at the new PEL of 0.2 μg/m³ (see this preamble at Section VII, Significance of Risk).

The comments OSHA received on its preliminary risk analysis generally supported OSHA's overall approach and conclusions. NIOSH indicated that OSHA relied on the best available evidence in its risk assessment and concurred with ''OSHA's careful review of the available literature on [beryllium sensitization] and CBD, OSHA's recognition of dermal exposure as a potential pathway for sensitization, and OSHA's careful approach to assessing risk for [beryllium sensitization] and CBD'' (Document ID 1725, p. 3). NIOSH agreed with OSHA's approach to the preliminary lung cancer risk assessment (Document ID 1725, p. 7) and the selection of a 2011 analysis (Schubauer-Berigan *et al.,* 2011, Document ID 1265) as the basis of that risk assessment (Document ID 1725, p. 7). NIOSH further supported OSHA's preliminary conclusions regarding the significance of risk of material health impairment at the preceding TWA PEL of 2 μg/m³, and the substantial reduction of such risk at the new TWA PEL of 0.2 μg/m³ (Document ID 1725, p. 3). Finally, NIOSH agreed with OSHA's preliminary conclusion that compliance with the new PEL would lessen but not eliminate risk to exposed workers, noting that OSHA likely underestimated the risks of beryllium sensitization and CBD (Document ID 1725, pp. 3–4).

Other commenters also agreed with the general approach and conclusions of OSHA's preliminary risk assessment. NJH, for example, determined that ''OSHA performed a thorough assessment of risk for [beryllium sensitization], CBD and lung cancer using all available studies and literature'' (Document ID 1664, p. 5). Dr. Kenny Crump and Ms. Deborah Proctor commented, on behalf of beryllium producer Materion, that they ''agree with OSHA's conclusion that there is a significant risk (>1/1000 risk of CBD) at the [then] current PEL, and that risk is reduced at the proposed PEL (0.2 μg/m³) in combination with stringent measures (ancillary provisions) to reduce worker's exposures'' (Document ID 1660, p. 2). They further stated that OSHA's ''finding is evident based on the available literature . . . and the prevalence data [OSHA] presented for the Cullman facility'' (Document ID 1660, p. 2).

OSHA also received comments objecting to OSHA's conclusions regarding risk of lung cancer from beryllium exposure and suggesting additional published analyses for OSHA's consideration (*e.g.,* Document ID 1659; 1661, pp. 1–3). One comment critiqued the statistical exposure-response model OSHA presented as one part of its preliminary risk analysis for sensitization and CBD (Document ID 1660). These comments are discussed and addressed in the remainder of this chapter.

A. Review of Epidemiological Literature on Sensitization and Chronic Beryllium Disease

As discussed in the Health Effects section, studies of beryllium-exposed workers conducted using the beryllium lymphocyte proliferation test (BeLPT) have found high rates of beryllium sensitization and CBD among workers in many industries, including at some facilities where exposures were primarily below OSHA's preceding PEL of 2 μg/m³ (*e.g.,* Kreiss *et al.,* 1993, Document ID 1478; Henneberger *et al.,* 2001 (1313); Schuler *et al.,* 2005 (0919); Schuler *et al.,* 2012 (0473)). In the mid-1990s, some facilities using beryllium began to aggressively monitor and reduce workplace exposures. In the NPRM, OSHA reviewed studies of workers at four plants where several rounds of BeLPT screening were conducted before and after implementation of new exposure control methods. These studies provide the best available evidence on the effectiveness of various exposure control measures in reducing the risk of sensitization and CBD. The experiences of these plants—a copper-beryllium processing facility in Reading, PA, a ceramics facility in Tucson, AZ, a beryllium processing facility in Elmore, OH, and a machining facility in Cullman, AL—show that comprehensive exposure control programs that used engineering controls to reduce airborne exposure to beryllium, required the use of respiratory protection, controlled dermal contact with beryllium using PPE, and employed stringent housekeeping methods to keep work areas clean and prevent transfer of beryllium between work areas, sharply curtailed new cases of sensitization among newly-hired workers. In contrast, efforts to prevent sensitization and CBD by using engineering controls to reduce workers' beryllium exposures to median levels around 0.2 μg/m³, with no corresponding emphasis on PPE, were less effective than comprehensive exposure control programs implemented more recently. OSHA also reviewed additional, but more limited, information on the occurrence of sensitization and CBD among workers with low-level beryllium exposures at nuclear facilities and aluminum smelting plants. A summary discussion of the experiences at all of these facilities is provided in this section. Additional discussion of studies on these facilities and several other studies of sensitization and CBD among beryllium-exposed workers is provided in Section V, Health Effects.

The Health Effects section also discusses OSHA's findings and the supporting evidence concerning the role of particle characteristics and beryllium compound solubility in the development of sensitization and CBD among beryllium-exposed workers. First, it finds that respirable particles small enough to reach the deep lung are responsible for CBD. However, larger inhalable particles that deposit in the upper respiratory tract may lead to sensitization. Second, it finds that both soluble and poorly soluble forms of beryllium are able to induce sensitization and CBD. Poorly soluble forms of beryllium that persist in the lung for longer periods may pose greater risk of CBD while soluble forms may more easily trigger immune sensitization. Although particle size and solubility may influence the toxicity of beryllium, the available data are too limited to reliably account for these factors in the Agency's estimates of risk.

1. Reading, PA, Plant

Schuler *et al.* (2005, Document ID 0919) and Thomas *et al.* (2009, Document ID 0590) conducted studies of workers at a copper-beryllium processing facility in Reading, PA. Exposures at this plant were believed to be low throughout its history due to both the low percentage of beryllium in the metal alloys used and the relatively low exposures found in general area samples collected starting in 1969 (sample median ≤0.1 μg/m³, 97% < 0.5 μg/m³) (Schuler *et al.,* 2005). Ninety-nine percent of personal lapel sample measurements were below the preceding OSHA TWA PEL of 2 μg/m³; 93 percent were below the new TWA

PEL of 0.2 μg/m³ (Schuler *et al.,* 2005). Schuler *et al.* (2005) screened 152 workers at the facility with the BeLPT in 2000. The reported prevalences of sensitization (6.5 percent) and CBD (3.9 percent) showed substantial risk at this facility, even though airborne exposures were primarily below both the preceding and final TWA PELs.[11] The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with the lowest recorded exposures (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³ (Schuler *et al.,* 2005).

After the initial BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium (Thomas *et al.* 2009, Document ID 0590). Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000–2002. In 2001, the company installed local exhaust ventilation (LEV) in die grinding and polishing operations (Thomas *et al.,* 2009, Figure 1). Personal lapel samples collected between June 2000 and December 2001, showed reduced exposures plant-wide (98 percent were below 0.2 μg/m³). Median, arithmetic mean, and geometric mean values less than or equal to 0.03 μg/m³ were reported in this period for all processes except one, a wire annealing and pickling process. Samples for this process remained elevated, with a median of 0.1 μg/m³ (arithmetic mean of 0.127 μg/m³, geometric mean of 0.083 μg/m³) (Thomas *et al.,* 2009, Table 3). In January 2002, the company enclosed the wire annealing and pickling process in a restricted access zone (RAZ). Beginning in 2002, the company required use of powered air-purifying respirators (PAPRs) in the RAZ, and implemented stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone, such as requiring RAZ workers to shower before leaving the zone (Thomas *et al.,* 2009, Figure 1). While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–2001 samples in areas other than the RAZ (Thomas *et al.,* 2009, Table 3). The authors reported that outside the RAZ, ''the vast majority of employees do not wear any form of respiratory protection due to very low airborne beryllium concentrations'' (Thomas *et al.,* 2009, p. 122).

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers (Thomas *et al.,* 2009, Document ID 0590). Among 82 workers hired after 1999, three cases of sensitization were found (3.7 percent). Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process, which had been releasing beryllium into the surrounding area, were found to be sensitized within 3 and 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was built was confirmed as sensitized. From these early results comparing the screening conducted on workers hired before 2000 and those hired in 2000 and later, especially following the enclosure of the RAZ, it appears that the greatest reduction in sensitization risk (to one sensitized worker, or 2.2 percent) was achieved after workers' exposures were reduced to below 0.1 μg/m³ and PPE to prevent dermal contact was instituted (Thomas *et al.,* 2009).

2. Tucson, AZ, Plant

Kreiss *et al.* (1996, Document ID 1477), Cummings *et al.* (2007, Document ID 1369), and Henneberger *et al.* (2001, Document ID 1313) conducted studies of workers at a beryllia ceramics plant in Tucson, Arizona. Kreiss *et al.* (1996) screened 136 workers at this plant with the BeLPT in 1992. Full-shift area samples collected between 1983 and 1992 showed primarily low airborne beryllium levels at this facility (76 percent of area samples were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³). 4,133 short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m³. A small set (75) of personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m³ and ranged from 0.1 to 1.8 μg/m³ (arithmetic and geometric mean values not reported) (Kreiss *et al.,* 1996).

Kreiss *et al.* reported that eight (5.9 percent) of the 136 workers tested in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. One sensitized worker was one of 13 administrative workers screened, and was among those diagnosed with CBD. Exposures of administrative workers were not well characterized, but were believed to be among the lowest in the plant. Personal lapel samples taken on administrative workers during the 1990s were below the detection limit at the time, 0.2 μg/m³ (Cummings *et al.,* 2007, Document ID 1369).

Following the 1992 screening, the facility reduced exposures in machining areas (for example, by enclosing additional machines and installing additional exhaust ventilation), resulting in median exposures of 0.2 μg/m³ in production jobs and 0.1 μg/m³ in production support jobs (Cummings *et al.,* 2007). In 1998, a second screening found that 7 out of 74 tested workers hired after the 1992 screening (9.5 percent) were sensitized, one of whom was diagnosed with CBD. All seven of these sensitized workers had been employed at the plant for less than two years (Henneberger *et al.,* 2001, Document ID 1313, Table 3). Of 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and 7 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001).

Following the 1998 screening, the company continued efforts to reduce exposures, along with risk of sensitization and CBD, by implementing additional engineering and administrative controls and a comprehensive PPE program which included the use of respiratory protection (1999) and latex gloves (2000) (Cummings *et al.,* 2007, Document ID 1369). Enclosures were installed for various beryllium-releasing processes by 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment. These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 97 workers hired between 2000 and 2004, one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007).

3. Elmore, OH, Plant

Kreiss *et al.* (1997, Document ID 1360), Bailey *et al.* (2010, Document ID 0676), and Schuler *et al.* (2012, Document ID 0473) conducted studies of workers at a beryllium metal, alloy, and oxide production plant in Elmore, Ohio. Workers participated in several plant-wide BeLPT surveys beginning in 1993–1994 (Kreiss *et al.,* 1997; Schuler *et al.,* 2012) and in a series of screenings

[11] Although OSHA reports percentages to indicate the risks of sensitization and CBD in this section, the benchmark OSHA typically uses to demonstrate significant risk, as discussed in Pertinent Legal Authority, is greater than or equal to 1 in 1,000 workers. One in 1,000 workers is equivalent to 0.1 percent. Therefore, any value of 0.1 percent or higher when reporting occurrence of a health effect is considered by OSHA to indicate a significant risk.

for workers hired in 2000 and later, conducted beginning in 2000 (Bailey *et al.,* 2010).

Exposure levels at the plant between 1984 and 1993 were characterized using a mixture of general area, short-term breathing zone, and personal lapel samples (Kreiss *et al.,* 1997, Document ID 1360). Kreiss *et al.* reported that the median area samples for various work areas ranged from 0.1 to 0.7 μg/m³, with the highest values in the alloy arc furnace and alloy melting-casting areas. Personal lapel samples were available from 1990–1992, and showed high exposures overall (median value of 1.0 μg/m³), with very high exposures for some processes. Kreiss *et al.* reported median sample values from the personal lapel samples of 3.8 μg/m³ for beryllium oxide production, 1.75 μg/m³ for alloy melting and casting, and 1.75 μg/m³ for the arc furnace. The authors reported that 43 (6.9 percent) of 627 workers tested in 1993–1994 were sensitized. 29 workers (including 5 previously identified) were diagnosed with CBD (29/632, or 4.6 percent) (Kreiss *et al.,* 1997).

In 1996–1999, the company took further steps to reduce workers' beryllium exposures, including enclosure of some beryllium-releasing processes, establishment of restricted-access zones, and installation or updating of certain engineering controls (Bailey *et al.,* 2010, Document ID 0676, Tables 1–2). Beginning in 1999, all new employees were required to wear loose-fitting PAPRs in manufacturing buildings. Skin protection became part of the protection program for new employees in 2000, and glove use was required in production areas and for handling work boots beginning in 2001. By 2001, either half-mask respirators or PAPRs were required throughout the production facility (type determined by airborne beryllium levels) and respiratory protection was required for roof work and during removal of work boots (Bailey *et al.,* 2010).

Beginning in 2000, newly hired workers were offered periodic BeLPT testing to evaluate the effectiveness of the new exposure control program implemented by the company (Bailey *et al.,* 2010). Bailey *et al.* compared the occurrence of beryllium sensitization and disease among 258 employees who began work at the Elmore plant between January 15, 1993 and August 9, 1999 (the ''pre-program group'') with that of 290 employees who were hired between February 21, 2000 and December 18, 2006, and were tested at least once after hire (the ''program group''). They found that, as of 1999, 23 (8.9 percent) of the pre-program group were sensitized to beryllium. Six (2.1 percent) of the program group had confirmed abnormal results on their final round of BeLPTs, which occurred in different years for different employees. This four-fold reduction in sensitization suggests that beryllium-exposed workers' risk of sensitization (and therefore of CBD, which develops only following sensitization) can be much reduced by the combination of process controls, respiratory protection requirements, and PPE requirements applied in this facility. Because most of the workers in the study had been employed at the facility for less than two years, and CBD typically develops over a longer period of time (see section V, Health Effects), Bailey *et al.* did not report the incidence of CBD among the sensitized workers (Bailey *et al.,* 2010). Schuler *et al.* (2012, Document ID 0473) published a study examining beryllium sensitization and CBD among short-term workers at the Elmore, OH plant, using exposure estimates created by Virji *et al.* (2012, Document ID 0466). The study population included 264 workers employed in 1999 with up to 6 years tenure at the plant (91 percent of the 291 eligible workers). By including only short-term workers, Virji *et al.* were able to construct participants' exposures with more precision than was possible in studies involving workers exposed for longer durations and in time periods with less exposure sampling. A set of 1999 exposure surveys and employee work histories was used to estimate employees' long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposures for total, respirable, and submicron beryllium mass concentrations (Schuler *et al.,* 2012; Virji *et al.,* 2012).

As reported by Schuler *et al.* (2012), the overall prevalence of sensitization was 9.8 percent (26/264). Sensitized workers were offered further evaluation for CBD. Twenty-two sensitized workers consented to clinical testing for CBD via transbronchial biopsy. Although follow-up time was too short (at most 6 years) to fully evaluate CBD in this group, 6 of those sensitized were diagnosed with CBD (2.3 percent, 6/264). Schuler *et al.* (2012) found 17 cases of sensitization (8.6%) within the first 3 quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m³) and 4 cases of CBD (2.2%) within those first 3 quartiles (183 workers with LTW average total mass exposures lower than 1.07 μg/m³)[12] The authors found 3 cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m³, and no cases of sensitization among workers with total mass LTW average exposures below 0.09 μg/m³, suggesting that beryllium-exposed workers' risk can be much reduced or eliminated by reducing airborne exposures to average levels below 0.1 μg/m³.

Schuler *et al.* (2012, Document ID 0473) then used logistic regression to explore the relationship between estimated beryllium exposure and sensitization and CBD. For beryllium sensitization, the logistic models by Schuler *et al.* showed elevated odds ratios (OR) for LTW average (OR 1.48) and highest job (OR 1.37) exposure for total mass exposure; the OR for cumulative exposure was smaller (OR 1.23) and borderline statistically significant (95 percent CI barely included unity).[13] Relationships between sensitization and respirable exposure estimates were similarly elevated for LTW average (OR 1.37) and highest job (OR 1.32) exposures. Among the submicron exposure estimates, only highest job (OR 1.24) had a 95 percent CI that just included unity for sensitization. For CBD, elevated odds ratios were observed only for the cumulative exposure estimates and were similar for total mass and respirable exposure (total mass OR 1.66, respirable OR 1.68). Cumulative submicron exposure showed an elevated, borderline significant odds ratio (OR 1.58). The odds ratios for average exposure and highest-exposed job were not statistically significantly elevated. Schuler *et al.* concluded that both total and respirable mass concentrations of beryllium exposure were relevant predictors of risk for beryllium sensitization and CBD. Average and highest job exposures were predictive of risk for sensitization, while cumulative exposure was predictive of risk for CBD (Schuler *et al.,* 2012).

Materion submitted comments supporting OSHA's use of the Schuler *et al.* (2012) study as a basis for the final TWA PEL of 0.2 μg/m³. Materion stated that ''the best available evidence to establish a risk-based OEL [occupational exposure limit] is the study conducted by NIOSH and presented in Schuler 2012. The exposure assessment in

[12] The total number of workers Schuler *et al.* reported in their table of LTW average quartiles for sensitization differs from the total number of workers reported in their table of LTW average quartiles for CBD. The table for CBD appeared to exclude 20 workers with sensitization and no CBD.

[13] An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure.

Schuler *et al.* was based on a highly robust workplace monitoring dataset and the study provides improved data for determining OELs'' (Document ID 1661, pp. 9–10). Materion also submitted an unpublished manuscript documenting an analysis it commissioned, entitled ''Derived No-Effect Levels for Occupational Beryllium Exposure Using Cluster Analysis and Benchmark Dose Modeling'' (Proctor *et al.,* Document ID 1661, Attachment 5). In this document, Proctor *et al.* used data from Schuler *et al.* 2012 to develop a Derived No-Effect Level (DNEL) for beryllium measured as respirable beryllium, total mass of beryllium, and inhalable beryllium.[14] OSHA's beryllium standard measures beryllium as total mass; thus, the results for total mass are most relevant to OSHA's risk analysis for the beryllium standard. The assessment reported a DNEL of 0.14 μg/m^3 for total mass beryllium (Document ID 1661, Attachment 5, p. 16). Materion commented that this finding ''add[s] to the body of evidence that supports the fact that OSHA is justified in lowering the existing PEL to 0.2 μg/m^3'' (Document ID 1661, p. 11).

Proctor *et al.* characterized the DNEL of 0.14 μg/m^3 as ''inherently conservative because average exposure metrics were used to determine DNELs, which are limits not [to] be exceeded on a daily basis'' (Document ID 1661, Attachment 5, p. 22). Materion referred to the DNELs derived by Proctor *et al.* as providing an ''additional margin of safety'' for similar reasons (Document ID 1661, p. 11).

Consistent with NIOSH comments discussed in the next paragraph, OSHA disagrees with this characterization of the DNEL as representing a ''no effect level'' for CBD or as providing a margin of safety for several reasons. The DNEL from Proctor *et al.* is based on CBD findings among a short-term worker population and thus cannot represent the risk presented to workers who are exposed over a working lifetime. Proctor *et al.* noted that it is ''important to consider that these data are from relatively short-term exposures [median tenure 20.9 months] and are being used to support DNELs for lifetime occupational exposures,'' but considered the duration of exposure to be sufficient because ''CBD can develop with latency as short as 3 months of exposure, and . . . the risk of CBD declines over time'' (Document ID 1661, Attachment 5, p. 19). In stating this, Procter *et al.* cite studies by Newman *et al.* (2001, Document ID 1354) and Harber *et al.* (2009, as cited in Document ID 1661). Newman *et al.* (2001) studied a group of workers in a machining plant with job tenures averaging 11.7 years, considerably longer than the worker cohort from the study used by Procter *et al.,* and identified new cases of CBD from health screenings conducted up to 4 years after an initial screening. Harber *et al.,* (2009) developed an analytic model of disease progression from beryllium exposure and found that, although the rate at which new cases of CBD declined over time, the overall proportion of individuals with CBD increased over time from initial exposure (see Figure 2 of Haber *et al.,* 2009). Furthermore, the study used by Proctor *et al.* to derive the DNEL, Schuler *et al.* (2012), did report finding that the risk of CBD increased with cumulative exposure to beryllium, as summarized above. Therefore, OSHA is not convinced that a ''no effect level'' for beryllium that is based on the health experience of workers with a median job tenure of 20.9 months can represent a ''no-effect level'' for workers exposed to beryllium for as long as 45 years.

NIOSH commented on the results of Proctor *et al.'*s analysis and the underlying data set, noting several features of the dataset that are common to the beryllium literature, such as uncertain date of sensitization or onset of CBD and no ''background'' rate of beryllium sensitization or CBD, that make statistical analyses of the data difficult and add uncertainty to the derivation of a DNEL (Document ID 1725, p. 5). NIOSH also noted that risk of CBD may be underestimated in the underlying data set if workers with CBD were leaving employment due, in part, to adverse health effects (''unmeasured survivor bias'') and estimated that as much as 30 percent of the cohort could have been lost over the 6-year testing period (Document ID 1725, p. 5). NIOSH concluded that Proctor *et al.'*s analysis ''does not contribute to the risk assessment for beryllium workers'' (Document ID 1725, p. 5). OSHA agrees with NIOSH that the DNEL identified by Proctor *et al.* cannot be considered a reliable estimate of a no-effect level for beryllium.

4. Cullman, AL, Plant

Newman *et al.* (2001, Document ID 1354), Kelleher *et al.* (2001, Document ID 1363), and Madl *et al.* (2007, Document ID 1056) studied beryllium workers at a precision machining facility in Cullman, Alabama. After a case of CBD was diagnosed at the plant in 1995, the company began BeLPT screenings to identify workers at risk of CBD and implemented engineering and administrative controls designed to reduce workers' beryllium exposures in machining operations. Newman *et al.* (2001) conducted a series of BeLPT screenings of workers at the facility between 1995 and 1999. The authors reported 22 (9.4 percent) sensitized workers among 235 tested, 13 of whom were diagnosed with CBD within the study period. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m^3 in all job titles except maintenance (median 3.1 μg/m^3 during 1980–1995) and gas bearings (1.05 μg/m^3 during 1980–1995)).

Between 1995 and 1999, the company built enclosures around several beryllium-releasing operations; installed or updated LEV for several machining departments; replaced pressurized air hoses and dry sweeping with wet methods and vacuum systems for cleaning; changed the layout of the plant to keep beryllium-releasing processes close together; limited access to the production area of the plant; and required the use of company uniforms. Madl *et al.* (2007, Document ID 1056) reported that engineering and work process controls, rather than personal protective equipment, were used to limit workers' exposure to beryllium. In contrast to the Reading and Tucson plants, gloves were not required at this plant. Personal lapel samples collected extensively between 1996 and 1999 in machining and non-machining jobs had medians of 0.16 μg/m^3 and 0.08 μg/m^3, respectively (Madl *et al.,* 2007, Table IV). At the time that Newman *et al.* reviewed the results of BeLPT screenings conducted in 1995–1999, a subset of 60 workers had been employed at the plant for less than a year and had therefore benefitted to some extent from the controls described above. Four (6.7 percent) of these workers were found to be sensitized, of whom two were diagnosed with CBD and one with probable CBD (Newman *et al.,* 2001, Document ID 1354). The later study by Madl. *et al.* reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (2007, Table II) (total number of workers hired between 1995 and 1999 not reported).

Beginning in 2000 (after the implementation of controls between 1997 and 1999), exposures in all jobs at the machining facility were reduced to

[14] Derived No-Effect Level (DNEL) is used in REACH quantitative risk characterizations to mean the level of exposure above which humans should not be exposed. It is intended to represent a safe level of exposure for humans., REACH is the European Union's regulation on Registration, Evaluation, Authorization and Restriction of Chemicals.

extremely low levels (Madl *et al.,* 2007, Document ID 1056). Personal lapel samples collected between 2000 and 2005 had a median of 0.12 μg/m³ or less in all machining and non-machining processes (Madl. *et al.,* 2007, Table IV). Only one worker hired after 1999 became sensitized (Madl *et al.* 2007, Table II). The worker had been employed for 2.7 years in chemical finishing, which had the highest median exposure of 0.12 μg/m³ (medians for other processes ranged from 0.02 to 0.11 μg/m³); Madl *et al.* 2007, Table II). This result from Madl *et al.* (2007) suggests that beryllium-exposed workers' risk of sensitization can be much reduced by steps taken to reduce workers' airborne exposures in this facility, including enclosure of beryllium-releasing processes, LEV, wet methods and vacuum systems for cleaning, and limiting worker access to production areas.

The Cullman, AL facility was also the subject of a case-control study published by Kelleher *et al.* in 2001 (Document ID 1363). After the diagnosis of a case of CBD at the plant in 1995, NJH researchers, including Kelleher, worked with the plant to conduct the medical surveillance program mentioned above, using the BeLPT to screen workers biennially for beryllium sensitization and offering sensitized workers further evaluation for CBD (Kelleher *et al.,* 2001). Concurrently, research was underway by Martyny *et al.* to characterize the particle size distribution of beryllium exposures generated by processes at this plant (Martyny *et al.,* 2000, Document ID 1358). Kelleher *et al.* used the dataset of 100 personal lapel samples collected by Martyny *et al.* and other NJH researchers to characterize exposures for each job in the plant. Detailed work history information gathered from plant data and worker interviews was used in combination with job exposure estimates to characterize cumulative and LTW average beryllium exposures for workers in the surveillance program. In addition to cumulative and LTW average exposure estimates based on the total mass of beryllium reported in their exposure samples, Kelleher *et al.* calculated cumulative and LTW average estimates based specifically on exposure to particles <6 μm and particles <1 μm in diameter. To analyze the relationship between exposure level and risk of sensitization and CBD, Kelleher *et al.* performed a case-control analysis using measures of both total beryllium exposure and particle size-fractionated exposure. The results, however, were inconclusive, probably due to the relatively small size of the dataset (Kelleher *et al.,* 2001).

5. Aluminum Smelting Plants

Taiwo *et al.* (2008, Document ID 0621; 2010 (0583) and Nilsen *et al.* (2010, Document ID 0460) studied the relationship between beryllium exposure and adverse health effects among workers at aluminum smelting plants. Taiwo *et al.* (2008) studied a population of 734 employees at 4 aluminum smelters located in Canada (2), Italy (1), and the United States (1). In 2000, a company-wide beryllium exposure limit of 0.2 μg/m³ and an action level of 0.1 μg/m³, expressed as 8-hour TWAs, and a short-term exposure limit (STEL) of 1.0 μg/m³ (15-minute sample) were instituted at these plants. Sampling to determine compliance with the exposure limit began at all four smelters in 2000. Table VI–1 below, adapted from Taiwo *et al.* (2008), shows summary information on samples collected from the start of sampling through 2005.

TABLE VI–1—EXPOSURE SAMPLING DATA BY PLANT—2000–2005

Smelter	Number samples	Median (μg/m³)	Arithmetic mean (μg/m³)	Geometric mean (μg/m³)
Canadian smelter 1	246	0.03	0.09	0.03
Canadian smelter 2	329	0.11	0.29	0.08
Italian smelter	44	0.12	0.14	0.10
US smelter	346	0.03	0.26	0.04

Adapted from Taiwo *et al.,* 2008, Document ID 0621, Table 1.

All employees potentially exposed to beryllium levels at or above the action level for at least 12 days per year, or exposed at or above the STEL 12 or more times per year, were offered medical surveillance, including the BeLPT (Taiwo *et al.,* 2008). Table VI–2 below, adapted from Taiwo *et al.* (2008), shows test results for each facility between 2001 and 2005.

TABLE VI–2—BELPT RESULTS BY PLANT—2001–2005

Smelter	Employees tested	Normal	Abnormal BeLPT (unconfirmed)	Confirmed sensitized
Canadian smelter 1	109	107	1	1
Canadian smelter 2	291	290	1	0
Italian smelter	64	63	0	1
US smelter	270	268	2	0

Adapted from Taiwo *et al.,* 2008, Document ID 0621, Table 2

The two workers with confirmed beryllium sensitization were offered further evaluation for CBD. Both were diagnosed with CBD, based on broncho-alveolar lavage (BAL) results in one case and pulmonary function tests, respiratory symptoms, and radiographic evidence in the other.

In 2010, Taiwo *et al.* (Document ID 0583) published a study of beryllium-exposed workers from four companies, with a total of nine smelting operations. These workers included some of the workers from the 2008 study. 3,185 workers were determined to be ''significantly exposed'' to beryllium and invited to participate in BeLPT screening. Each company used different

criteria to determine ''significant'' exposure, and the criteria appeared to vary considerably (Taiwo *et al.,* 2010); thus, it is difficult to compare rates of sensitization across companies in this study. 1932 workers, about 60 percent of invited workers, participated in the program between 2000 and 2006, of whom 9 were determined to be sensitized (.4 percent). The authors stated that all nine workers were referred to a respiratory physician for further evaluation for CBD. Two were diagnosed with CBD (.1 percent), as described above (*see* Taiwo *et al.,* 2008).

In general, there appeared to be a low level of sensitization and CBD among employees at the aluminum smelters studied by Taiwo *et al.* (2008; 2010). This is striking in light of the fact that many of the employees tested had worked at the smelters long before the institution of exposure limits for beryllium at some smelters in 2000. However, the authors noted that respiratory and dermal protection had been used at these plants to protect workers from other hazards (Taiwo *et al.,* 2008).

A study by Nilsen *et al.* (2010, Document ID 0460) of aluminum workers in Norway also found a low rate of sensitization. In the study, 362 workers and 31 control individuals received BeLPT testing for beryllium sensitization. The authors found one sensitized worker (0.28 percent). No borderline results were reported. The authors reported that exposure measurements in this plant ranged from 0.1 μg/m^3 to 0.31 μg/m^3 (Nilsen *et al.,* 2010) and that respiratory protection was in use, as was the case in the smelters studied by Taiwo *et al.* (2008; 2010).

6. Nuclear Weapons Facilities

Viet *et al.* (2000, Document ID 1344) and Arjomandi *et al.* (2010, Document ID 1275) evaluated beryllium-exposed nuclear weapons workers. In 2000, Viet *et al.* published a case-control study of participants in the Rocky Flats Beryllium Health Surveillance Program (BHSP), which was established in 1991 to screen workers at the Department of Energy's Rocky Flats, CO, nuclear weapons facility for beryllium sensitization and evaluate sensitized workers for CBD. The program, which the authors reported had tested over 5,000 current and former Rocky Flats employees for sensitization, had identified a total of 127 sensitized individuals as of 1994 when Viet *et al.* initiated their study; 51 of these sensitized individuals had been diagnosed with CBD.

Using subjects from the BHSP, Viet *et al.* (2000) matched a total of 50 CBD cases to 50 controls who tested negative for beryllium sensitization and had the same age (± 3 years), gender, race and smoking status, and were otherwise randomly selected from the database. Using the same matching criteria, 74 sensitized workers who were not diagnosed with CBD were matched to 74 control individuals from the BHSP database who tested negative for beryllium sensitization.

Viet *et al.* (2000) developed exposure estimates for the cases and controls based on daily fixed airhead (FAH) beryllium air samples collected in one of 36 buildings at Rocky Flats where beryllium was used, the Building 444 Beryllium Machine Shop. Annual mean FAH samples in Building 444 collected between 1960 and 1988 ranged from a low of 0.096 μg/m^3 (1988) to a high of 0.622 μg/m^3 (1964) (Viet *et al.,* 2000, Table II). Because exposures in this shop were better characterized than in other buildings, the authors developed estimates of exposures for all workers based on samples from Building 444. The authors' statistical analysis of the resulting data set included conditional logistic regression analysis, modeling the relationship between risk of each health outcome and individuals' log-transformed cumulative exposure estimate (CEE) and mean exposure estimate (MEE). These coefficients corresponded to odds ratios of 6.9 and 7.2 per 10-fold increase in exposure, respectively. Risk of sensitization without CBD did not show a statistically significant relationship with log-CEE (coef = 0.111, p = 0.32), but showed a nearly-significant relationship with log-MEE (coef = 0.230, p = 0.097). Viet *et al.* found highly statistically significant relationships between log-CEE and risk of CBD (coef = 0.837, p = 0.0006) and between log-MEE (coef = 0.855, p = 0.0012) and risk of CBD, indicating that risk of CBD increases with exposure level.

Arjomandi *et al.* (2010) published a study of 50 sensitized workers from a nuclear weapons research and development facility who were evaluated for CBD. Quantitative exposure estimates for the workers were not presented; however, the authors characterized their likely exposures as low (possibly below 0.1 μg/m^3 for most jobs). In contrast to the studies of low-exposure populations discussed previously, this group had much longer follow-up time (mean time since first exposure = 32 years) and length of employment at the facility (mean of 18 years).

Five of the 50 evaluated workers (10 percent) were diagnosed with CBD based on histology or high-resolution computed tomography. An additional three (who had not undergone full clinical evaluation for CBD) were identified as probable CBD cases, bringing the total prevalence of CBD and probable CBD in this group to 16 percent. OSHA notes that this prevalence of CBD among sensitized workers is lower than the prevalence of CBD that has been observed in some other worker groups known to have exposures exceeding the action level of 0.1 μg/m^3. For example, as discussed above, Newman *et al.* (2001, Document ID 1354) reported 22 sensitized workers, 13 of whom (59 percent) were diagnosed with CBD within the study period. Comparison of these results suggests that controlling respiratory exposure to beryllium may reduce risk of CBD among already-sensitized workers as well as reducing risk of CBD via prevention of sensitization. However, it also demonstrates that some workers in low-exposure environments can become sensitized and then develop CBD.

7. Conclusions

The published literature on beryllium sensitization and CBD discussed above shows that risk of both health effects can be significant in workplaces in compliance with OSHA's preceding PEL (*e.g.,* Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Newman *et al.,* 2001 (1354); Schuler *et al.,* 2005 (0919), 2012 (0473); Madl *et al.,* 2007 (1056)). For example, in the Tucson beryllia ceramics plant discussed above, Kreiss *et al.* (1996) reported that 8 (5.9 percent) of the 136 workers tested in 1992 were sensitized, 6 (4.4 percent) of whom were diagnosed with CBD. In addition, of 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and 7 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001, Document ID 1313). Full-shift area samples showed airborne beryllium levels below the preceding PEL (76 percent of area samples collected between 1983 and 1992 were at or below 0.1 μg/m^3 and less than 1 percent exceeded 2 μg/m^3; short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m^3; personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m^3) (Kreiss *et al.,* 1996).

Results from the Elmore, OH beryllium metal, alloy, and oxide production plant and Cullman, AL machining facility also showed significant risk of sensitization and CBD

among workers with exposures below the preceding TWA PEL. Schuler *et al.* (2012, Document ID 0473) found 17 cases of sensitization (8.6%) among Elmore, OH workers within the first three quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m³) and 4 cases of CBD (2.2%) within the first three quartiles of LTW average exposure (183 workers with LTW average total mass exposures lower than 1.07 μg/m³; note that follow-up time of up to 6 years for all study participants was very short for development of CBD). At the Cullman, AL machining facility, Newman *et al.* (2001, Document ID 1354) reported 22 (9.4 percent) sensitized workers among 235 tested in 1995–1999, 13 of whom were diagnosed with CBD. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m³ in all job titles except maintenance (median 3.1 μg/m³ during 1980–1995) and gas bearings (1.05 μg/m³ during 1980–1995)).

There is evidence in the literature that although risk will be reduced by compliance with the new TWA PEL, significant risk of sensitization and CBD will remain in workplaces in compliance with OSHA's new TWA PEL of 0.2 μg/m³ and could extend down to the new action level of 0.1 μg/m³, although there is less information and therefore greater uncertainty with respect to significant risk from airborne beryllium exposures at and below the action level. For example, Schuler *et al.* (2005, Document ID 0919) reported substantial prevalences of sensitization (6.5 percent) and CBD (3.9 percent) among 152 workers at the Reading, PA facility who had BeLPT screening in 2000. These results showed significant risk at this facility, even though airborne exposures were primarily below both the preceding and final TWA PELs due to the low percentage of beryllium in the metal alloys used (median general area samples ≤0.1 μg/m³, 97% ≤0.5 μg/m³); 93% of personal lapel samples were below the new TWA PEL of 0.2 μg/m³). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with exposures below the new action level of 0.1 μg/m³ (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³ (Schuler *et al.,* 2005). The Schuler *et al.* (2012, Document ID 0473) study of short-term workers in the Elmore, OH facility found 3 cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m³; 3 of these workers had LTW average exposures of approximately 0.09 μg/m³.

Furthermore, cases of sensitization and CBD continued to arise in the Cullman, AL machining plant after control measures implemented beginning in 1995 brought median airborne exposures below 0.2 μg/m³ (personal lapel samples between 1996 and 1999 in machining jobs had a median of 0.16 μg/m³ and 0.08 μg/m³ in non-machining jobs) (Madl *et al.,* 2007, Document ID 1056, Table IV). At the time that Newman *et al.* (2001, Document ID 1354) reviewed the results of BeLPT screenings conducted in 1995–1999, a subset of 60 workers had been employed at the plant for less than a year and had therefore benefitted to some extent from the exposure reductions. Four (6.7 percent) of these workers were found to be sensitized, two of whom were diagnosed with CBD and one with probable CBD (Newman *et al.,* 2001). A later study by Madl. *et al.* (2007, Document ID 1056) reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (Table II; total number of workers hired between 1995 and 1999 not reported).

The experiences of several facilities in developing effective industrial hygiene programs have shown the importance of minimizing both airborne exposure and dermal contact to effectively reduce risk of sensitization and CBD. Exposure control programs that have used a combination of engineering controls and PPE to reduce workers' airborne exposure and dermal contact have substantially lowered risk of sensitization among newly hired workers.[15] Of 97 workers hired between 2000 and 2004 in the Tucson, AZ plant after the introduction of mandatory respirator use in production areas beginning in 1999 and mandatory use of latex gloves beginning in 2000, one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007, Document ID 1369). In Elmore, OH, where all workers were required to wear respirators and skin PPE in production areas beginning in 2000–2001, the estimated prevalence of sensitization among workers hired after these measures were put in place was around 2 percent (Bailey *et al.,* 2010, Document ID 0676). In the Reading, PA facility, only one (2.2 percent) of 45 workers hired after workers' exposures were reduced to below 0.1 μg/m³ and PPE to prevent dermal contact was instituted was sensitized (Thomas *et al.,* 2009, Document ID 0590). And, in the aluminum smelters discussed by Taiwo *et al.* (2008, Document ID 0621), where available exposure samples from four plants indicated median beryllium levels of about 0.1 μg/m³ or below (measured as an 8-hour TWA) and workers used respiratory and dermal protection, confirmed cases of sensitization were rare (zero or one case per location).

OSHA recognizes that the studies on recent programs to reduce workers' risk of sensitization and CBD were conducted on populations with very short exposure and follow-up time. Therefore, they could not adequately address the question of how frequently workers who become sensitized in environments with extremely low airborne exposures (median <0.1 μg/m³) develop CBD. Clinical evaluation for CBD was not reported for sensitized workers identified in the studies examining the post-2000, very low-exposed worker cohorts in Tucson, Reading, and Elmore (Cummings *et al.* 2007, Document ID 1369; Thomas *et al.* 2009 (0590); Bailey *et al.* 2010 (0676)). In Cullman, however, two of the workers with CBD had been employed for less than a year and worked in jobs with very low exposures (median 8-hour personal sample values of 0.03–0.09 μg/m³) (Madl *et al.,* 2007, Document ID 1056, Table III). The body of scientific literature on occupational beryllium disease also includes case reports of workers with CBD who are known or believed to have experienced minimal beryllium exposure, such as a worker employed only in shipping at a copper-beryllium distribution center (Stanton *et al.,* 2006, Document ID 1070), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996, Document ID 1477). Therefore, there is some evidence that cases of CBD can occur in work environments where beryllium exposures are quite low.

8. Community-Acquired CBD

In the NPRM, OSHA discussed an additional source of information on low-level beryllium exposure and CBD: Studies of community-acquired chronic beryllium disease (CA–CBD) in residential areas surrounding beryllium

[15] As discussed in Section V, Health Effects, beryllium sensitization can occur from dermal contact with beryllium. Studies conducted in the 1950s by Curtis *et al.* showed that soluble beryllium particles could cause beryllium hypersensitivity (Curtis, 1951, Document ID 1273; NAS, 2008, Document ID 1355). Tinkle *et al.* established that 0.5- and 1.0-μm particles can penetrate intact human skin surface and reach the epidermis, where beryllium particles would encounter antigen-presenting cells and initiate sensitization (Tinkle *et al.,* 2003, Document ID 1483). Tinkle *et al.* further demonstrated that beryllium oxide and beryllium sulfate, applied to the skin of mice, generate a beryllium-specific, cell-mediated immune response similar to human beryllium sensitization.

production facilities. The literature on CA–CBD, including the Eisenbud (1949, Document ID 1284), Leiben and Metzner (1959, Document ID 1343), and Maier *et al.* (2008, Document ID 0598) studies, documents cases of CBD among individuals exposed to airborne beryllium at concentrations below the new PEL. OSHA included a review of these studies in the NPRM as a secondary source of information on risk of CBD from low-level beryllium exposure. However, the available studies of CA–CBD have important limitations. These case studies do not provide information on how frequently individuals exposed to very low airborne levels develop CBD. In addition, the reconstructed exposure estimates for CA–CBD cases are less reliable than the exposure estimates for working populations reviewed in the previous sections. The literature on CA–CBD therefore was not used by OSHA as a basis for its quantitative risk assessment for CBD, and the Agency did not receive any comments or testimony on this literature. Nevertheless, these case reports and the broader CA–CBD literature indicate that individuals exposed to airborne beryllium below the final TWA PEL can develop CBD (*e.g.,* Leiben and Metzner, 1959; Maier *et al.,* 2008).

B. OSHA's Prevalence Analysis for Sensitization and CBD

OSHA evaluated exposure and health outcome data on a population of workers employed at the Cullman machining facility as one part of the Agency's Preliminary Risk Analysis presented in the NPRM. A summary of OSHA's preliminary analyses of these data, a discussion of comments received on the analyses and OSHA's responses to these comments, as well as a summary OSHA's final quantitative analyses, are presented in the remainder of this section. A more detailed discussion of the data, background information on the facility, and OSHA's analyses appears in the background document OSHA has placed in the record (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016).

NJH researchers, with consent and information provided by the Cullman facility, compiled a dataset containing employee work histories, medical diagnoses, and air sampling results and provided it to OSHA for analysis. OSHA's contractors from Eastern Research Group (ERG) gathered additional information about work operations and conditions at the plant, developed exposure estimates for individual workers in the dataset, and helped to conduct quantitative analyses of the data to inform OSHA's risk assessment (Document ID tbd).

1. Worker Exposure Reconstruction

The work history database contains job history records for 348 workers. ERG calculated cumulative and average exposure estimates for each worker in the database. Cumulative exposure was calculated as,

$$\sum_i e_i \cdot t_i \quad ,$$

where e(i) is the exposure level for job (i), and t(i) is the time spent in job (i). Cumulative exposure was divided by total exposure time to estimate each worker's long-term average exposure. These exposures were computed in a time-dependent manner for the statistical modeling.[16] For workers with beryllium sensitization or CBD, exposure estimates excluded exposures following diagnosis.

Workers who were employed for long time periods in jobs with low-level exposures tend to have low average and cumulative exposures due to the way these measures are constructed, incorporating the worker's entire work history. As discussed in the Health Effects chapter, higher-level exposures or short-term peak exposures such as those encountered in machining jobs may be highly relevant to risk of sensitization. However, individuals' beryllium exposure levels and sensitization status are not continuously monitored, so it is not known exactly when workers became sensitized or what their ''true'' peak exposures leading up to sensitization were. Only a rough approximation of the upper levels of exposure a worker experienced is possible. ERG attempted to represent workers' highest exposures by constructing a third type of exposure estimate reflecting the exposure level associated with the highest-exposure job (HEJ) and time period experienced by each worker. This exposure estimate (HEJ), the cumulative exposure estimate, and the average exposure were used in the quartile analysis and statistical analyses presented below.

2. Prevalence of Sensitization and CBD

In the database provided to OSHA, 7 workers were reported as sensitized only (that is, sensitized with no known development of CBD). Sixteen workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three workers, first shown to be sensitized only, were later diagnosed with CBD. Tables VI–3, VI–4, and VI–5 below present the prevalence of sensitization and CBD cases across several categories of LTW average, cumulative, and HEJ exposure. Exposure values were grouped by quartile. For this analysis, OSHA excluded 8 workers with no job title listed in the data set (because their exposures could not be estimated); 7 workers whose date of hire was before 1969 (because this indicates they worked in the company's previous plant, for which no exposure measurements were available); and 14 workers who had zero exposure time in the data set, perhaps indicating that they had been hired but had not come to work at Cullman. After these exclusions, a total of 319 workers remained. None of the excluded workers were identified as having beryllium sensitization or CBD.

Note that all workers with CBD are also sensitized. Thus, the columns ''Total Sensitized'' and ''Total %'' refer to all sensitized workers in the dataset, including workers with and without a diagnosis of CBD.

TABLE VI–3—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET

LTW average exposure (μg/m³)	Group size	Sensitized only	CBD	Total sensitized	Total (%)	CBD (%)
0.0–0.080	91	1	1	2	2.2	1.0
0.081–0.18	73	2	4	6	8.2	5.5
0.19–0.51	77	0	6	6	7.8	7.8
0.51–2.15	78	4	8	12	15.4	10.3

[16] Each worker's exposure was calculated at each time that BeLPT testing was conducted.

TABLE VI–3—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET—Continued

LTW average exposure (μg/m³)	Group size	Sensitized only	CBD	Total sensitized	Total (%)	CBD (%)
Total	319	7	19	26	8.2	6.0

TABLE VI–4—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJH DATA SET

Cumulative exposure (μg/m³-yrs)	Group size	Sensitized only	CBD	Total sensitized	Total (%)	CBD (%)
0.0–0.147	81	2	2	4	4.9	2.5
0.148–1.467	79	0	2	2	2.5	2.5
1.468–7.008	79	3	8	11	13.9	8.0
7.009–61.86	80	2	7	9	11.3	8.8
Total	319	7	19	26	8.2%	6.0%

TABLE VI–5—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJH DATA SET

HEJ exposure (μg/m³)	Group size	Sensitized only	CBD	Total sensitized	Total (%)	CBD (%)
0.0–0.086	86	1	0	1	1.2	0.0
0.091–0.214	81	1	6	7	8.6	7.4
0.387–0.691	76	2	9	11	14.5	11.8
0.954–2.213	76	3	4	7	9.2	5.3
Total	319	7	19	26	8.2	6.0

Table VI–3 shows increasing prevalence of total sensitization and CBD with increasing LTW average exposure. The lowest prevalence of sensitization and CBD was observed among workers with average exposure levels less than or equal to 0.08 μg/m³, where two sensitized workers (2.2 percent), including one case of CBD (1.0 percent), were found. The sensitized worker in this category without CBD had worked at the facility as an inspector since 1972, one of the lowest-exposed jobs at the plant. Because the job was believed to have very low exposures, it was not sampled prior to 1998. Thus, estimates of exposures in this job are based on data from 1998–2003 only. It is possible that exposures earlier in this worker's employment history were somewhat higher than reflected in his estimated average exposure. The worker diagnosed with CBD in this group had been hired in 1996 in production control, and had an estimated average exposure of 0.08 μg/m³. This worker was diagnosed with CBD in 1997.

The second quartile of LTW average exposure (0.081–0.18 μg/m³) shows a marked rise in overall prevalence of beryllium-related health effects, with 6 workers sensitized (8.2 percent), of whom 4 (5.5 percent) were diagnosed with CBD. Among 6 sensitized workers in the third quartile (0.19–0.51 μg/m³), all were diagnosed with CBD (7.8 percent). Another increase in prevalence is seen from the third to the fourth quartile, with 12 cases of sensitization (15.4 percent), including eight (10.3 percent) diagnosed with CBD.

The quartile analysis of cumulative exposure also shows generally increasing prevalence of sensitization and CBD with increasing exposure. As shown in Table VI–4, the lowest prevalences of CBD and sensitization are in the first two quartiles of cumulative exposure (0.0–0.147 μg/m³-yrs, 0.148–1.467 μg/m³-yrs). The upper bound on this cumulative exposure range, 1.467 μg/m³-yrs, is the cumulative exposure that a worker would have if exposed to beryllium at a level of 0.03 μg/m³ for a working lifetime of 45 years; 0.15 μg/m³ for ten years; or 0.3 μg/m³ for five years. These exposure levels are in the range of those OSHA was interested in evaluating for purposes of this rulemaking.

A sharp increase in prevalence of sensitization and CBD occurs in the third quartile (1.468–7.008 μg/m³-yrs), with roughly similar levels of both in the highest group (7.009–61.86 μg/m³-yrs). Cumulative exposures in the third quartile would be experienced by a worker exposed for 45 years to levels between 0.03 and 0.16 μg/m³, for 10 years to levels between 0.15 and 0.7 μg/m³, or for 5 years to levels between 0.3 and 1.4 μg/m³.

When workers' exposures from their highest-exposed job are considered, the exposure-response pattern is similar to that for LTW average exposure in the lower quartiles. In Table VI–5, the lowest prevalence is observed in the first quartile (0.0–0.086 μg/m³), with sharply rising prevalence from first to second and second to third exposure quartiles. The prevalence of sensitization and CBD in the top quartile (0.954–2.213 μg/m³) decreases relative to the third, with levels similar to the overall prevalence in the dataset. Many workers in the highest exposure quartiles are long-time employees, who were hired during the early years of the shop when exposures were highest. One possible explanation for the drop in prevalence in the highest exposure quartiles is that other highly-exposed workers from early periods may have developed CBD and left the plant before sensitization testing began in 1995 (*i.e.,* the healthy worker survivor effect).

The results of this prevalence analysis support OSHA's conclusion that maintaining exposure levels below the new TWA PEL will help to reduce risk

of beryllium sensitization and CBD, and that maintaining exposure levels below the action level can further reduce risk of beryllium sensitization and CBD. However, risk of both sensitization and CBD remains even among the workers with the lowest airborne exposures in this data set.

C. OSHA's Statistical Modeling for Sensitization and CBD

1. OSHA's Preliminary Analysis of the NJH Data Set

In the course of OSHA's development of the proposed rule, OSHA's contractor (ERG) also developed a statistical analysis using the NJH data set and a discrete time proportional hazards analysis (DTPHA). This preliminary analysis predicted significant risks of both sensitization (96–394 cases per 1,000, or 9.6–39.4 percent) and CBD (44–313 cases per 1,000, or 4.4–31.3 percent) at the preceding TWA PEL of 2 μg/m^3 for an exposure duration of 45 years (90 μg/m^3-yr). The predicted risks of 8.2–39.9 cases of sensitization per 1,000 (0.8–3.9 percent) and 3.6 to 30.0 cases of CBD per 1,000 (0.4–3 percent) were approximately 10-fold less, but still significant, for a 45-year exposure at the new TWA PEL of 0.2 μg/m^3 (9 μg/m^3-yr).

In interpreting the risk estimates, OSHA took into consideration limitations in the preliminary statistical analysis, primarily study size-related constraints. Consequently, as discussed in the NPRM, OSHA did not rely on the preliminary statistical analysis for its significance of risk determination or to develop its benefits analysis. The Agency relied primarily on the previously-presented analysis of the epidemiological literature and the prevalence analysis of the Cullman data for its preliminary significance of risk determination, and on the prevalence analysis for its preliminary estimate of benefits. Although OSHA did not rely on the results of the preliminary statistical analysis for its findings, the Agency presented the DTPHA in order to inform the public of its results, explain its limitations, and solicit public comment on the Agency's approach.

Dr. Kenny Crump and Ms. Deborah Proctor submitted comments on OSHA's preliminary risk assessment (Document ID 1660). Crump and Proctor agreed with OSHA's review of the epidemiological literature and the prevalence analysis presented previously in this section. They stated, ''we agree with OSHA's conclusion that there is a significant risk (>1/1000 risk of CBD) at the [then] current PEL, and that risk is reduced at the [then] proposed PEL (0.2 μg/m^3) in combination with stringent measures (ancillary provisions) to reduce worker's exposures. This finding is evident based on the available literature, as described by OSHA, and the prevalence data presented for the Cullman facility'' (Document ID 1660, p. 2). They also presented a detailed evaluation of the statistical analysis of the Cullman data presented in the NPRM, including a critique of OSHA's modeling approach and interpretation and suggestions for alternate analyses. However, they emphasized that the new beryllium rule should not be altered or delayed due to their comments regarding the statistical model (Document ID 1660, p. 2).

After considering comments on this preliminary model, OSHA instructed its contractor to change the statistical analysis to address technical concerns and to incorporate suggestions from Crump and Proctor, as well as NIOSH (Document ID 1660; 1725). OSHA reviews and addresses these comments on the preliminary statistical analysis and provides a presentation of the final statistical analysis in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016). The results of the final statistical analysis are summarized here.

2. OSHA's Final Statistical Analysis of the NJH Data Set

As noted above, Dr. Roslyn Stone of University of Pittsburgh School of Public Health reanalyzed for OSHA the Cullman data set in order to address concerns raised by Crump and Proctor (Document ID 1660). The reanalysis uses a Cox proportional hazards model instead of the DTPHA. The Cox model, a regression method for survival data, provides an estimate of the hazard ratio (HR) and its confidence interval.[17] Like the DTPHA, the Cox model can accommodate time-dependent data; however, the Cox model has an advantage over the DTPHA for OSHA's purpose of estimating risk to beryllium-exposed workers in that it does not estimate different ''baseline'' rates of sensitization and CBD for different years. Time-specific risk sets were constructed to accommodate the time-dependent exposures. P-values were based on likelihood ratio tests (LRTs), with p-values <0.05 considered to be statistically significant.

As in the preliminary statistical analysis, Dr. Stone used fractional polynomials[18] to check for possible nonlinearities in the exposure-response models, and checked the effects of age and smoking habits using data on birth year and smoking (current, former, never) provided in the Cullman data set. Data on workers' estimated exposures and health outcomes through 2005 were included in the reanalysis.[19] The 1995 risk set (*e.g.,* analysis of cases of sensitization and CBD identified in 1995) was excluded from all models in the reanalysis so as not to analyze long-standing (prevalent) cases of sensitization and CBD together with newly arising (incident) cases of sensitization and CBD. Finally, Dr. Stone used the testing protocols provided in the literature on the Cullman study population to determine the years in which each employee was scheduled to be tested, and excluded employees from the analysis for years in which they were not scheduled to be tested (Newman *et al.,* 2001, Document ID 1354).

In the reanalysis of the NJH data set, the HR for sensitization increased significantly with increasing LTW average exposure (HR = 2.92, 95% CI = 1.51–5.66, p = 0.001; note that HRs are rounded to the second decimal place). Cumulative exposure was also a statistically significant predictor for beryllium sensitization, although it was not as strongly related to sensitization as LTW average exposure (HR = 1.04, 95% CI 1.00–1.07, p = 0.03). The HR for CBD increased significantly with increasing cumulative exposure (HR = 1.04, 95% CI = 1.01–1.08, p = 0.02). The HR for CBD increased somewhat with increasing LTW average exposure, but this increase was not significant at the 0.05 level (HR = 2.25, 95% CI = 0.94–5.35, p = 0.07).

None of the analyses Dr. Stone performed to check for nonlinearities in exposure-response or the effects of smoking or age substantially impacted the results of the analyses for beryllium sensitization or CBD. The sensitivity analysis recommended by Crump and Proctor, excluding workers hired prior to 1980 (see Document ID 1660, p. 11), did not substantially impact the results

[17] The hazard ratio is an estimate of the ratio of the hazard rate in the exposed group to that of the control group.

[18] Fractional polynomials are linear combinations of polynomials that provide flexible shapes of exposure response.

[19] Data from 2003 to 2005 were excluded in some previous analyses due to uncertainty in some employees' work histories. OSHA accepted the.Crump and Proctor recommendation that these data should be included, so as to treat uncertain exposure estimates consistently in the reanalysis (data prior to the start of sampling in 1980 were included in the previous analysis and most models in the reanalysis).

of the analyses for beryllium sensitization, but did affect the results for CBD. The HR for CBD using cumulative exposure dropped to slightly below 1 and was not statistically significant following exclusion of workers hired before 1980 (HR 0.96, 95% CI 0.81–1.13, p = 0.6). OSHA discusses this result further in the background document, concluding that the reduced follow-up time for CBD in the subcohort hired in 1980 or later, in combination with genetic risk factors that may attenuate both exposure-response and disease latency in some people, may explain the lack of significant exposure-response observed in this sensitivity analysis.

Because LTW average exposure was most strongly associated with beryllium sensitization, OSHA used the final model for LTW average exposure to estimate risk of sensitization at the preceding TWA PEL, the final TWA PEL, and several alternate TWA PELs it considered. Similarly, because cumulative exposure was most strongly associated with CBD, OSHA used the final model for cumulative exposure to estimate risk of CBD at the preceding, final, and alternate TWA PELs. In calculating these risks, OSHA used a small, fixed estimate of ''baseline'' risk (*i.e.,* risk of sensitization or CBD among persons with no known exposure to beryllium), as suggested by Crump and Proctor (Document ID 1660) and NIOSH (Document ID 1725). Table VI–6 presents the risk estimates for sensitization and the corresponding 95 percent confidence intervals using two different fixed ''background'' rates of sensitization, 1 percent and 0.5 percent. Table VI–7 presents the risk estimates for sensitization and the corresponding 95 percent confidence intervals using a fixed ''background'' rate of CBD of 0.5 percent. The corresponding interval is based on the uncertainty in the exposure coefficient (*i.e.,* the predicted values based on the 95 percent confidence limits for the exposure coefficient). Since the Cox proportional hazards model does not estimate a baseline risk, this 95 percent interval fully represents statistical uncertainty in the risk estimates.

TABLE VI–6—PREDICTED CASES OF SENSITIZATION PER 1,000 WORKERS EXPOSED AT THE PRECEDING AND ALTERNATE PELS BASED ON COX PROPORTIONAL HAZARDS MODEL, LTW AVERAGE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT.

[1 Percent and 0.5 percent baselines]

Exposure level (μg/m³)	Estimated cases/1000, .5% baseline	95% CI	Estimated cases/1000, 1% baseline	95% CI
2.0	42.75	11.4–160.34	85.49	22.79–320.69
1.0	14.62	7.55–28.31	29.24	15.10–56.63
0.5	8.55	6.14–11.90	17.10	12.29–23.80
0.2	6.20	5.43–7.07	12.39	10.86–14.15
0.1	5.57	5.21–5.95	11.13	10.42–11.89

TABLE VI–7—PREDICTED CASES OF CBD PER 1,000 WORKERS EXPOSED AT THE PRECEDING AND ALTERNATIVE PELS BASED ON COX PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[0.5 percent baseline]

Exposure level (μg/m³)	Exposure Duration							
	5 years		10 years		20 years		45 years	
	Cumulative (μg/m³-yrs)	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI	μg/m³-yrs	Estimated cases/1000 95% CI
2.0	10.0	7.55 5.34–10.67	20.0	11.39 5.70–22.78	40.0	25.97 6.5–103.76	90.0	203.60 9.02–4595.67
1.0	5.0	6.14 5.17–7.30	10.0	7.55 5.34–10.67	20.0	11.39 5.70–22.78	45.0	31.91 6.72–151.59
0.5	2.5	5.54 5.08–6.04	5.0	6.14 5.17–7.30	10.0	7.55 5.34–10.67	22.5	12.63 5.79–27.53
0.2	1.0	5.21 5.03–5.39	2.0	5.43 5.07–5.82	4.0	5.9 5.13–6.77	9.0	7.24 5.30–9.89
0.1	0.5	5.1 5.02–5.19	1.0	5.21 5.03–5.39	2.0	5.43 5.07–5.82	4.5	6.02 5.15–7.03

The Cox proportional hazards model, used with the fixed ''baseline'' rates of 0.5 percent and 1 percent, predicted risks of sensitization totaling 43 and 86 cases per 1,000 workers, respectively, or 4.3 and 8.6 percent, at the preceding PEL of 2 μg/m³. The predicted risk of CBD is 203 cases per 1,000 workers, or 20.3 percent, at the preceding PEL of 2 μg/m³, assuming 45 years of exposure (cumulative exposure of 90 μg/m³-yr).[20] The predicted risks of sensitization at the new PEL of 0.2 μg/m³ are substantially lower, at 6 and 12 cases per 1,000 for the baselines of 0.5% and 1.0%, respectively. The predicted risk of CBD is also much lower at the new TWA PEL of 0.2 μg/m³ (9 μg/m³-year), at 7 cases per 1,000 assuming 45 years of exposure.

Due to limitations in the Cox analysis, including the small size of the dataset, relatively limited exposure data from the plant's early years, study size-related constraints on the statistical analysis of the dataset, limited follow-

[20] The predictions for each model represent the estimated probability of being sensitized or having CBD at one point in time, rather than the cumulative risk over a lifetime of exposure, which would be higher. Lifetime risks are presented in the FEA, Benefits Analysis.

up time on many workers, and sensitivity of the results to the ''baseline'' values assumed for sensitization and CBD, OSHA must interpret the model-based risk estimates presented in Tables VI–6 and VI–7 with caution. Uncertainties in these risk estimates are discussed in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016). However, these uncertainties do not alter OSHA's conclusions with regard to the significance of risk at the preceding PEL and alternate PELs that OSHA considered, which are based primarily on the Agency's review of the literature and the prevalence analysis presented earlier in this section (also see Section VII, Significance of Risk).

D. Lung Cancer

As discussed more fully in the Health Effects section of the preamble, OSHA has determined beryllium to be a carcinogen based on an extensive review of the scientific literature regarding beryllium and cancer (see Section V.E). This review included an evaluation of the human epidemiological, animal cancer, and mechanistic studies described in the Health Effects section of this preamble. OSHA's conclusion is supported by the findings of public health organizations such as the International Agency for Research on Cancer (IARC), which has determined beryllium and its compounds to be carcinogenic to humans (Group 1 category) (IARC 2012, Document ID 0650); the National Toxicology Program (NTP), which classifies beryllium and its compounds as known carcinogens (NTP 2014, Document ID 0389); and the Environmental Protection Agency (EPA), which considers beryllium to be a probable human carcinogen (EPA 1998, Document ID 0661).

The Sanderson *et al.* study previously discussed in Health Effects evaluated the association between beryllium exposure and lung cancer mortality based on data from a beryllium processing plant in Reading, PA (Sanderson *et al.,* 2001, Document ID 1419). Specifically, this case-control study evaluated lung cancer mortality in a cohort of 3,569 male workers employed at the plant from 1940 to 1969 and followed through 1992. For each lung cancer victim, 5 age- and race-matched controls were selected by incidence density sampling, for a total of 142 identified lung cancer cases and 710 controls.

A conditional logistic regression analysis showed an increased risk of death from lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years (Sanderson *et al.,* 2001, Document ID 1419). This lag was incorporated in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer. The authors noted that there was considerable uncertainty in the estimation of exposure levels for the 1940s and 1950s and in the shape of the dose-response curve for lung cancer. In a 2008 study, Schubauer-Berigan *et al.* reanalyzed the data, adjusting for potential confounders of hire age and birth year (Schubauer-Berigan *et al.,* 2008, Document ID 1350). The study reported a significant increasing trend ($p < 0.05$) in lung cancer mortality when average (log transformed) exposure was lagged by 10 years. However, it did not find a significant trend when cumulative (log transformed) exposure was lagged by 0, 10, or 20 years (Schubauer-Berigan *et al.,* 2008, Table 3).

In formulating the final rule, OSHA was particularly interested in lung cancer risk estimates from a 45-year (*i.e.,* working lifetime) exposure to beryllium levels between 0.1 $\mu g/m^3$ and 2 $\mu g/m^3$. The majority of case and control workers in the Sanderson *et al.* (2001, Document ID 1419) case-control analysis were first hired during the 1940s and 50s when exposures were extremely high (estimated daily weighted averages (DWAs) >20 $\mu g/m^3$ for most jobs) in comparison to the exposure range of interest to OSHA (Sanderson *et al.* 2001, Document ID 1419, Table II). About two-thirds of cases and half of controls worked at the plant for less than a year. Thus, a risk assessment based on this exposure-response analysis would have needed to extrapolate from very high to low exposures, based on a working population with extremely short tenure. While OSHA risk assessments must often make extrapolations to estimate risk within the range of exposures of interest, the Agency acknowledges that these issues of short tenure and high exposures would have created substantial uncertainty in a risk assessment based on this particular study population.

In addition, the relatively high exposures of the least-exposed workers in the study population might have created methodological issues for the lung cancer case-control study design. Mortality risk is expressed as an odds ratio that compares higher exposure quartiles to the lowest quartile. It is preferable that excess risks attributable to occupational beryllium be determined relative to an unexposed or minimally exposed reference population. However, in this study population, workers in the lowest quartile were exposed well above the preceding OSHA TWA PEL (average exposure <11.2 $\mu g/m^3$) and may have had a significant lung cancer risk. This issue would have introduced further uncertainty into the lung cancer risks.

In 2011, Schubauer-Berigan *et al.* published a quantitative risk assessment that addressed several of OSHA's concerns regarding the Sanderson *et al.* analysis. This new risk assessment was based on an update of the Reading cohort analyzed by Sanderson *et al.,* as well as workers from two smaller plants (Schubauer-Berigan *et al.* 2011, Document ID 1265). This study population was exposed, on average, to lower levels of beryllium and had fewer short-term workers than the previous cohort analyzed by Sanderson *et al.* (2001, Document ID 1250) and Schubauer-Berigan *et al.* (2008, Document ID 1350). Schubauer-Berigan *et al.* (2011) followed the study population through 2005 where possible, increasing the length of follow-up time overall by an additional 17 years of observation compared to the previous analyses. For these reasons, OSHA considered the Schubauer-Berigan (2011) analysis more appropriate than Sanderson *et al.* (2001) and Schubauer-Berigan (2008) for its risk assessment. OSHA therefore based its preliminary QRA for lung cancer on the results from Schubauer-Berigan *et al.* (2011).

OSHA received several comments about its choice of Schubauer-Berigan *et al.* (2011) as the basis for its preliminary QRA for lung cancer. NIOSH commented that OSHA's choice of Schubauer-Berigan *et al.* for its preliminary analysis was appropriate because ''[n]o other study is available that presents quantitative dose-response information for lung cancer, across a range of beryllium processing facilities'' (Document ID 1725, p. 7). In supporting OSHA's use of this study, NIOSH emphasized in particular the study's inclusion of relatively low-exposed workers from two facilities that began operations in the 1950s (after employer awareness of acute beryllium disease (ABD) and CBD led to efforts to minimize worker exposures to beryllium), as well as the presence of both soluble and poorly soluble forms of beryllium in the facilities studied (Document ID 1725, p. 7).

According to Dr. Paolo Boffetta, who submitted comments on this study,

Schubauer-Berigan *et al.* (2011) is not the most relevant study available to OSHA for its lung cancer risk analysis. Dr. Boffetta argued that the most informative study of lung cancer risk in the beryllium industry after 1965 is one that he developed in 2015 (Boffetta *et al.,* 2015), which he described as a pooled analysis of 11 plants and 4 distribution centers (Document ID 1659, p. 1). However, Dr. Boffetta did not provide OSHA with the manuscript of his study, which he stated was under review for publication. Instead, he reported some results of the study and directed OSHA to an abstract of the study in the 2015 Annual Conference of the Society for Epidemiologic Research (Document ID 1659; Document ID 1661, Attachment 1).

Because only an abstract of Boffetta *et al.*'s 2015 study was available to OSHA (*see* Document ID 1661, Attachment 1), OSHA could not properly evaluate it or use it as the basis of a quantitative risk assessment for lung cancer. Nevertheless, OSHA has addressed comments Dr. Boffetta submitted based on his analyses in the relevant sections of the final QRA for lung cancer below. Because it was not possible to use this study for its lung cancer QRA and OSHA is not aware of other studies appropriate for use in its lung cancer QRA (nor did commenters besides Dr. Boffetta suggest that OSHA use any additional studies for this purpose), OSHA finds that the body of available evidence has not changed since the Agency conducted its preliminary QRA based on Schubauer-Berigan *et al.* (2011, Document ID 1265). Therefore, OSHA concludes that Schubauer-Berigan *et al.* (2011) is the most appropriate study for its final lung cancer QRA, presented below.

1. QRA for Lung Cancer Based on Schubauer-Berigan *et al.* (2011)

The cohort studied by Schubauer-Berigan *et al.* (2011, Document ID 1265) included 5,436 male workers who had worked for at least 2 days at the Reading facility or at the beryllium processing plants in Hazleton, PA and Elmore, OH prior to 1970. The authors developed job-exposure matrices (JEMs) for the three plants based on extensive historical exposure data, primarily short-term general area and personal breathing zone samples, collected on a quarterly basis from a wide variety of operations. These samples were used to create DWA estimates of workers' full-shift exposures, using records of the nature and duration of tasks performed by workers during a shift. Details on the JEM and DWA construction can be found in Sanderson *et al.* (2001, Document ID 1250), Chen *et al.* (2001, Document ID 1593), and Couch *et al.* (2010, Document ID 0880).

Workers' cumulative exposures (μg/m³-days) were estimated by summing daily average exposures (assuming five workdays per week) (Schubauer-Berigan *et al.,* 2011). To estimate mean exposure (μg/m³), cumulative exposure was divided by exposure time (in days), accounting where appropriate for lag time. Maximum exposure (μg/m³) was calculated as the highest annual DWA on record for a worker from the first exposure until the study cutoff date of December 31, 2005, again accounting where appropriate for lag time. Exposure estimates were lagged by 5, 10, 15, and 20 years in order to account for exposures that may not have contributed to lung cancer because of the long latency required for manifestation of the disease. The authors also fit models with no lag time.

As shown in Table VI–8 below, estimated exposure levels for workers from the Hazleton and Elmore plants were on average far lower than those for workers from the Reading plant (Schubauer-Berigan *et al.,* 2011). Whereas the median worker from Hazleton had a mean exposure across his tenure of less than 1.5 μg/m³ and the median worker from Elmore had a mean exposure of less than 1 μg/m³, the median worker from Reading had a mean exposure of 25 μg/m³. The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. This was particularly evident at Hazleton, where the median value for cumulative exposure among cases was higher than at Reading despite the much lower mean and maximum exposure levels.

TABLE VI–8—COHORT DESCRIPTION AND DISTRIBUTION OF CASES BY EXPOSURE LEVEL

		All plants	Reading plant	Hazleton plant	Elmore plant
Number of cases		293	218	30	45
Number of non-cases		5143	3337	583	1223
Median value for mean exposure	*No lag*	15.42	25	1.443	0.885
(μg/m³) among cases	*10-year lag*	15.15	25	1.443	0.972
Median value for cumulative exposure	*No lag*	2843	2895	3968	1654
(μg/m³-days) among cases	*10-year lag*	2583	2832	3648	1449
Median value for maximum exposure	*No lag*	25	25.1	3.15	2.17
(μg/m³) among cases	*10-year lag*	25	25	3.15	2.17
Number of cases with potential asbestos exposure		100 (34%)	68 (31%)	16 (53%)	16 (36%)
Number of cases who were professional workers		26 (9%)	21 (10%)	3 (10%)	2 (4%)

Table adapted from Schubauer-Berigan *et al.,* 2011, Document ID 1265, Table 1.

Schubauer-Berigan *et al.* analyzed the data set using a variety of exposure-response modeling approaches, including categorical analyses, continuous-variable piecewise log-linear models, and power models (2011, Document ID 1265). All models adjusted for birth cohort and plant. Because exposure values were log-transformed for the power model analyses, the authors added small values to exposures of 0 in lagged analyses (0.05 μg/m³ for mean and maximum exposure, 0.05 μg/m³-days for cumulative exposure). The authors used restricted cubic spline models to assess the shape of the exposure-response curves and suggest appropriate parametric model forms. The Akaike Information Criterion (AIC) value was used to evaluate the fit of different model forms and lag times.

Because smoking information was available for only about 25 percent of the cohort (those employed in 1968), smoking could not be controlled for directly in the models. Schubauer-Berigan *et al.* reported that within the subset with smoking information, there was little difference in smoking by cumulative or maximum exposure category, suggesting that smoking was unlikely to act as a confounder in the cohort. In addition to models based on the full cohort, Schubauer-Berigan *et al.* also prepared risk estimates based on models excluding professional workers (ten percent of cases) and workers believed to have asbestos exposure (one-third of cases). These models were

intended to mitigate the potential impact of smoking and asbestos as confounders.[21]

The authors found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure (all models reported in Schubauer-Berigan *et al.,* 2011, Document ID 1265). They selected the best-fitting categorical, power, and monotonic piecewise log-linear (PWL) models with a 10-year lag to generate HRs for male workers with a mean exposure of 0.5 μg/m³ (the current NIOSH Recommended Exposure Limit for beryllium).[22] In addition, they estimated the daily weighted average exposure that would be associated with an excess lung cancer mortality risk of one in one thousand (.005 μg/m³ to .07 μg/m³ depending on model choice). To estimate excess risk of cancer, they multiplied these hazard ratios by the 2004 to 2006 background lifetime lung cancer rate among U.S. males who had survived, cancer-free, to age 30. At OSHA's request, Dr. Schubauer-Berigan also estimated excess lung cancer risks for workers with mean exposures at the preceding PEL of 2 μg/m³ and at each of the other alternate PELs that were under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³ (Document ID 0521). The resulting risk estimates are presented in Table VI–9 below.

TABLE VI–9—EXCESS LUNG CANCER RISK PER 1,000 [95% CONFIDENCE INTERVAL] FOR MALE WORKERS AT ALTERNATE PELS

[Based on Schubauer-Berigan *et al.,* 2011]

Exposure-response model	Mean exposure				
	0.1 μg/m³	0.2 μg/m³	0.5 μg/m³	1 μg/m³	2 μg/m³
Best monotonic PWL—all workers	7.3 [2.0–13]	15 [3.3–29]	45 [9–98]	120 [20–340]	140 [29–370]
Best monotonic PWL—excluding professional and asbestos workers	3.1 [<0–11]	6.4 [<0–23]	17 [<0–74]	39 [39–230]	61 [<0–280]
Best categorical—all workers	4.4 [1.3–8]	9 [2.7–17]	25 [6–48]	59 [13–130]	170 [29–530]
Best categorical—excluding professional and asbestos workers	1.4 [<0–6.0]	2.7 [<0–12]	7.1 [<0–35]	15 [<0–87]	33 [<0–290]
Power model—all workers	12 [6–19]	19 [9.3–29]	30 [15–48]	40 [19–66]	52 [23–88]
Power model—excluding professional and asbestos workers	19 [8.6–31]	30 [13–50]	49 [21–87]	68 [27–130]	90 [34–180]

SOURCE: Schubauer-Berigan, Document ID 0521, pp. 6–10.

Schubauer-Berigan *et al.* (2011, Document ID 1265) discuss several strengths, weaknesses, and uncertainties of their analysis. Strengths include a long (>30 years) follow-up time and the extensive exposure and work history data available for the development of exposure estimates for workers in the cohort. Weaknesses and uncertainties of the study include the limited information available on workers' smoking habits: As mentioned above, smoking information was available only for workers employed in 1968, about 25 percent of the cohort. Another potential weakness was that the JEMs used did not account for possible respirator use among workers in the cohort. The authors note that workers' exposures may therefore have been overestimated, and that overestimation may have been especially severe for workers with high estimated exposures. They suggest that overestimation of exposures for workers in highly exposed positions may have caused attenuation of the exposure-response curve in some models at higher exposures. This could cause the relationship between exposure level and lung cancer risk to appear weaker than it would in the absence of this source of error in the estimation of workers' beryllium exposures.

Schubauer-Berigan *et al.* (2011) did not discuss the reasons for basing risk estimates on mean exposure rather than cumulative exposure, which is more commonly used for lung cancer risk analysis. OSHA believes the decision may involve the non-monotonic relationship the authors observed between cancer risk and cumulative exposure level. As discussed previously, workers from the Reading plant frequently had very short tenures and high exposures, yielding lower cumulative exposures compared to cohort workers from other plants with longer employment. Despite the low estimated cumulative exposures among the short-term Reading workers, they may have been at high risk of lung cancer due to the tendency of beryllium to persist in the lung for long periods. This could lead to the appearance of a non-monotonic relationship between cumulative exposure and lung cancer risk. It is possible that a dose-rate effect may exist for beryllium, such that the risk from a cumulative exposure gained by long-term, low-level exposure is not equivalent to the risk from a cumulative exposure gained by very short-term, high-level exposure. In this case, mean exposure level may better correlate with the risk of lung cancer than cumulative exposure level. For these reasons, OSHA considers the authors' use of the mean exposure metric to be appropriate and scientifically defensible for this particular dataset.

Dr. Boffetta's comment, mentioned above, addressed the relevance of the Schubauer-Berigan *et al.* (2011) cohort to determining whether workers currently employed in the beryllium industry experience an increased lung cancer hazard (Document ID 1659, pp. 1–2). His comment also analyzed the methods and findings in Schubauer-Berigan *et al.* (2011) (Document ID 1659, pp. 2–3). Notably, he stated that his own study, Boffetta *et al.* (2015) provides better information for risk assessment than does Schubauer-Berigan *et al.* (2011) (Document ID 1659, pp. 1–2). As discussed above, OSHA cannot rely on a study for its QRA (Boffetta *et al.,* 2015) that has not been submitted to the record and is not otherwise available to OSHA. However, in the discussion below, OSHA addresses Dr. Boffetta's study to the extent it can given the

[21] The authors appeared to reason that if professional workers had both lower beryllium exposures and lower smoking rates than production workers, smoking could be a confounder in the cohort comprising both production and professional workers. However, smoking was unlikely to be correlated with beryllium exposure among production workers, and would therefore probably not act as a confounder in a cohort excluding professional workers.

[22] Here, ''monotonic PWL model'' means a model producing a monotonic exposure-response curve in the 0 to 2 μg/m³ range.

limited information available to the Agency. OSHA also responds to Dr. Boffetta's comments on Schubauer-Berigan *et al.* (2011, Document ID 1265) and Boffetta *et al.* (2014, Document ID 0403), which Dr. Boffetta asserts provides evidence that poorly soluble beryllium compounds are not associated with lung cancer (Document ID 1659, p. 1).

Boffetta argued that the most informative study in the modern (post-1965) beryllium industry is Boffetta *et al.* (2015, Document ID 1661, Attachment 1). According to Boffetta's comment, the study found an SMR of 1.02 (95% CI 0.94–1.10, based on 672 deaths) for the overall cohort and an SMR for lung cancer among workers exposed only to insoluble beryllium of 0.93 (95% CI 0.79–1.08, based on 157 deaths). Boffetta noted that his study was based on 23 percent more overall deaths than the Schubauer-Berigan *et al.* cohort (Document ID 1659, pp. 1–2). As stated earlier, this study is unpublished and was not provided to OSHA. The abstract provided by Materion (Document ID 1661, Attachment 1) included very little information beyond the SMRs reported; for example, it provided no information about the manufacturing plants and distribution centers included, workers' beryllium exposure levels, how the cohorts were defined, or how the authors determined the solubility of the beryllium to which workers were exposed. OSHA is therefore unable to evaluate the quality or conclusions of this study.

Dr. Boffetta also commented that there is a lack of evidence of increased lung cancer risk among workers exposed only to poorly soluble beryllium compounds (Document ID 1659, p. 1). To support this statement, he cited a study he published in 2014 of workers at four ''insoluble facilities'' (Boffetta *et al.,* 2014) and Schubauer-Berigan *et al.*'s 2011 study, arguing that increased cancer risk in beryllium-exposed workers in those two studies was only observed in workers employed in Reading and Lorain prior to 1955. Workers employed at the other plants and workers who were first employed in Reading and Lorain after 1955, according to Dr. Boffetta, were exposed primarily to poorly soluble forms of beryllium and did not experience an increased risk of lung cancer. Dr. Boffetta further stated that his unpublished paper (Boffetta *et al.,* 2015) shows a similar result (Document ID 1659, p. 1).

OSHA carefully considered Dr. Boffetta's argument regarding the status of poorly soluble beryllium compounds, and did not find persuasive evidence showing that the solubility of the beryllium to which the workers in the studies he cited were exposed accounts for the lack of statistically significantly elevated risk in the Boffetta *et al.* (2014) cohort or the Schubauer-Berigan *et al.* (2011) subcohort. While it is true that the SMR for lung cancer was not statistically significantly elevated in the Schubauer-Berigan *et al.* (2011) study when workers hired before 1955 in the Reading and Lorain plants were excluded from the study population, or in the study of four facilities published by Boffetta *et al.* in 2014, there are various possible reasons for these results that Dr. Boffetta did not consider in his comment. As discussed below, OSHA finds that the type of beryllium compounds to which these workers were exposed is not likely to explain Dr. Boffetta's observations.

As discussed in Section V, Health Effects and in comments submitted by NIOSH, animal toxicology evidence shows that poorly soluble beryllium compounds can cause cancer. IARC determined that poorly soluble forms of beryllium are carcinogenic to humans in its 2012 review of Group I carcinogens (see section V.E.5 of this preamble; Document ID 1725, p. 9; IARC, 2012, Document ID 0650). NIOSH noted that poorly soluble forms of beryllium remain in the lung for longer time periods than soluble forms, and can therefore create prolonged exposure of lung tissue to beryllium (Document ID 1725, p. 9). This prolonged exposure may lead to the sustained tissue inflammation that causes many forms of cancer and is believed to be one pathway for carcinogenesis due to beryllium exposure (see Section V, Health Effects).

The comments from NIOSH also demonstrate that the available information cannot distinguish between the effects of soluble and poorly soluble beryllium. NIOSH submitted information on the solubility of beryllium in the Schubauer-Berigan *et al.* (2011) cohort, stating that operations typically involving both soluble and poorly soluble beryllium were performed at all three of the beryllium plants included in the study (Document ID 1725, p. 9; Ward *et al.,* 1992, Document ID 1378). Based on evaluations of the JEMs and work histories of employees in the cohort (which were not published in the 2011 Schubauer-Berigan *et al.* paper), NIOSH stated that ''the vast majority of beryllium work-time at all three of these facilities was due to either insoluble or mixed chemical forms. In fact, insoluble beryllium was the largest single contributor to work-time (for beryllium exposure of known solubility class) at the three facilities across most time periods'' (Document ID 1725, p. 9). NIOSH also provided figures showing the contribution of insoluble beryllium to exposure over time in the Schubauer-Berigan *et al.* (2011) study, as well as the relatively small proportion of work years during which workers in the study were exposed exclusively to either soluble or poorly soluble forms (Document ID 1725, pp. 10–11).

Boffetta *et al.* (2014, Document ID 0403) examined a population of workers allegedly exposed exclusively to poorly soluble beryllium compounds, in which overall SMR for lung cancer was not statistically significantly elevated (SMR 96.0, 95% CI 80.0–114.3). Boffetta *et al.* concluded, ''[a]lthough a small risk for lung cancer is compatible with our results, we can confidently exclude an excess greater than 20%'' in the study population (Boffetta *et al.,* 2014, p. 592). Limitations of the study include a lack of information on many workers' job titles, a lack of any beryllium exposure measurements, and the very short-term employment of most cohort members at the study facilities (less than 5 years for 72 percent of the workers) (Boffetta *et al.,* 2014).

OSHA reviewed this study, and finds that it does not contradict the findings of the Schubauer-Berigan *et al.* (2011) lung cancer risk analysis for several reasons. First, as shown in Table VI–9 above, none of the predictions of excess risk in the risk analysis exceed 20 percent (200 per 1,000 workers); most are well below this level, and thus are well within the range that Boffetta *et al.* (2014) state they cannot confidently exclude. Thus, the statement by Boffetta *et al.* that the risk of excess lung cancer is no higher than 20 percent is actually consistent with the risk findings from Schubauer-Berigan *et al.* (2011) presented above. Second, the fact that most workers in the cohort were employed for less than five years suggests that most workers' cumulative exposures to beryllium were likely to be quite low, which would explain the non-elevated SMR for lung cancer in the study population regardless of the type of beryllium to which workers were exposed. The SMR for workers employed in the study facilities for at least 20 years was elevated (112.7, CI 66.8–178.1) (Boffetta *et al.,* 2014, Document ID 0403, Table 3),[23] supporting OSHA's observation that the lack of elevated SMR in the cohort overall may be due to short-term

[23] This SMR was not statistically significantly elevated, probably due to the small size of this subcohort (153 total deaths, 18 lung cancer deaths).

employment and low cumulative exposures.

Finally, the approach of Boffetta *et al.* (2014), which relies on SMR analyses, does not account for the healthy worker effect. SMRs are calculated by comparing disease levels in the study population to disease levels in the general population, using regional or national reported disease rates. However, because working populations tend to have lower disease rates than the overall population, SMRs can underestimate excess risk of disease in those populations. The SMR in Boffetta *et al.* (2014) for overall mortality in the study population was statistically significantly reduced (94.7, 95 percent CI 89.9–99.7), suggesting a possible healthy worker effect. The SMR for overall mortality was even further reduced in the category of workers with at least 20 years of employment (87.7, 95 percent CI 74.3–102.7), in which an elevated SMR for lung cancer was observed. NIOSH commented that ''[i]n a modern industrial population, the expected SMR for lung cancer would be approximately 0.93 [Park *et al.* (1991)]'' (Document ID 1725, p. 8). This is lower than the SMR for lung cancer (96) observed in Boffetta *et al.* (2014) and much lower than the SMR for lung cancer in the category of workers employed for at least 20 years (112.7), which is the group most likely to have had sufficient exposure and latency to show excess lung cancer (Boffetta *et al.,* 2014, Document ID 0403, Tables 2 and 3). Thus, it appears that the healthy worker effect is another factor (in addition to low cumulative exposures) that may account for the findings of Boffetta *et al.'*s 2014 study.

Taken together, OSHA finds that the animal toxicology evidence on the carcinogenicity of poorly soluble beryllium forms, the long residence of poorly soluble beryllium in the lung, the likelihood that most workers in Schubauer-Berigan *et al.* (2011) were exposed to a mixture of soluble and poorly soluble beryllium forms, and the points raised above regarding Boffetta *et al.* (2014) rebut Boffetta's claim that low solubility of beryllium compounds is the most likely explanation for the lack of statistically significantly elevated SMR results.

Dr. Boffetta's comment also raised technical questions regarding the Schubauer-Berigan *et al.* (2011, Document ID 1265) risk analysis. He noted that risk estimates at low exposures are dependent on choice of model in their analysis; the authors' choice of a single ''best'' model was based on purely statistical criteria, and the results of the statistics used (AIC) were similar between the models'' (Document ID 1659, p. 2). Therefore, according to Dr. Boffetta, ''there is ample uncertainty about the shape of the dose-response function in the low-dose range'' (Document ID 1659, p. 3).

OSHA agrees that it is difficult to distinguish a single ''best'' model from the set of models presented by Schubauer-Berigan *et al.* (2011), and that risk estimates at low exposure levels vary depending on choice of model. That is one reason OSHA presented results from all of the models (see Table VI–9). OSHA further agrees that there is uncertainty in the lung cancer risk estimates, the estimation of which (unlike for CBD) required extrapolation below beryllium exposure levels experienced by workers in the Schubauer-Berigan *et al.* (2011) study. However, the Schubauer-Berigan risk assessment's six best-fitting models all support OSHA's significant risk determination, as they all predict a significant risk of lung cancer at the preceding TWA PEL of 2 μg/m^3 (estimates ranging from 33 to 170 excess lung cancers per 1,000 workers) and a substantially reduced, though still significant, risk of lung cancer at the new TWA PEL of 0.2 μg/m^3 (estimates ranging from 3 to 30 excess lung cancers per 1,000 workers) (see Table VI–9).

Dr. Boffetta also noted that the risk estimates provided by Schubauer-Berigan *et al.* (2011, Document ID 1265) for OSHA's lung cancer risk assessment depend on the background lung cancer rate used in excess risk calculations, and that industrial workers may have a different background lung cancer risk than the U.S. population as a whole (Document ID 1659, p. 2). OSHA agrees that choice of background risk could influence the number of excess lung cancers predicted by the models the Agency relied on for its lung cancer risk estimates. However, choice of background risk did not influence OSHA's finding that excess lung cancer risks would be substantially reduced by a decrease in exposure from the preceding TWA PEL to the final TWA PEL, because the same background risk was factored into estimates of risk at both levels. Furthermore, the Schubauer-Berigan *et al.* (2011) estimates of excess lung cancer from exposure at the preceding PEL of 2 μg/m^3 (ranging from 33 to 170 excess lung cancers per 1,000 workers, depending on the model) are much higher than the level of 1 per 1,000 that OSHA finds to be clearly significant. Even at the final TWA PEL of 0.2 μg/m^3, the models demonstrate a range of risks of excess lung cancers of 3 to 30 per 1,000 workers, estimates well above the threshold for significant risk (see Section II, Pertinent Legal Authority). Small variations in background risk across different populations are highly unlikely to influence excess lung cancer risk estimates sufficiently to influence OSHA's finding of significant risk at the preceding TWA PEL, which is the finding OSHA relies on to support the need for a new standard.

Finally, Dr. Boffetta noted that the models that exclude professional and asbestos workers (the groups that Schubauer-Berigan *et al.* believed could be affected by confounding from tobacco and asbestos exposure) showed non-significant increases in lung cancer with increasing beryllium exposure. According to Dr. Boffetta, this suggests that confounding may contribute to the results of the models based on the full population. He speculates that if more precise information on confounding exposures were available, excess risk estimates might be further reduced (Document ID 1659, p. 2).

OSHA agrees with Dr. Boffetta that there is uncertainty in the Schubauer-Berigan *et al.* (2011) lung cancer risk estimates, including uncertainty due to limited information on possible confounding from associations between beryllium exposure level and workers' smoking habits or occupational co-exposures. However, in the absence of detailed smoking and co-exposure information, the models excluding professional and asbestos workers are a reasonable approach to addressing the possible effects of unmeasured confounding. OSHA's decision to include these models in its preliminary and final QRAs therefore represents the Agency's best available means of dealing with this uncertainty.

E. Risk Assessment Conclusions

As described above, OSHA's risk assessment for beryllium sensitization and CBD relied on two approaches: (1) Review of the literature, and (2) analysis of a data set provided by NJH. OSHA has a high level of confidence in its finding that the risks of sensitization and CBD are above the benchmark of 1 in 1,000 at the preceding PEL, and the Agency believes that a comprehensive standard requiring a combination of more stringent controls on beryllium exposure will reduce workers' risk of both sensitization and CBD. Programs that have reduced median levels to below 0.1 μg/m^3 and tightly controlled both respiratory exposure and dermal contact have substantially reduced risk of sensitization within the first years of exposure. These conclusions are supported by the results of several studies conducted in facilities dealing

with a variety of production activities and physical forms of beryllium that have reduced workers' exposures substantially by implementing stringent exposure controls and PPE requirements since approximately 2000. In addition, these conclusions are supported by OSHA's analyses of the NJH data set, which contains highly-detailed exposure and work history information on several hundred beryllium workers.

Furthermore, OSHA believes that more stringent control of airborne beryllium exposures will reduce beryllium-exposed workers' significant risk of lung cancer. The risk estimates from the lung cancer study by Schubauer-Berigan *et al.* (2011, Document ID 1265; 0521), described above, range from 33 to 170 excess lung cancers per 1,000 workers exposed at the preceding PEL of 2 μg/m³, based on the study's six best-fitting models. These models each predict substantial reductions in risk with reduced exposure, ranging from 3 to 30 excess lung cancers per 1,000 workers exposed at the final PEL of 0.2 μg/m³. The evidence of lung cancer risk from the Schubauer-Berigan *et al.* (2011) risk assessment provides additional support for OSHA's conclusions regarding the significance of risk of adverse health effects for workers exposed to beryllium levels at and below the preceding PEL. However, the lung cancer risks required a sizable low dose extrapolation below beryllium exposure levels experienced by workers in the Schubauer-Berigan *et al.* (2011) study. As a result, there is greater uncertainty regarding the lung cancer risk estimates than there is for the risk estimates for beryllium sensitization and CBD. The conclusions with regard to significance of risk are presented and further discussed in section VII of the preamble.

VII. Significance of Risk

In this section, OSHA discusses its findings that workers exposed to beryllium at and below the preceding TWA PEL face a significant risk of material impairment of health or functional capacity within the meaning of the OSH Act, and that the new standards will substantially reduce this risk. To make the significance of risk determination for a new final or proposed standard, OSHA uses the best available scientific evidence to identify material health impairments associated with potentially hazardous occupational exposures and to evaluate exposed workers' risk of these impairments assuming exposure over a working lifetime. As discussed in section II, Pertinent Legal Authority, courts have stated that OSHA should consider all forms and degrees of material impairment—not just death or serious physical harm. To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on epidemiological, toxicological, and experimental evidence. The Agency uses both qualitative and quantitative methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime (generally 45 years) at levels of exposure reflecting compliance with the preceding standard and compliance with the new standards (see Section II, Pertinent Legal Authority). When determining whether a significant risk exists OSHA considers whether there is a risk of at least one-in-a-thousand of developing a material health impairment from a working lifetime of exposure. The Supreme Court has found that OSHA is not required to support its finding of significant risk with scientific certainty, but may instead rely on a body of reputable scientific thought and may make conservative assumptions (*i.e.,* err on the side of protecting the worker) in its interpretation of the evidence (Section II, Pertinent Legal Authority).

OSHA's findings in this section follow in part from the conclusions of the preceding sections V, Health Effects, and VI, Risk Assessment. In this preamble at section V, Health Effects, OSHA reviewed the scientific evidence linking occupational beryllium exposure to a variety of adverse health effects and determined that beryllium exposure causes sensitization, CBD, and lung cancer, and is associated with various other adverse health effects (see section V.D, V.E, and V.F). In this preamble at section VI, Risk Assessment, OSHA found that the available epidemiological data are sufficient to evaluate risk for beryllium sensitization, CBD, and lung cancer among beryllium-exposed workers. OSHA evaluated the risk of sensitization, CBD, and lung cancer from levels of airborne beryllium exposure that were allowed under the previous standard, as well as the expected impact of the new standards on risk of these conditions. In this section of the preamble, OSHA explains its determination that the risk of material impairments of health, particularly CBD and lung cancer, from occupational exposures allowable under the preceding TWA PEL of 2 μg/m³ is significant, and is substantially reduced but still significant at the new TWA PEL of 0.2 μg/m³. Furthermore, evidence reviewed in section VI, Risk Assessment, shows that significant risk of CBD and lung cancer could remain in workplaces with exposures as low as the new action level of 0.1 μg/m³. OSHA also explains here that the new standards will reduce the occurrence of sensitization.

In the NPRM, OSHA preliminarily determined that both CBD and lung cancer are material impairments of health. OSHA also preliminarily determined that a working lifetime (45 years) of exposure to airborne beryllium at the preceding time-weighted average permissible exposure limit (TWA PEL) of 2 μg/m³ would pose a significant risk of both CBD and lung cancer, and that this risk is substantially reduced but still significant at the new TWA PEL of 0.2 μg/m³. OSHA did not make a preliminary determination as to whether beryllium sensitization is a material impairment of health because, as the Agency explained in the NPRM, it was not necessary to make such a determination. The Agency's preliminary findings on CBD and lung cancer were sufficient to support the promulgation of new beryllium standards.

Upon consideration of the entire rulemaking record, including the comments and information submitted to the record in response to the preliminary Health Effects, Risk Assessment, and Significance of Risk analyses (NPRM Sections V, VI, and VIII), OSHA reaffirms its preliminary findings that long-term exposure at the preceding TWA PEL of 2 μg/m³ poses a significant risk of material impairment of workers' health, and that adoption of the new TWA PEL of 0.2 μg/m³ and other provisions of the final standards will substantially reduce this risk.

Material Impairment of Health

As discussed in Section V, Health Effects, CBD is a respiratory disease caused by exposure to beryllium. CBD develops when the body's immune system reacts to the presence of beryllium in the lung, causing a progression of pathological changes including chronic inflammation and tissue scarring. CBD can also impair other organs such as the liver, skin, spleen, and kidneys and cause adverse health effects such as granulomas of the skin and lymph nodes and cor pulmonale (*i.e.,* enlargement of the heart) (Conradi *et al.,* 1971 (Document ID 1319); ACCP, 1965 (1286); Kriebel *et al.,* 1988a (1292) and b (1473)).

In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. Over time, the granulomas can spread and lead to lung fibrosis (scarring) and

moderate to severe loss of pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000, Document ID 1421). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite, and unexplained weight loss may occur as the disease progresses (Conradi *et al.,* 1971, Document ID 1319; ACCP, 1965 (1286); Kriebel *et al.*, 1988 (1292); Kriebel *et al.,* 1988 (1473)).

Dr. Lee Newman, speaking at the public hearing on behalf of the American College of Occupational and Environmental Medicine (ACOEM), testified on his experiences treating patients with CBD: ''as a physician who has spent most of my [practicing] career seeing patients with exposure to beryllium, with beryllium sensitization, and with chronic beryllium disease including those who have gone on to require treatment and to die prematurely of this disease . . . [I've seen] hundreds and hundreds, probably over a thousand individuals during my career who have suffered from this condition'' (Document ID 1756, Tr. 79). Dr. Newman further testified about his 30 years of experience treating CBD in patients at various stages of the disease:

> . . . some of them will go from being sensitized to developing subclinical disease, meaning that they have no symptoms. As I mentioned earlier, most of those will, if we actually do the tests of their lung function and their oxygen levels in their blood, those people are already demonstrating physiologic abnormality. They already have disease affecting their health. They go on to develop symptomatic disease and progress to the point where they require treatment. And sometimes to the extent of even requiring a [lung] transplant (Document ID 1756, Tr. 131).

Dr. Newman described one example of a patient who developed CBD from his occupational beryllium exposure and ''who went on to die prematurely with a great deal of suffering along the way due to the condition chronic beryllium disease'' (Document ID 1756, Tr. 80).

During her testimony at the public hearing, Dr. Lisa Maier of National Jewish Health (NJH) provided an example from her experience with treating CBD patients. ''This gentleman started to have a cough, a dry cough in 2011 . . . His symptoms progressed and he developed shortness of breath, wheezing, chills, night sweats, and fatigue. These were so severe that he was eventually hospitalized'' (Document ID 1756, Tr. 105). Dr. Maier noted that this patient had no beryllium exposure prior to 2006, and that his CBD had developed from beryllium exposure in his job melting an aluminum alloy in a foundry casting airplane parts (Document ID 1756, Tr. 105–106). She described how her patient could no longer work because of his condition. ''He requires oxygen and systemic therapy . . . despite aggressive treatment [his] test findings continue to demonstrate worsening of his disease and increased needs for oxygen and medications as well as severe side effects from medications. This patient may well need a lung transplant if this disease continues to progress . . . '' (Document ID 1756, Tr. 106–107).

The likelihood, speed, and severity of individuals' transition from asymptomatic to symptomatic CBD is understood to vary widely, with some individuals responding differently to exposure cessation and treatment than others (Sood, 2009, Document ID 0456; Mroz *et al.,* 2009 (1443)). In the public hearing, Dr. Newman testified that the great majority of individuals with very early stage CBD in a cross-sectional study he published (Pappas and Newman, 1993) had physiologic impairment. Thus, even before x-rays or CAT scans found evidence of CBD, the lung functions of those individuals were abnormal (Document ID 1756, Tr. 112). Materion commented that the best available evidence on the transition from asymptomatic to more severe CBD is a recent longitudinal study by Mroz *et al.* (2009, Document ID 1443), which found that 19.3 percent of individuals with CBD developed clinical abnormalities requiring oral immunosuppressive therapy (Document ID 1661, pp. 5–6). The authors' overall conclusions in that study include a finding that adverse physiological changes among initially asymptomatic CBD patients progress over time, requiring many individuals to be treated with corticosteroids, and that the patients' levels of beryllium exposure may affect progression (Mroz *et al.,* 2009). Dr. Maier, a co-author of the study, testified that studies ''indicate that higher levels of exposure not only are risk factors for [developing CBD in general] but also for more severe [CBD] (Document ID 1756, Tr. 111).[24]

Treatment of CBD using inhaled and systemic steroid therapy has been shown to ease symptoms and slow or prevent some aspects of disease progression. As explained below, these treatments can be most effectively applied when CBD is diagnosed prior to development of symptoms. In addition, the forms of treatment that can be used to manage early-stage CBD have relatively minor side effects on patients, while systemic steroid treatments required to treat later-stage CBD often cause severe side effects.

In the public hearing, Dr. Newman and Dr. Maier testified about their experiences treating patients with CBD at various stages of the disease. Dr. Newman stated that patients' outcomes depend greatly on how early they are diagnosed. ''So there are those people who are diagnosed very late in the course of disease where there's little that we can do to intervene and they are going to die prematurely. There are those people who may be detected with milder disease where there are opportunities to intervene'' (Document ID 1756, Tr. 132). Both Dr. Maier and Dr. Newman emphasized the importance of early detection and diagnosis, stating that removing the patient from exposure and providing treatment early in the course of the disease can slow or even halt progression of the disease (Document ID 1756, Tr. 111, 132).

Dr. Maier testified that inhaled steroids can be used to treat relatively mild symptoms that may occur in early stages of the disease, such as a cough during exercise (Document ID 1756, Tr. 139). Inhaled steroids, she stated, are commonly used to treat other health conditions and have fewer and milder side effects than forms of steroid treatment that are used to treat more severe forms of CBD (Document ID 1756, Tr. 140). Early detection of CBD helps physicians to properly treat early-onset symptoms, since appropriate forms of treatment for early stage CBD can differ from treatments for conditions it is commonly mistaken for, such as chronic obstructive pulmonary disease

[24] The study by Mroz *et al.* (2009, Document ID 1443) included all individuals who were clinically evaluated at NJH between 1982 and 2002 and were found to have CBD on baseline clinical evaluation. All cohort members were identified by abnormal BeLPTs before identification of symptoms, physiologic abnormalities, or radiographic changes. All members were offered evaluation for clinical abnormalities every 2 years through 2002, including pulmonary function testing, exercise testing, chest radiograph with International Labor Organization (ILO) B-reading, fiberoptic bronchoscopy with bronchoalveolar lavage (BAL), and transbronchial lung biopsies. Of 171 CBD cases, 33 (19.3%) developed clinical abnormalities requiring oral immunosuppressive therapy, at an average of 1.4 years after the initial diagnosis of CBD. To examine the effect of beryllium exposure level on the progression of CBD, Mroz *et al.* compared clinical manifestations of CBD among machinists (the group of patients likely to have had the highest beryllium exposures) to non- machinists, including only CBD patients who had never smoked. Longitudinal analyses showed significant declines in some clinical indicators over time since first exposure for machinists ($p < 0.01$) as well as faster development of illness ($p < 0.05$), compared to a control group of non-machinists.

(COPD) and asthma (Document ID 1756, Tr. 140–141).

CBD in later stages is often managed using systemic steroid treatments such as corticosteroids. In workers with CBD whose beryllium exposure has ceased, corticosteroid therapy has been shown to control inflammation, ease symptoms (*e.g.,* difficulty breathing, fever, cough, and weight loss), and in some cases prevent the development of fibrosis (Marchand-Adam *et al.,* 2008, Document ID 0370). Thus, although there is no cure for CBD, properly-timed treatment can lead to CBD regression in some patients (Sood, 2004, Document ID 1331). Other patients have shown short-term improvements from corticosteroid treatment, but then developed serious fibrotic lesions (Marchand-Adam *et al.,* 2008). Ms. Peggy Mroz, of NJH, discussed the results of the Marchand-Adam *et al.* study in the hearing, stating that treatment of CBD using steroids has been most successful when treatment begins prior to the development of lung fibrosis (Document ID 1756, Tr. 113). Once fibrosis has developed in the lungs, corticosteroid treatment cannot reverse the damage (Sood, 2009, Document ID 0456). Persons with late-stage CBD experience severe respiratory insufficiency and may require supplemental oxygen (Rossman, 1991, Document 1332). Historically, late-stage CBD often ended in death (NAS, 2008, Document ID 1355). While the use of steroid treatments can help to reduce the effects of CBD, OSHA is not aware of any studies showing the effect of these treatments on the frequency of premature death among patients with CBD.

Treatment with corticosteroids has severe side effects (Trikudanathan and McMahon, 2008, Document ID 0366; Lipworth, 1999 (0371); Gibson *et al.,* 1996 (1521); Zaki *et al.,* 1987 (1374)). Adverse effects associated with long-term corticosteroid use include, but are not limited to: increased risk of opportunistic infections (Lionakis and Kontoyiannis, 2003, Document ID 0372; Trikudanathan and McMahon, 2008 (0366)); accelerated bone loss or osteoporosis leading to increased risk of fractures or breaks (Hamida *et al.,* 2011, Document ID 0374; Lehouck *et al.,* 2011 (0355); Silva *et al.,* 2011 (0388); Sweiss *et al.,* 2011 (0367); Langhammer *et al.,* 2009 (0373)); psychiatric effects including depression, sleep disturbances, and psychosis (Warrington and Bostwick, 2006, Document ID 0365; Brown, 2009 (0377)); adrenal suppression (Lipworth, 1999, Document ID 0371; Frauman, 1996 (0356)); ocular effects including cataracts, ocular hypertension, and glaucoma (Ballonzoli and Bourcier, 2010, Document ID 0391; Trikudanathan and McMahon, 2008 (0366); Lipworth, 1999 (0371)); an increase in glucose intolerance (Trikudanathan and McMahon, 2008, Document ID 0366); excessive weight gain (McDonough *et al.,* 2008, Document ID 0369; Torres and Nowson, 2007 (0387); Dallman *et al.,* 2007 (0357); Wolf, 2002 (0354); Cheskin *et al.,* 1999 (0358)); increased risk of atherosclerosis and other cardiovascular syndromes (Franchimont *et al.,* 2002, Document ID 0376); skin fragility (Lipworth, 1999, Document ID 0371); and poor wound healing (de Silva and Fellows, 2010, Document ID 0390).

Based on the above, OSHA considers late-stage CBD to be a material impairment of health, as it involves permanent damage to the pulmonary system, causes additional serious adverse health effects, can have adverse occupational and social consequences, requires treatment that can cause severe and lasting side effects, and may in some cases cause premature death.

Furthermore, OSHA has determined that early-stage CBD, an asymptomatic period during which small lesions and inflammation appear in the lungs, is also a material impairment of health. OSHA bases this conclusion on evidence and expert testimony that early-stage CBD is a measurable change in an individual's state of health that, with and sometimes without continued exposure, can progress to symptomatic disease (*e.g.,* Mroz *et al.,* 2009 (1443); 1756, Tr. 131). Thus, prevention of the earliest stages of CBD will prevent development of more serious disease. In OSHA's Lead standard, promulgated in 1978, the Agency stated its position that a ''subclinical'' health effect may be regarded as a material impairment of health. In the preamble to that standard, the Agency said:

> OSHA believes that while incapacitating illness and death represent one extreme of a spectrum of responses, other biological effects such as metabolic or physiological changes are precursors or sentinels of disease which should be prevented. . . . Rather than revealing the beginnings of illness the standard must be selected to prevent an earlier point of measurable change in the state of health which is the first significant indicator of possibly more severe ill health in the future. The basis for this decision is twofold—first, pathophysiologic changes are early stages in the disease process which would grow worse with continued exposure and which may include early effects which even at early stages are irreversible, and therefore represent material impairment themselves. Secondly, prevention of pathophysiologic changes will prevent the onset of the more serious, irreversible and debilitating manifestations of disease (43 FR 52952, 52954).

Since the Lead rulemaking, OSHA has also found other non-symptomatic (or sub-clinical) health conditions to be material impairments of health. In the Bloodborne Pathogens rulemaking, OSHA maintained that material impairment includes not only workers with clinically ''active'' hepatitis from the hepatitis B virus (HBV) but also includes asymptomatic HBV ''carriers'' who remain infectious and are able to put others at risk of serious disease through contact with body fluids (*e.g.,* blood, sexual contact) (56 FR 64004). OSHA stated: ''Becoming a carrier [of HBV] is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier's blood or certain other body fluids will be at risk of becoming infected'' (56 FR 64004, 64036).

OSHA finds that early-stage CBD is the type of asymptomatic health effect the Agency determined to be a material impairment of health in the Lead and Bloodborne Pathogens standards. Early stage CBD involves lung tissue inflammation without symptoms that can worsen with—or without—continued exposure. The lung pathology progresses over time from a chronic inflammatory response to tissue scarring and fibrosis accompanied by moderate to severe loss in pulmonary function. Early stage CBD is clearly a precursor of advanced clinical disease, prevention of which will prevent symptomatic disease. OSHA determined in the Lead standard that such precursor effects should be considered material health impairments in their own right, and that the Agency should act to prevent them when it is feasible to do so. Therefore, OSHA finds all stages of CBD to be material impairments of health within the meaning of section 6(b)(5) of the OSH Act (29 U.S.C. 655(b)(5)).

In reviewing OSHA's Lead standard in *United Steelworkers of America, AFL–CIO* v. *Marshall,* 647 F.2d 1189, 1252 (D.C. Cir. 1980) (*Lead I*), the D.C. Circuit affirmed that the OSH Act ''empowers OSHA to set a PEL that prevents the subclinical effects of lead that lie on a continuum shared with overt lead disease.'' *See also AFL–CIO* v. *Marshall,* 617 F.2d 636, 654 n.83 (D.C. Cir. 1979) (upholding OSHA's authority to prevent early symptoms of a disease, even if the effects of the disease are, at that point, reversible). According to the Court, OSHA only had to demonstrate,

on the basis of substantial evidence, that preventing the subclinical effects would help prevent the clinical phase of disease (*United Steelworkers of America, AFL–CIO,* 647 F.2d at 1252). Thus, OSHA has the authority to regulate to prevent asymptomatic CBD whether or not it is properly labeled as a material impairment of health.

OSHA has also determined that exposure to beryllium can cause beryllium sensitization. Sensitization is a precursor to development of CBD and an essential step for development of the disease. As discussed in Section V, Health Effects, only sensitized individuals can develop CBD (NAS, 2008, Document ID 1355).[25] As explained above, OSHA has the authority to promulgate regulations designed to prevent precursors to material impairments of health. Therefore, OSHA's new beryllium standards aim to prevent sensitization as well as the development of CBD and lung cancer. OSHA's risk assessment for sensitization, presented in section VI, informs the Agency's understanding of what exposure control measures have been successful in preventing sensitization, which in turn prevents development of CBD. Therefore, OSHA addresses sensitization in this section on significance of risk.

Risk Assessment

As discussed in Section VI, Risk Assessment, the risk assessment for beryllium sensitization and CBD relied on two approaches: (1) OSHA's review of epidemiological studies of sensitization and CBD that contain information on exposures in the range of interest to OSHA (2 μg/m³ and below), and (2) OSHA's analysis of a NJH data set on sensitization and CBD in a group of beryllium-exposed machinists in Cullman, AL.

OSHA's review of the literature includes studies of beryllium-exposed workers at a Tucson, AZ ceramics plant (Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Cummings *et al.,* 2007 (1369)); a Reading, PA copper-beryllium processing plant (Schuler *et al.,* 2005, Document ID 0919; Thomas *et al.,* 2009 (0590)); a Cullman, AL beryllium machining plant (Newman *et al.,* 2001, Document ID 1354; Kelleher *et al.,* 2001 (1363); Madl *et al.,* 2007 (1056)); an Elmore, OH metal, alloy, and oxide production plant (Kreiss *et al.,* 1993 Document ID 1478; Bailey *et al.,* 2010 (0676); Schuler *et al.,* 2012 (0473)); aluminum smelting facilities (Taiwo *et al.* 2008, Document ID 0621; 2010 (0583); Nilsen *et al.,* 2010 (0460)); and nuclear facilities (Viet *et al.,* 2000, Document ID 1344; Arjomandi *et al.,* 2010 (1275)).

The published literature on beryllium sensitization and CBD discussed in section VI shows that the risk of both can be significant in workplaces where exposures are at or below OSHA's preceding PEL of 2 μg/m³ (*e.g.,* Kreiss *et al.,* 1996, Document ID 1477; Henneberger *et al.,* 2001 (1313); Newman *et al.,* 2001 (1354); Schuler *et al.,* 2005 (0919), 2012 (0473); Madl *et al.,* 2007 (1056)). For example, in the Tucson ceramics plant mentioned above, Kreiss *et al.* (1996) reported that eight (5.9 percent) [26] of the 136 workers tested in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. In addition, of 77 Tucson workers hired prior to 1992 who were tested in 1998, eight (10.4 percent) were sensitized and seven of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.,* 2001, Document ID 1313). Full-shift area samples showed most airborne beryllium levels below the preceding PEL: 76 percent of area samples collected between 1983 and 1992 were at or below 0.1 μg/m³ and less than 1 percent exceeded 2 μg/m³; short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3 μg/m³; and personal lapel samples collected at the plant beginning in 1991 had a median of 0.2 μg/m³ (Kreiss *et al.,* 1996).

Results from the Elmore, OH beryllium metal, alloy, and oxide production plant and the Cullman, AL machining facility also showed significant risk of sensitization and CBD among workers with exposures below the preceding TWA PEL. Schuler *et al.* (2012, Document ID 0473) found 17 cases of sensitization (8.6 percent) among Elmore, OH workers within the first three quartiles of LTW average exposure (198 workers with LTW average total mass exposures lower than 1.1 μg/m³) and 4 cases of CBD (2.2 percent) within those quartiles of LTW average exposure (183 workers with LTW average total mass exposures lower than 1.07 μg/m³; note that follow-up time of up to 6 years for all study participants was very short for development of CBD). At the Cullman, AL machining facility, Newman *et al.* (2001, Document ID 1354) reported 22 (9.4 percent) sensitized workers among 235 tested in 1995–1999, 13 of whom were diagnosed with CBD within the study period. Personal lapel samples collected between 1980 and 1999 indicate that median exposures were generally well below the preceding PEL (≤0.35 μg/m³ in all job titles except maintenance (median 3.1 μg/m³ during 1980–1995) and gas bearings (1.05 μg/m³ during 1980–1995)).

Although risk will be reduced by compliance with the new TWA PEL, evidence in the epidemiological studies reviewed in section VI, Risk Assessment, shows that significant risk of sensitization and CBD could remain in workplaces with exposures as low as the new action level of 0.1 μg/m³. For example, Schuler *et al.* (2005, Document ID 0919) reported substantial prevalences of sensitization (6.5 percent) and CBD (3.9 percent) among 152 workers at the Reading, PA facility screened with the BeLPT in 2000. These results showed significant risk at this facility, even though airborne exposures were primarily below both the preceding and final TWA PELs due to the low percentage of beryllium in the metal alloys used (median general area samples ≤0.1 μg/m³, 97% < 0.5 μg/m³; 93% of personal lapel samples below the new TWA PEL of 0.2 μg/m³). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with exposures below the new action level of 0.1 μg/m³ (median personal sample 0.01 μg/m³, range <0.01–0.06 μg/m³) (Schuler *et al.,* 2005). The Schuler *et al.* (2012, Document ID 0473) study of short-term workers in the Elmore, OH facility found three cases (4.6%) of sensitization among 66 workers with total mass LTW average exposures below 0.1 μg/m³. All three of these sensitized workers had LTW average exposures of approximately 0.09 μg/m³.

Furthermore, cases of sensitization and CBD continued to arise in the Cullman, AL machining plant after control measures implemented beginning in 1995 brought median airborne exposures below 0.2 μg/m³ (personal lapel samples between 1996 and 1999 in machining jobs had a median of 0.16 μg/m³ and the median was 0.08 μg/m³ in non-machining jobs)

[25] In the NPRM, OSHA took no position on whether beryllium sensitization by itself is a material impairment of health, stating it was unnecessary to do so as part of this rulemaking. The only comment on this issue came from Materion, which argued that ''BeS does not constitute a material impairment of health or functional capacity'' (document ID 1958). Because BeS is also a precursor to CBD, OSHA finds it unnecessary to resolve this issue here.

[26] Although OSHA reports percentages to indicate the risks of sensitization and CBD in this section, the benchmark OSHA typically uses to demonstrate significant risk, as discussed earlier, is greater than or equal to 1 in 1,000 workers. One in 1,000 workers is equivalent to 0.1 percent. Therefore, any value of 0.1 percent or higher when reporting occurrence of a health effect is considered by OSHA to indicate a significant risk.

(Madl *et al.,* 2007, Document ID 1056, Table IV). At the time that Newman *et al.* (2001, Document ID 1354) reviewed the results of BeLPT screenings conducted in 1995–1999, a subset of 60 workers had been employed at the plant for less than a year and had therefore benefitted to some extent from the exposure reductions. Four (6.7 percent) of these workers were found to be sensitized, of whom two were diagnosed with CBD and one with probable CBD (Newman *et al.,* 2001). A later study by Madl. *et al.* (2007, Document ID 1056) reported seven sensitized workers who had been hired between 1995 and 1999, of whom four had developed CBD as of 2005 (Table II; total number of workers hired between 1995 and 1999 not reported).

The enhanced industrial hygiene programs that have proven effective in several facilities demonstrate the importance of minimizing both airborne exposure and dermal contact to effectively reduce risk of sensitization and CBD. Exposure control programs that have used a combination of engineering controls, PPE, and stringent housekeeping measures to reduce workers' airborne exposure and dermal contact have substantially lowered risk of sensitization among newly-hired workers.[27] Of 97 workers hired between 2000 and 2004 in the Tucson, AZ plant after the introduction of a comprehensive program which included the use of respiratory protection (1999) and latex gloves (2000), one case of sensitization was identified (1 percent) (Cummings *et al.,* 2007, Document ID 1369). In Elmore, OH, where all workers were required to wear respirators and skin PPE in production areas beginning in 2000–2001, the estimated prevalence of sensitization among workers hired after these measures were put in place was around 2 percent (Bailey *et al.,* 2010, Document ID 0676). In the Reading, PA facility, after workers' exposures were reduced to below 0.1 μg/m^3 and PPE to prevent dermal contact was instituted, only one (2.2 percent) of 45 workers hired was sensitized (Thomas *et al.* 2009, Document ID 0590). And, in the aluminum smelters discussed by Taiwo *et al.* (2008, Document ID 0621), where available exposure samples from four plants indicated median beryllium levels of about 0.1 μg/m^3 or below (measured as an 8-hour TWA) and workers used respiratory and dermal protection, confirmed cases of sensitization were rare (zero or one case per location).

OSHA notes that the studies on recent programs to reduce workers' risk of sensitization and CBD were conducted on populations with very short exposure and follow-up time. Therefore, they could not adequately address the question of how frequently workers who become sensitized in environments with extremely low airborne exposures (median <0.1 μg/m^3) develop CBD. Clinical evaluation for CBD was not reported for sensitized workers identified in the studies examining the post-2000 worker cohorts with very low exposures in Tucson, Reading, and Elmore (Cummings *et al.* 2007, Document ID 1369; Thomas *et al.* 2009, (0590); Bailey *et al.* 2010, (0676)). In Cullman, however, two of the workers with CBD had been employed for less than a year and worked in jobs with very low exposures (median 8-hour personal sample values of 0.03–0.09 μg/m^3) (Madl *et al.,* 2007, Document ID 1056, Table III). The body of scientific literature on occupational beryllium disease also includes case reports of workers with CBD who are known or believed to have experienced minimal beryllium exposure, such as a worker employed only in shipping at a copper-beryllium distribution center (Stanton *et al.,* 2006, Document ID 1070), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.,* 1996, Document ID 1477). Therefore, there is some evidence that cases of CBD can occur in work environments where beryllium exposures are quite low.

In summary, the epidemiological literature on beryllium sensitization and CBD that OSHA's risk assessment relied on show sufficient occurrence of sensitization and CBD to be considered significant within the meaning of the OSH Act. These demonstrated risks are far in excess of 1 in 1,000 among workers who had full-shift exposures well below the preceding TWA PEL of 2 μg/m^3 and workers who had median full-shift exposures down to the new action level of 0.1 μg/m^3. These health effects occurred among populations of workers whose follow-up time was much less than 45 years. As stated earlier, OSHA is interested in the risk associated with a 45-year (*i.e.,* working lifetime) exposure. Because CBD often develops over the course of years following sensitization, the risk of CBD that would result from 45 years of occupational exposure to airborne beryllium is likely to be higher than the prevalence of CBD observed among these workers.[28] In either case, based on these studies, the risks to workers from long-term exposure at the preceding TWA PEL and below are clearly significant. OSHA's review of epidemiological studies further showed that worker protection programs that effectively reduced the risk of beryllium sensitization and CBD incorporated engineering controls, work practice controls, and personal protective equipment (PPE) that reduce workers' airborne beryllium exposure and dermal contact with beryllium. OSHA has therefore determined that an effective worker protection program should incorporate both airborne exposure reduction and dermal protection provisions.

OSHA's conclusions on significance of risk at the final PEL and action level are further supported by its analysis of the data set provided to OSHA by NJH from which OSHA derived additional information on sensitization and CBD at exposure levels of interest. The data set describes a population of 319 beryllium-exposed workers at a Cullman, AL machining facility. It includes exposure samples collected between 1980 and 2005, and has updated work history and screening information through 2003. Seven (2.2 percent) workers in the data set were reported as sensitized only. Sixteen (5.0 percent) workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three (0.9 percent) workers, first shown to be sensitized only, were later diagnosed with CBD. The data set includes workers exposed at airborne beryllium levels near the new TWA PEL of 0.2 μg/m^3, and extensive exposure data collected in workers' breathing zones, as is preferred by OSHA. Unlike the Tucson, Reading, and Elmore facilities after 2000, respirator use was not generally required for workers at the Cullman facility. Thus, analysis of this data set shows the risk associated with varying levels of airborne exposure rather than estimating exposure accounting for respirators. Also unlike the Tucson, Elmore, and Reading facilities, glove use was not reported to be mandatory in the Cullman facility. Therefore, OSHA believes reductions in risk at the Cullman facility to be the result of airborne exposure control, rather than the combination of airborne and dermal exposure controls used at other facilities.

OSHA analyzed the prevalence of beryllium sensitization and CBD among

[27] As discussed in Section V, Health Effects, beryllium sensitization can occur from dermal contact with beryllium.

[28] This point was emphasized by members of the scientific peer review panel for OSHA's Preliminary Risk Assessment (see the NPRM preamble at section VII).

workers at the Cullman facility who were exposed to airborne beryllium levels at and below the preceding TWA PEL of 2 μg/m³. In addition, a statistical modeling analysis of the NJH Cullman data set was conducted under contract with Dr. Roslyn Stone of the University of Pittsburgh Graduate School of Public Heath, Department of Biostatistics. OSHA summarizes these analyses briefly below, and in more detail in section VI, Risk Assessment and in the background document (Risk Analysis of the NJH Data Set from the Beryllium Machining Facility in Cullman, Alabama—CBD and Sensitization, OSHA, 2016).

Tables VII–1 and VII–2 below present the prevalence of sensitization and CBD cases across several categories of lifetime-weighted (LTW) average and highest-exposed job (HEJ) exposure at the Cullman facility. The HEJ exposure is the exposure level associated with the highest-exposure job and time period experienced by each worker. The columns ''Total'' and ''Total percent'' refer to all sensitized workers in the data set, including workers with and without a diagnosis of CBD.

TABLE VII–1—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJH DATA SET

LTW average exposure (μg/m³)	Group size	Sensitized only	CBD	Total	Total (%)	CBD (%)
0.0–0.080	91	1	1	2	2.2	1.0
0.081–0.18	73	2	4	6	8.2	5.5
0.19–0.51	77	0	6	6	7.8	7.8
0.51–2.15	78	4	8	12	15.4	10.3
Total	319	7	19	26	8.2	6.0

Source: Section VI, Risk Assessment.

TABLE VII–2—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJH DATA SET

HEJ exposure (μg/m³)	Group size	Sensitized only	CBD	Total	Total (%)	CBD (%)
0.0–0.086	86	1	0	1	1.2	0.0
0.091–0.214	81	1	6	7	8.6	7.4
0.387–0.691	76	2	9	11	14.5	11.8
0.954–2.213	76	3	4	7	9.2	5.3
Total	319	7	19	26	8.2	6.0

Source: Section VI, Risk Assessment.

The preceding PEL of 2 μg/m³ is close to the upper bound of the highest quartile of LTW average (0.51–2.15 μg/m³) and HEJ (0.954–2.213 μg/m³) exposure levels. In the highest quartile of LTW average exposure, there were 12 cases of sensitization (15.4 percent), including eight (10.3 percent) diagnosed with CBD. Notably, the Cullman workers had been exposed to beryllium dust for considerably less than 45 years at the time of testing. A high prevalence of sensitization (9.2 percent) and CBD (5.3 percent) is seen in the top quartile of HEJ exposure as well, with even higher prevalences in the third quartile (0.387–0.691 μg/m³).[29]

The new TWA PEL of 0.2 μg/m³ is close to the upper bound of the second quartile of LTW average (0.81–0.18 μg/m³) and HEJ (0.091–0.214 μg/m³) exposure levels and to the lower bound of the third quartile of LTW average (0.19–0.50 μg/m³) exposures. The second quartile of LTW average exposure shows a high prevalence of beryllium-related health effects, with six workers sensitized (8.2 percent), of whom four (5.5 percent) were diagnosed with CBD. The second quartile of HEJ exposure also shows a high prevalence of beryllium-related health effects, with seven workers sensitized (8.6 percent), of whom six (7.4 percent) were diagnosed with CBD. Among six sensitized workers in the third quartile of LTW average exposures, all were diagnosed with CBD (7.8 percent). The prevalence of CBD among workers in these quartiles was approximately 5–8 percent, and overall sensitization (including workers with and without CBD) was about 8–9 percent. OSHA considers these rates to be evidence that the risks of developing sensitization and CBD are significant among workers exposed at and below the preceding TWA PEL, and even below the new TWA PEL. These risks are much higher than the benchmark for significant risk of 1 in 1,000. Much lower prevalences of sensitization and CBD were found among workers with exposure levels less than or equal to about 0.08 μg/m³, although these risks are still significant. Two sensitized workers (2.2 percent), including one case of CBD (1.0 percent), were found among workers with LTW average exposure levels less than or equal to 0.08 μg/m³. One case of sensitization (1.2 percent) and no cases of CBD were found among workers with HEJ exposures of at most 0.086 μg/m³. Strict control of airborne exposure to levels below 0.1 μg/m³ using engineering and work practice controls can, therefore, substantially reduce risk of sensitization and CBD. Although OSHA recognizes that maintaining exposure levels below 0.1 μg/m³ may not be feasible in some operations (see this preamble at section VIII, Summary of the Economic Analysis and Regulatory Flexibility Analysis), the Agency finds that workers in facilities that meet the action level of 0.1 μg/m³ will face lower risks of sensitization and CBD than workers in facilities that cannot meet the action level.

Table VII–3 below presents the prevalence of sensitization and CBD cases across cumulative exposure quartiles, based on the same Cullman data used to derive Tables 1 and 2. Cumulative exposure is the sum of a worker's exposure across the duration of his or her employment.

[29] This exposure-response pattern, wherein higher rates of response are seen in workers with lower exposures, is sometimes attributed to a ''healthy worker effect'' or to exposure misclassification, as discussed in this preamble at section VI, Risk Assessment.

TABLE VII–3—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJH DATA SET

Cumulative exposure (μg/m³-yrs)	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.147	81	2	2	4	4.9	2.5
0.148–1.467	79	0	2	2	2.5	2.5
1.468–7.008	79	3	8	11	13.9	8.0
7.009–61.86	80	2	7	9	11.3	8.8
Total	319	7	19	26	8.2	6.0

SOURCE: Section VI, Risk Assessment.

A 45-year working lifetime of occupational exposure at the preceding PEL would result in 90 μg/m³-years of exposure, a value far higher than the cumulative exposures of workers in this data set, who worked for periods of time less than 45 years and whose exposure levels were mostly well below the previous PEL. Workers with 45 years of exposure to the new TWA PEL of 0.2 μg/m³ would have a cumulative exposure (9 μg/m³-years) in the highest quartile for this worker population. As with the average and HEJ exposures, the greatest risk of sensitization and CBD appears at the higher exposure levels (<1.467 μg/m³-years). The third cumulative quartile, at which a sharp increase in sensitization and CBD appears, is bounded by 1.468 and 7.008 μg/m³-years. This is equivalent to 0.73–3.50 years of exposure at the preceding PEL of 2 μg/m³, or 7.34–35.04 years of exposure at the new TWA PEL of 0.2 μg/m³. Prevalence of both sensitization and CBD is substantially lower in the second cumulative quartile (0.148–1.467 μg/m³-years). This is equivalent to approximately 0.7 to 7 years at the new TWA PEL of 0.2 μg/m³, or 1.5 to 15 years at the action level of 0.1 μg/m³. Risks at all levels of cumulative exposure presented in Table 3 are significant. These findings support OSHA's determination that maintaining exposure levels below the new TWA PEL will help to protect workers against risk of beryllium sensitization and CBD. Moreover, while OSHA finds that significant risk remains at the PEL, OSHA's analysis shows that further reductions of risk will ensue if employers are able to reduce exposure to the action level or even below.

Lung Cancer

Lung cancer, a frequently fatal disease, is a well-recognized material impairment of health. OSHA has determined that beryllium causes lung cancer based on an extensive review of the scientific literature regarding beryllium and cancer. This review included an evaluation of the human epidemiological, animal cancer, and mechanistic studies described in section V, Health Effects. OSHA's conclusion that beryllium is carcinogenic is supported by the findings of expert public health and governmental organizations such as the International Agency for Research on Cancer (IARC), which has determined beryllium and its compounds to be carcinogenic to humans (Group 1 category) (IARC, 2012, Document ID 0650); the National Toxicology Program (NTP), which classifies beryllium and its compounds as known carcinogens (NTP, 2014, Document ID 0389); and the Environmental Protection Agency (EPA), which considers beryllium to be a probable human carcinogen (EPA, 1998, Document ID 0661).

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most of them did not characterize exposure levels sufficiently to evaluate the risk of lung cancer at the preceding and new TWA PELs. However, as discussed in this preamble at section V, Health Effects and section VI, Risk Assessment, Schubauer-Berigan *et al.* published a quantitative risk assessment based on beryllium exposure and lung cancer mortality among 5,436 male workers first employed at beryllium processing plants in Reading, PA, Elmore, OH, and Hazleton, PA, prior to 1970 (Schubauer-Berigan *et al.,* 2011, Document ID 1265). This risk assessment addresses important sources of uncertainty for previous lung cancer analyses, including the sole prior exposure-response analysis for beryllium and lung cancer, conducted by Sanderson *et al.* (2001) on workers from the Reading plant alone. Workers from the Elmore and Hazleton plants who were added to the analysis by Schubauer-Berigan *et al.* were, in general, exposed to lower levels of beryllium than those at the Reading plant. The median worker from Hazleton had a LTW average exposure of less than 1.5 μg/m³, while the median worker from Elmore had a LTW average exposure of less than 1 μg/m³. The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. Finally, the updated cohorts followed the worker populations through 2005, increasing the length of follow-up time compared to the previous exposure-response analysis. For these reasons, OSHA based the preliminary risk assessment for lung cancer on the Schubauer-Berigan risk analysis.

Schubauer-Berigan *et al.* (2011, Document ID 1265) analyzed the data set using a variety of exposure-response modeling approaches, described in this preamble at section VI, Risk Assessment. The authors found that lung cancer mortality risk was strongly and significantly correlated with mean, cumulative, and maximum measures of workers' exposure to beryllium (all of the models reported in the study). They selected the best-fitting models to generate risk estimates for male workers with a mean exposure of 0.5 μg/m³ (the current NIOSH Recommended Exposure Limit for beryllium). In addition, they estimated the daily weighted average exposure that would be associated with an excess lung cancer mortality risk of one in one thousand (.005 μg/m³ to .07 μg/m³ depending on model choice). At OSHA's request, the authors also estimated excess lifetime risks for workers with mean exposures at the preceding TWA PEL of 2 μg/m³ as well as at each of the alternate TWA PELs that were under consideration: 1 μg/m³, 0.2 μg/m³, and 0.1 μg/m³. Table VII–4 presents the estimated excess risk of lung cancer mortality associated with various levels of beryllium exposure, based on the final models presented in Schubauer-Berigan *et al's* risk assessment.[30]

[30] The estimates for lung cancer represent ''excess'' risks in the sense that they reflect the risk of dying from lung cancer over and above the risk of dying from lung cancer faced by those who are not occupationally exposed to beryllium.

TABLE VII–4—EXCESS RISK OF LUNG CANCER MORTALITY PER 1,000 MALE WORKERS AT ALTERNATE PELS (BASED ON SCHUBAUER-BERIGAN *et al.,* 2011)

Exposure-response model	Mean exposure				
	0.1 μg/m³	0.2 μg/m³	0.5 μg/m³	1 μg/m³	2 μg/m³
Best monotonic PWL-all workers	7.3	15	45	120	140
Best monotonic PWL—excluding professional and asbestos workers	3.1	6.4	17	39	61
Best categorical—all workers	4.4	9	25	59	170
Best categorical—excluding professional and asbestos workers	1.4	2.7	7.1	15	33
Power model—all workers	12	19	30	40	52
Power model—excluding professional and asbestos workers	19	30	49	68	90

Source: Schubauer-Berigan, Document ID 0521, pp. 6–10.

The lowest estimate of excess lung cancer deaths from the six final models presented by Schubauer-Berigan *et al.* is 33 per 1,000 workers exposed at a mean level of 2 μg/m³, the preceding TWA PEL. Risk estimates as high as 170 lung cancer deaths per 1,000 result from the other five models presented. Regardless of the model chosen, the excess risk of about 33 to 170 per 1,000 workers is clearly significant, falling well above the level of risk the Supreme Court indicated a reasonable person might consider acceptable (see *Benzene,* 448 U.S. at 655). The new PEL of 0.2 μg/m³ is expected to reduce these risks significantly, to somewhere between 2.7 and 30 excess lung cancer deaths per 1,000 workers. At the new action level of 0.1 μg/m³, risk falls within the range of 1.4 to 19 excess lung cancer deaths. These risk estimates still fall above the threshold of 1 in 1,000 that OSHA considers clearly significant. However, the Agency believes the lung cancer risks should be regarded as less certain than the risk estimates for CBD and sensitization discussed previously. While the risk estimates for CBD and sensitization at the preceding and new TWA PELs were determined from exposure levels observed in occupational studies, the lung cancer risks were extrapolated from much higher exposure levels.

Conclusions

As discussed throughout this section, OSHA used the best available scientific evidence to identify adverse health effects of occupational beryllium exposure, and to evaluate exposed workers' risk of these impairments. The Agency reviewed extensive epidemiological and experimental research pertaining to adverse health effects of occupational beryllium exposure, including lung cancer, CBD, and beryllium sensitization, and has evaluated the risk of these effects from exposures allowed under the preceding and new TWA PELs. The Agency has, additionally, reviewed the medical literature, as well as previous policy determinations and case law regarding material impairment of health, and has determined that CBD, at all stages, and lung cancer constitute material health impairments.

OSHA has determined that long-term exposure to beryllium at the preceding TWA PEL would pose a risk of CBD and lung cancer greater than the risk of 1 per 1,000 exposed workers the Agency considers clearly significant, and that adoption of the new TWA PEL, action level, and dermal protection requirements of the final standards will substantially reduce this risk. OSHA believes substantial evidence supports its determinations, including its choices of the best available published studies on which to base its risk assessment, its examination of the prevalence of sensitization and CBD among workers with exposure levels comparable to the preceding TWA PEL and new TWA PEL in the NJH data set, and its selection of the Schubauer-Berigan QRA to form the basis for its lung cancer risk estimates. The previously-described analyses demonstrate that workers with occupational exposure to airborne beryllium at the preceding PEL face risks of developing CBD and dying from lung cancer that far exceed the value of 1 in 1,000 used by OSHA as a benchmark of clearly significant risk. Furthermore, OSHA's risk assessment indicates that risk of CBD and lung cancer can be significantly reduced by reduction of airborne exposure levels, and that dermal protection measures will additionally help reduce risk of sensitization and, therefore, of CBD.

OSHA's risk assessment also indicates that, despite the reduction in risk expected with the new PEL, the risks of CBD and lung cancer to workers with average exposure levels of 0.2 μg/m³ are still significant and could extend down to 0.1 μg/m³, although there is greater uncertainty in this finding for 0.1 μg/m³ since there is less information available on populations exposed at and below this level. Although significant risk remains at the new TWA PEL, OSHA is also required to consider the technological and economic feasibility of the standard in determining exposure limits. As explained in Section VIII, Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis, OSHA determined that the new TWA PEL of 0.2 μg/m³ is both technologically and economically feasible in the general industry, construction, and shipyard sectors. OSHA was unable to demonstrate, however, that a lower TWA PEL of 0.1 μg/m³ would be technologically feasible. Therefore, OSHA concludes that, in setting a TWA PEL of 0.2 μg/m³, the Agency is reducing the risk to the extent feasible, as required by the OSH Act (see section II, Pertinent Legal Authority). In this context, the Agency finds that the action level of 0.1 μg/m³, dermal protection requirements, and other ancillary provisions of the final rule are critically important in reducing the risk of sensitization, CBD, and lung cancer among workers exposed to beryllium. Together, these provisions, along with the new TWA PEL of 0.2 μg/m³, will substantially reduce workers' risk of material impairment of health from occupational beryllium exposure.

VIII. Summary of the Final Economic Analysis and Final Regulatory Flexibility Analysis

A. Introduction

OSHA's Final Economic Analysis and Final Regulatory Flexibility Analysis (FEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this final beryllium rule and evaluates regulatory alternatives to the final rule. Executive Orders 13563 and

12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full FEA has been placed in OSHA rulemaking docket OSHA–H005C–2006–0870. This rule is an economically significant regulatory action under Sec. 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order.

The purpose of the FEA is to:

- Identify the establishments and industries potentially affected by the final rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the final rule in terms of reductions in cases of lung cancer, chronic beryllium disease;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the final rule;
- Assess the economic feasibility of the final rule for affected industries; and
- Assess the impact of the final rule on small entities through a Final Regulatory Flexibility Analysis (FRFA), to include an evaluation of significant regulatory alternatives to the final rule that OSHA has considered.

Significant Changes to the FEA Between the Proposed Standards and the Final Standards

OSHA made changes to the Preliminary Economic Analysis (PEA) for several reasons:

- Changes to the rule, summarized in Section I of the preamble and discussed in detail in the Summary and Explanation;
- Comments on the PEA;
- Updates of economic data; and
- Recognition of errors in the PEA.

OSHA revised its technological and economic analysis in response to these changes and to comments received on the NPRM. The FEA contains some costs that were not included in the PEA and updates data to use more recent data sources and, in some cases, revised methodologies. Detailed discussions of these changes are included in the relevant sections throughout the FEA.

The Final Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Market Failure and the Need for Regulation
Chapter III. Profile of Affected Industries
Chapter IV. Technological Feasibility
Chapter V. Costs of Compliance
Chapter VI. Economic Feasibility Analysis and Regulatory Flexibility Determination
Chapter VII. Benefits and Net Benefits
Chapter VIII. Regulatory Alternatives
Chapter IX. Final Regulatory Flexibility Analysis

Table VIII–1 provides a summary of OSHA's best estimate of the costs and benefits of the final rule using a discount rate of 3 percent. As shown, the final rule is estimated to prevent 90 fatalities and 46 beryllium-related illnesses annually once it is fully effective, and the estimated cost of the rule is $74 million annually. Also as shown in Table VIII–1, the discounted monetized benefits of the final rule are estimated to be $561 million annually, and the final rule is estimated to generate net benefits of $487 million annually. Table VIII–1 also presents the estimated costs and benefits of the final rule using a discount rate of 7 percent.

TABLE VIII–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S FINAL BERYLLIUM STANDARD

[3 Percent Discount Rate, 2015 dollars]

Annualized Costs:	
Control Costs	$12,269,190
Rule Familiarization	180,158
Exposure Assessment	13,748,676
Regulated Areas	884,106
Beryllium Work Areas	129,648
Medical Surveillance	7,390,958
Medical Removal	1,151,058
Written Exposure Control Plan	2,339,058
Protective Work Clothing & Equipment	1,985,782
Hygiene Areas and Practices	2,420,584
Housekeeping	22,763,595
Training	8,284,531
Respirators	320,885
Total Annualized Costs (Point Estimate)	73,868,230
Annual Benefits: Number of Cases Prevented:	
Fatal Lung Cancers (Midpoint Estimate)	4
Fatal Chronic Beryllium Disease	86
Beryllium-Related Mortality	90
Beryllium Morbidity	46
Monetized Annual Benefits (Midpoint Estimate)	$560,873,424
Net Benefits:	
Net Benefits	$487,005,194

Sources: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

The remainder of this section (Section VIII) of the preamble is organized as follows:

B. Market Failure and the Need for Regulation
C. Profile of Affected Industries
D. Technological Feasibility
E. Costs of Compliance
F. Economic Feasibility Analysis and Regulatory Flexibility Determination
G. Benefits and Net Benefits
H. Regulatory Alternatives
I. Final Regulatory Flexibility Analysis.

B. Market Failure and the Need for Regulation

Employees in work environments addressed by the final beryllium rule are exposed to a variety of significant hazards that can and do cause serious injury and death. As described in Chapter II of the FEA in support of the final rule, OSHA concludes there is a demonstrable failure of private markets to protect workers from exposure to unnecessarily high levels beryllium and that private markets, as well as information dissemination programs, workers' compensation systems, and tort liability options, each may fail to protect workers from beryllium exposure, resulting in the need for a more protective OSHA beryllium rule.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA concludes that, in the case of beryllium exposure, the final mandatory standards represent the best choice for reducing the risks to employees.

C. Profile of Affected Industries

Chapter III of the FEA presents profile data for industries potentially affected by the final beryllium rule. This Chapter provides the background data used throughout the remainder of the FEA including estimates of what industries are affected, and their economic and beryllium exposure characteristics. OSHA identified the following application groups as affected by the standard:

- Beryllium Production
- Beryllium Oxide Ceramics and Composites
- Nonferrous Foundries
- Secondary Smelting, Refining, and Alloying
- Precision Turned Products
- Copper Rolling, Drawing, and Extruding
- Fabrication of Beryllium Alloy Products
- Welding
- Dental Laboratories
- Aluminum Production
- Coal-Fired Electric Power Generation

- Abrasive Blasting

Table VIII–3 shows the affected industries by application group and selected economic characteristics of these affected industries. Table VIII–4 provides industry-by-industry estimates of current exposure.

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Beryllium Production											
Beryllium Production	331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	163	186	10,773	1	1	616	$15,853,340	$97,259,754	$85,233,010
Beryllium Oxide Ceramics and Composites											
Be Oxide - Primary	327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	636	655	13,096	2	2	83	$2,224,322	$3,497,362	$3,395,911
Be Oxide - Secondary	334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	748	830	66,833	9	10	120	$29,075,882	$38,871,500	$35,031,183
Be Oxide - Secondary	334310	Audio and Video Equipment Manufacturing	459	463	8,767	5	5	60	$2,944,276	$6,414,545	$6,359,128
Be Oxide - Secondary	334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	376	418	19,796	11	12	144	$3,829,332	$10,184,393	$9,161,081

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Be Oxide - Secondary	334419	Other Electronic Component Manufacturing	1,162	1,259	54,693	28	30	360	$11,749,377	$10,111,340	$9,332,309
Be Oxide - Secondary	334510	Electrometrical and Electrotherapeutic Apparatus Manufacturing	674	749	64,271	8	9	108	$29,145,680	$43,242,849	$38,912,791
Be Oxide - Secondary	327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	636	655	13,096	14	14	168	$2,224,322	$3,497,362	$3,395,911
Be Oxide - Secondary	336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	9	10	120	$21,336,550	$34,525,161	$31,469,837
Nonferrous Foundries											
Non Sand Foundries	331523	Nonferrous Metal Die-Casting Foundries	396	434	31,010	45	50	822	$8,177,926	$20,651,328	$18,843,147
Non Sand Foundries	331524	Aluminum Foundries (except Die-Casting)	383	406	15,446	7	7	120	$2,953,370	$7,711,149	$7,274,311

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Non Sand Foundries	331529a	Other Nonferrous Metal Foundries (except Die-Casting)	293	300	9,522	18	18	304	$2,517,475	$8,592,063	$8,391,582
Sand Foundries	331529b	Other Nonferrous Metal Foundries (except Die-Casting)	293	300	9,522	22	23	430	$2,517,475	$8,592,063	$8,391,582
Secondary Smelting, Refining, and Alloying											
Smelting - Be Alloys	331314	Secondary Smelting and Alloying of Aluminum	92	114	5,415	1	1	9	$5,866,913	$63,770,798	$51,464,153
Smelting - Be Alloys	331420b	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	3	4	36	$24,370,147	$136,146,071	$97,872,075
Smelting - Precious metals	331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	228	261	10,913	26	30	270	$15,183,933	$66,596,198	$58,175,989

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Precision Machining											
Machining (high)	332721a	Precision turned product manufacturing (high beryllium content)	3,601	3,688	103,546	21	22	289	$18,818,245	$5,225,839	$5,102,561
Machining (low)	332721b	Precision turned product manufacturing (low beryllium content)	3,601	3,688	103,546	339	347	4,607	$18,818,245	$5,225,839	$5,102,561
Copper Rolling, Drawing and Extruding											
Rolling	331420a	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	8	11	1,086	$24,370,147	$136,146,071	$97,872,075
Drawing	331420c	Copper Rolling, Drawing, Extruding, and Alloying	179	249	21,408	32	45	3,597	$24,370,147	$136,146,071	$97,872,075
Stamping, Spring, and Connector Manufacturing											
Springs	332613	Spring Manufacturing	334	392	14,829	252	296	2,166	$3,751,288	$11,231,400	$9,569,611

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Stamping	332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,417	1,499	53,018	68	72	508	$12,329,183	$8,700,906	$8,224,939
Stamping	334417	Electronic Connector Manufacturing	195	234	21,132	39	47	328	$5,940,257	$30,462,858	$25,385,715
Stamping	336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	135	148	1,037	$21,336,550	$34,525,161	$31,469,837
Dental Laboratories											
Dental Labs – Substituting *	339116a	Dental Laboratories	4,900	5,114	33,073	1,225	1,278	5,954	$3,604,997	$735,751	$704,996
Dental Labs – Substituting *	621210a	Offices of Dentists	93,863	99,830	654,879	172	183	851	$81,961,314	$873,199	$821,007
Dental Labs – Non-Substituting **	339116b	Dental Laboratories	1,633	1,705	11,024	408	426	1,985	$1,201,666	$735,751	$704,996

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Dental Labs – Non-Substituting **	621210b	Offices of Dentists	31,288	33,277	218,293	57	61	284	$27,320,438	$873,199	$821,007
Arc and Gas Welding											
Welding GI	331110a	Iron and Steel Mills and Ferroalloy Manufacturing	414	562	105,309	5	6	24	$118,135,862	$285,352,323	$210,206,160
Welding GI	331221	Rolled Steel Shape Manufacturing	150	167	7,836	1	2	6	$6,250,961	$41,673,076	$37,430,907
Welding GI	331513	Steel Foundries (except Investment)	194	208	18,236	1	1	5	$4,733,402	$24,398,978	$22,756,739
Welding GI	332117	Powder Metallurgy Part Manufacturing	121	133	8,160	1	1	3	$2,111,591	$17,451,166	$15,876,625
Welding GI	332216	Saw Blade and Handtool Manufacturing	935	1,012	27,852	3	3	13	$7,043,067	$7,532,692	$6,959,553
Welding GI	332312	Fabricated Structural Metal Manufacturing	2,823	3,099	87,722	49	54	216	$27,839,554	$9,861,691	$8,983,399
Welding GI	332313	Plate Work Manufacturing	1,211	1,245	34,225	21	22	87	$7,461,246	$6,161,227	$5,992,968

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	332322	Sheet Metal Work Manufacturing	3,830	4,099	98,201	67	71	286	$20,892,732	$5,455,021	$5,097,031
Welding GI	332323	Ornamental and Architectural Metal Work Manufacturing	2,175	2,214	29,694	38	39	154	$6,058,633	$2,785,578	$2,736,510
Welding GI	332439	Other Metal Container Manufacturing	298	346	11,749	5	6	24	$3,885,743	$13,039,407	$11,230,472
Welding GI	332919	Other Metal Valve and Pipe Fitting Manufacturing	224	243	14,260	3	3	12	$5,062,721	$22,601,434	$20,834,244
Welding GI	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,483	3,553	70,118	38	38	153	$15,415,053	$4,425,798	$4,338,602
Welding GI	333111a	Farm Machinery and Equipment Manufacturing	1,048	1,124	65,302	19	20	82	$42,075,186	$40,148,079	$37,433,440
Welding GI	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	441	472	17,959	4	4	18	$5,535,698	$12,552,603	$11,728,174

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	333911	Pump and Pumping Equipment Manufacturing	441	539	33,772	6	7	27	$15,903,209	$36,061,699	$29,505,027
Welding GI	333922	Conveyor and Conveying Equipment Manufacturing	751	799	31,725	10	10	41	$8,945,712	$11,911,734	$11,196,135
Welding GI	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	340	360	22,389	4	5	18	$11,772,772	$34,625,801	$32,702,145
Welding GI	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,590	1,654	51,495	20	21	84	$15,726,526	$9,890,897	$9,508,178
Welding GI	336211	Motor Vehicle Body Manufacturing	656	741	40,544	13	15	60	$11,773,922	$17,948,052	$15,889,234
Welding GI	336214	Travel Trailer and Camper Manufacturing	571	663	39,267	12	13	54	$10,544,247	$18,466,282	$15,903,842
Welding GI	336390a	Other Motor Vehicle Parts Manufacturing	1,302	1,508	122,041	5	6	25	$60,628,177	$46,565,420	$40,204,361

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Welding GI	336510a	Railroad Rolling Stock Manufacturing	164	234	29,173	2	3	13	$17,944,334	$109,416,671	$76,685,188
Welding GI	336999	All Other Transportation Equipment Manufacturing	387	397	13,327	3	3	12	$7,731,109	$19,977,027	$19,473,827
Welding GI	337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,042	1,097	33,437	2	2	10	$6,809,534	$6,535,062	$6,207,415
Welding GI	811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	19,661	21,347	193,427	136	147	589	$34,529,038	$1,756,220	$1,617,512
Resistance Welding											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	414	491	24,138	17	20	428	$6,278,849	$15,166,303	$12,787,881
Resistance Welding	333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	729	878	84,823	29	35	766	$31,852,834	$43,693,874	$36,278,855
Resistance Welding	335210	Small Electrical Appliance Manufacturing	119	127	8,216	6	6	138	$3,560,517	$29,920,308	$28,035,564
Resistance Welding	335221	Household Cooking Appliance Manufacturing	95	98	10,408	5	5	107	$4,674,297	$49,203,131	$47,696,913

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	335222	Household Refrigerator and Home Freezer Manufacturing	23	30	9,374	1	2	33	$3,686,247	$160,271,594	$122,874,888
Resistance Welding	335224	Household Laundry Equipment Manufacturing	8	9	1,994	0	0	10	$951,577	$118,947,187	$105,730,833
Resistance Welding	335228	Other Major Household Appliance Manufacturing	30	36	9,059	2	2	39	$4,710,323	$157,010,751	$130,842,293
Resistance Welding	336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	788	849	52,752	39	42	925	$33,235,797	$42,177,407	$39,146,993
Resistance Welding	336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	618	678	50,017	31	34	739	$21,336,550	$34,525,161	$31,469,837
Resistance Welding	336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	210	245	28,663	11	12	267	$12,290,261	$58,525,051	$50,164,329

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Resistance Welding	336340	Motor Vehicle Brake System Manufacturing	156	195	21,859	8	10	213	$10,467,412	$67,098,794	$53,679,036
Resistance Welding	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	424	503	58,248	21	25	548	$35,792,318	$84,415,844	$71,157,690
Resistance Welding	336360	Motor Vehicle Seating and Interior Trim Manufacturing	302	398	47,010	15	20	434	$23,631,348	$78,249,498	$59,375,247
Resistance Welding	336370	Motor Vehicle Metal Stamping	645	773	81,018	32	39	843	$32,802,040	$50,855,876	$42,434,722
Resistance Welding	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	441	472	17,959	18	19	412	$5,535,698	$12,552,603	$11,728,174
Resistance Welding	336390b	Other Motor Vehicle Parts Manufacturing	1,302	1,508	122,041	65	75	1,644	$60,628,177	$46,565,420	$40,204,361
Aluminum Production											
Aluminum Production	331313	Alumina Refining and Primary Aluminum Production	3	8	5,433	2	6	859	$370,719	$123,573,107	$46,339,915
Coal Fired Utilities											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Coal Fired Utilities	221112	Fossil Fuel Electric Power Generation	456	2,716	142,164	70	418	10,534	$167,481,521	$367,284,037	$61,664,772
Coal Fired Utilities	311221	Wet Corn Milling	31	63	6,687	6	12	338	$12,894,946	$415,965,994	$204,681,680
Coal Fired Utilities	311313	Beet Sugar Manufacturing	15	31	5,790	7	14	395	$4,822,174	$321,478,252	$155,553,993
Coal Fired Utilities	311942	Spice and Extract Manufacturing	344	383	17,101	2	2	56	$9,644,849	$28,037,353	$25,182,374
Coal Fired Utilities	312120	Breweries	843	880	27,740	2	2	56	$29,912,097	$35,482,914	$33,991,019
Coal Fired Utilities	321219	Reconstituted Wood Product Manufacturing	149	219	13,423	1	1	28	$6,708,744	$45,025,125	$30,633,533
Coal Fired Utilities	322110	Pulp Mills	33	42	8,678	1	1	28	$6,842,997	$207,363,540	$162,928,496
Coal Fired Utilities	322121	Paper (except Newsprint) Mills	125	209	60,053	7	11	310	$45,144,793	$361,158,345	$216,003,795
Coal Fired Utilities	322122	Newsprint Mills	17	20	4,398	20	24	677	$3,218,103	$189,300,167	$160,905,142
Coal Fired Utilities	322130	Paperboard Mills	82	177	35,545	7	16	451	$29,706,665	$362,276,407	$167,834,268
Coal Fired Utilities	325211	Plastics Material and Resin Manufacturing	899	1,161	69,352	3	4	113	$97,687,597	$108,662,511	$84,140,910

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish-ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Coal Fired Utilities	325611	Soap and Other Detergent Manufacturing	615	664	23,229	1	1	28	$28,371,519	$46,132,552	$42,728,192
Coal Fired Utilities	327310	Cement Manufacturing	122	240	12,617	1	2	56	$6,246,422	$51,200,178	$26,026,757
Coal Fired Utilities	333111b	Farm Machinery and Equipment Manufacturing	1,048	1,124	65,302	1	1	28	$42,075,186	$40,148,079	$37,433,440
Coal Fired Utilities	336510b	Railroad Rolling Stock Manufacturing	164	234	29,173	1	1	28	$17,944,334	$109,416,671	$76,685,188
Coal Fired Utilities	611310	Colleges, Universities, and Professional Schools	2,282	4,329	1,805,199	5	9	254	$232,517,218	$101,891,857	$53,711,531
Abrasive Blasting - Construction											
Abrasive Blasting - Construction	238320	Painting and Wall Covering Contractors	31,317	31,376	163,073	1,088	1,090	4,360	$19,595,278	$625,707	$624,531
Abrasive Blasting - Construction	238990	All Other Specialty Trade Contractors	28,734	29,072	193,631	998	1,010	4,040	$39,396,242	$1,371,067	$1,355,127
Abrasive Blasting Shipyards***											

Table VIII-2: Characteristics of Industries Affected by OSHA's Final Standard for Beryllium—All Entities (continued)

Application Group	NAICS	Industry	Total Entities [a]	Total Establish-ments [a]	Total Employees [a]	Affected Entities [b]	Affected Establish -ments [b]	Affected Employees [b]	Total Revenues ($1,000) [a]	Revenues/ Entity	Revenues/ Establishment
Abrasive Blasting - Shipyards	336611a	Ship Building and Repairing	604	689	108,311	604	689	3,825	$26,136,187	$43,271,832	$37,933,508
Welding in Shipyards****											
Welding in Shipyards	336611b	Ship Building and Repairing	604	689	108,311	6	7	26	$26,136,187	$43,271,832	$37,933,508
Total											
General Industry Subtotal			206,928	226,165	5,877,434	3,869	4,538	50,261	$1,931,626,954	$9,334,778	$8,540,786
Construction Subtotal			60,051	60,448	356,704	2,086	2,100	8,400	$58,991,519	$982,357	$975,905
Maritime Subtotal			1,208	1,378	216,622	610	696	3,086	$52,272,373	$43,271,832	$37,933,508
Total, All Industries			268,187	287,991	6,450,760	6,565	7,333	61,747	$2,042,890,847	$7,617,412	$7,093,593

[a] US Census Bureau, Statistics of US Businesses: 2012.

[b] OSHA estimates of employees potentially exposed to beryllium and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees. Within each NAICS industry, the number of affected entities was calculated as the product of total number of entities for that industry and the ratio of the number of affected establishments to the number of total establishments.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

*** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
Beryllium Oxide - Primary										
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	9	9	15	6	32	7	3	2	83
Beryllium Oxide - Secondary										
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	41	41	16	2	11	5	2	1	120
334310	Audio and Video Equipment Manufacturing	21	21	8	1	6	3	1	1	60
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	50	50	19	3	13	7	2	1	144
334419	Other Electronic Component Manufacturing	124	124	47	7	34	16	5	4	360
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	37	37	14	2	10	5	1	1	108

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	58	58	22	3	16	8	2	2	168
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	41	41	16	2	11	5	2	1	120
Beryllium Production										
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	183	183	85	12	62	39	25	28	616
Dental Labs Substituting*										
339116a	Dental Laboratories	216	216	1,726	173	863	1,381	345	1,035	5,954
621210a	Offices of Dentists	31	31	247	25	123	197	49	148	851
Dental Labs – Non-Substituting**										
339116a	Dental Laboratories	992	992	0	0	0	0	0	0	1,985
621210a	Offices of Dentists	142	142	0	0	0	0	0	0	284
Drawing										
331420c	Copper Rolling, Drawing, Extruding, and Alloying	1,447	1,447	327	40	201	41	41	52	3,597
Machining - High										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
332721a	Precision Turned Product Manufacturing	20	20	34	21	106	44	20	24	289
Machining - Low										
332721b	Precision Turned Product Manufacturing	1,699	1,699	518	58	288	115	58	173	4,607
Non Sand Foundries										
331523	Nonferrous Metal Die-Casting Foundries	17	17	183	45	224	159	49	128	822
331524	Aluminum Foundries (except Die-Casting)	2	2	27	7	33	23	7	19	120
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	6	6	68	17	83	59	18	47	304
Rolling										
331420a	Copper Rolling, Drawing, Extruding, and Alloying	512	512	42	3	14	4	0	0	1,086
Sand Foundries										
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	8	8	85	21	104	74	72	59	430
Smelting - Beryllium Alloys										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
331314	Secondary Smelting and Alloying of Aluminum	0	0	2	0	0	0	2	5	9
331420b	Copper Rolling, Drawing, Extruding, and Alloying	2	2	9	0	0	0	6	18	36
Smelting - Precious Metals										
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	60	60	60	15	75	0	0	0	270
Springs										
332613	Spring Manufacturing	986	986	117	13	64	0	0	0	2,166
Stamping										
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	224	224	13	8	39	0	0	0	508
334417	Electronic Connector Manufacturing	145	145	9	5	25	0	0	0	328
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	457	457	27	16	79	0	0	0	1,037

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
Welding - Arc and Gas										
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	7	7	3	1	3	3	0	1	24
331221	Rolled Steel Shape Manufacturing	2	2	1	0	1	1	0	0	6
331513	Steel Foundries (except Investment)	1	1	1	0	1	1	0	0	5
332117	Powder Metallurgy Part Manufacturing	1	1	0	0	0	0	0	0	3
332216	Saw Blade and Handtool Manufacturing	4	4	2	0	2	1	0	0	13
332312	Fabricated Structural Metal Manufacturing	61	61	29	6	29	23	0	6	216
332313	Plate Work Manufacturing	25	25	12	2	12	9	0	2	87
332322	Sheet Metal Work Manufacturing	81	81	39	8	39	31	0	8	286
332323	Ornamental and Architectural Metal Work Manufacturing	44	44	21	4	21	17	0	4	154
332439	Other Metal Container Manufacturing	7	7	3	1	3	3	0	1	24

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
332919	Other Metal Valve and Pipe Fitting Manufacturing	3	3	2	0	2	1	0	0	12
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	44	44	21	4	21	17	0	4	153
333111a	Farm Machinery and Equipment Manufacturing	23	23	11	2	11	9	0	2	82
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	5	5	2	0	2	2	0	0	18
333911	Pump and Pumping Equipment Manufacturing	8	8	4	1	4	3	0	1	27
333922	Conveyor and Conveying Equipment Manufacturing	12	12	5	1	5	4	0	1	41
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	5	5	2	0	2	2	0	0	18

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	24	24	11	2	11	9	0	2	84
336211	Motor Vehicle Body Manufacturing	17	17	8	2	8	7	0	2	60
336214	Travel Trailer and Camper Manufacturing	15	15	7	1	7	6	0	1	54
336390a	Other Motor Vehicle Parts Manufacturing	7	7	3	1	3	3	0	1	25
336510a	Railroad Rolling Stock Manufacturing	4	4	2	0	2	1	0	0	13
336999	All Other Transportation Equipment Manufacturing	3	3	2	0	2	1	0	0	12
337215	Showcase, Partition, Shelving, and Locker Manufacturing	3	3	1	0	1	1	0	0	10

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	167	167	80	16	80	64	0	16	589
Welding - Resistance Welding										
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	214	214	0	0	0	0	0	0	428
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	383	383	0	0	0	0	0	0	766
335210	Small Electrical Appliance Manufacturing	69	69	0	0	0	0	0	0	138
335221	Household Cooking Appliance Manufacturing	53	53	0	0	0	0	0	0	107

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
335222	Household Refrigerator and Home Freezer Manufacturing	16	16	0	0	0	0	0	0	33
335224	Household Laundry Equipment Manufacturing	5	5	0	0	0	0	0	0	10
335228	Other Major Household Appliance Manufacturing	20	20	0	0	0	0	0	0	39
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	463	463	0	0	0	0	0	0	925
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	370	370	0	0	0	0	0	0	739
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	134	134	0	0	0	0	0	0	267
336340	Motor Vehicle Brake System Manufacturing	106	106	0	0	0	0	0	0	213

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	274	274	0	0	0	0	0	0	548
336360	Motor Vehicle Seating and Interior Trim Manufacturing	217	217	0	0	0	0	0	0	434
336370	Motor Vehicle Metal Stamping	421	421	0	0	0	0	0	0	843
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	206	206	0	0	0	0	0	0	412
336390b	Other Motor Vehicle Parts Manufacturing	822	822	0	0	0	0	0	0	1,644
Aluminum Production										
331313	Alumina Refining and Primary Aluminum Production	322	322	77	9	43	34	34	17	859
Coal Fired Utilities										
221112	Fossil Fuel Electric Power Generation w/o Objective Data	3,950	3,950	2,633	0	0	0	0	0	10,534
311221	Wet Corn Milling	127	127	85	0	0	0	0	0	338
311313	Beet Sugar Manufacturing	148	148	99	0	0	0	0	0	395

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
311942	Spice and Extract Manufacturing	21	21	14	0	0	0	0	0	56
312120	Breweries	21	21	14	0	0	0	0	0	56
321219	Reconstituted Wood Product Manufacturing	11	11	7	0	0	0	0	0	28
322110	Pulp Mills	11	11	7	0	0	0	0	0	28
322121	Paper (except Newsprint) Mills	116	116	78	0	0	0	0	0	310
322122	Newsprint Mills	254	254	169	0	0	0	0	0	677
322130	Paperboard Mills	169	169	113	0	0	0	0	0	451
325211	Plastics Material and Resin Manufacturing	42	42	28	0	0	0	0	0	113
325611	Soap and Other Detergent Manufacturing	11	11	7	0	0	0	0	0	28
327310	Cement Manufacturing	21	21	14	0	0	0	0	0	56
333111b	Farm Machinery and Equipment Manufacturing	11	11	7	0	0	0	0	0	28
336510b	Railroad Rolling Stock Manufacturing	11	11	7	0	0	0	0	0	28
611310	Colleges, Universities, and Professional Schools	95	95	63	0	0	0	0	0	254
Abrasive Blasting - Construction										

Table VIII-3: Number of Workers Exposed to Beryllium by Affected Industry and Exposure Range (μg/m³) (continued)

Application Group/ NAICS	Industry	Exposure Level (μg/m³)								
		0 to ≤0.0.5	>0.05 to ≤0.1	>0.1 to ≤0.2	>0.2 to ≤0.25	>0.25 to ≤0.5	>0.5 to ≤1.0	>1.0 to ≤2.0	>2.0	Total
238320	Painting and Wall Covering Contractors	1,046	1,046	1,443	43	216	82	123	359	4,360
238990	All Other Specialty Trade Contractors	970	970	1,337	40	200	76	114	333	4,040
Abrasive Blasting Shipyards***										
336611a	Ship Building and Repairing	734	734	1,013	30	152	58	87	252	3,060
Welding in Shipyards****										
336611b	Ship Building and Repairing	7	7	4	1	4	3	0	1	26
Total										
General Industry Subtotal		17,222	17,222	7,428	568	2,842	2,445	736	1,798	50,261
Construction Subtotal		2,016	2,016	2,781	83	416	159	238	692	8,400
Maritime Subtotal		742	742	1,017	31	155	61	87	253	3,086
Total, All Industries		19,979	19,979	11,225	683	3,413	2,665	1,060	2,742	61,747

Note: Data may not sum to totals due to rounding.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Sources: US DOL OSHA, Directorate of Standards and Guidance, Office of Technological Feasibility.

D. Technological Feasibility of the Final Standard on Occupational Exposure to Beryllium

The OSH Act requires OSHA to demonstrate that a proposed health standard is technologically feasible (29 U.S.C. 655(b)(5)). As described in the preamble to the final rule (see Section II, Pertinent Legal Authority), technological feasibility has been interpreted broadly to mean ''capable of being done'' (*Am. Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 509–510 (1981) (''Cotton Dust'')). A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed, *i.e.,* technology that ''looms on today's horizon'' (*United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980) (''Lead I''); *Amer. Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (''Lead II''); *AFL–CIO* v. *Brennan*, 530 F.2 109, 121 (3rd Cir. 1975)). Courts have also interpreted technological feasibility to mean that, for health standards, a typical firm in each affected industry will reasonably be able to implement engineering and work practice controls that can reduce workers' exposures to meet the permissible exposure limit in most operations most of the time, without reliance on respiratory protection (see Lead I, 647 F.2d at 1272; Lead II, 939 F.2d at 990).

OSHA's technological feasibility analysis is presented in Chapter IV of the FEA. The technological feasibility analysis identifies the affected industries and application groups in which employees can reasonably be expected to be exposed to beryllium, summarizes the available air sampling data used to develop employee exposure profiles, and provides descriptions of engineering controls and other measures employers can take to reduce their employees' exposures to beryllium. For each affected industry sector or application group, OSHA provides an assessment of the technological feasibility of compliance with the final permissible exposure limit (PEL) of 0.2 μg/m^3 as an 8-hour TWA and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m^3.

The technological feasibility analysis covers twelve application groups that correspond to specific industries or production processes that involve the potential for occupational exposures to materials containing beryllium and that OSHA has determined fall within the scope of this final beryllium standard. Within each of these application groups, exposure profiles have been developed to characterize the distribution of the available exposure measurements by job title or group of jobs. Each section includes descriptions of existing, or baseline, engineering controls for operations that generate beryllium exposure. For those job groups in which current exposures were found to exceed the final PEL, OSHA identifies and describes additional engineering and work practice controls that can be implemented to reduce exposure and achieve compliance with the final PEL. For each application group or industry, a final determination is made regarding the technological feasibility of achieving the proposed permissible exposure limits based on the use of engineering and work practice controls and without reliance on the use of respiratory protection. The determination is made based on the legal standard of whether the PEL can be achieved for most operations most of the time using such controls. In a separate chapter on short-term exposures, OSHA also analyzes the feasibility of achieving compliance with the Short-Term Exposure Limit (STEL).

The analysis is based on the best evidence currently available to OSHA, including a comprehensive review of the industrial hygiene literature, National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations and case studies of beryllium exposure, site visits conducted by an OSHA contractor (Eastern Research Group (ERG)), and inspection data from OSHA's Integrated Management Information System (IMIS) and OSHA's Information System (OIS). OSHA also obtained information on beryllium production processes, worker exposures, and the effectiveness of existing control measures from Materion Corporation, the primary beryllium producer in the United States, interviews with industry experts, and comments submitted to the rulemaking docket in response to the Notice of Proposed Rulemaking and informal public hearings. All of this evidence is in the rulemaking record.

The twelve application groups are:

- Primary Beryllium Production,
- Beryllium Oxide Ceramics and Composites,
- Nonferrous Foundries,
- Secondary Smelting, Refining, and Alloying, Including Handling of Scrap and Recycled Materials,
- Precision Turned Products,
- Copper Rolling, Drawing, and Extruding,
- Fabrication of Beryllium Alloy Products,
- Welding,
- Dental Laboratories,
- Abrasive Blasting,
- Coal-Fired Electric Power Generation,
- Aluminum Production

For discussion purposes, the twelve application groups are divided into four general categories based on the distribution of exposures in the exposure profiles: (1) Application groups in which baseline exposures for most jobs are already at or below the final PEL of 0.2 μg/m^3; (2) application groups in which baseline exposures for one or more jobs exceed the final PEL of 0.2 μg/m^3, but additional controls have been identified that could achieve exposures at or below the final PEL for most of the operations most of the time; (3) application groups in which exposures in one or more jobs routinely exceed the preceding PEL of 2.0 μg/m^3, and therefore substantial reductions in exposure would be required to achieve the final PEL; and (4) application groups in which exposure to beryllium occurs due to trace levels of beryllium found in dust or fumes that nonetheless can result in exposures that exceed 0.1 μg/m^3 as an 8-hour TWA under foreseeable conditions.

The application groups in category 1, where exposures for most jobs are already at or below the final PEL of 0.2 μg/m^3, typically handle beryllium alloys containing a low percentage of beryllium (<2 percent) using processes that do not result in significant airborne exposures. These four application groups are (1) copper rolling, drawing, and extruding; (2) fabrication of beryllium alloy products; (3) welding; and (4) aluminum production. The handling of beryllium alloys in solid form is not expected to result in exposures of concern. For example, beryllium alloys used in copper rolling, drawing, and extruding typically contain 2 percent beryllium by weight or less (Document ID 0081, Attachment 1). One facility noted that the copper-beryllium alloys it used contained as little as 0.1 percent beryllium (Document ID 0081, Attachment 1). These processes, such as rolling operations that consist of passing beryllium alloys through a rolling press to conform to a desired thickness, tend to produce less particulate and fume than high energy processes. Exposures can be controlled using containment, exhaust ventilation, and work practices that include rigorous housekeeping. In addition, the heating of metal during welding operations results in the release of fume, but the beryllium in the welding fume accounts for a relatively small percentage of the beryllium exposure. Worker exposure to beryllium

during welding activities is largely attributable to flaking oxide scale on the base metal, which can be reduced through chemically stripping or pickling the beryllium alloy piece prior to welding on it, and/or enhancing exhaust ventilation (Corbett, 2006; Kent, 2005; Materion Information Meeting, 2012).

For application groups in category 2, where baseline exposures for one or more jobs exceed the final PEL of 0.2 μg/m³, but additional controls have been identified that could achieve exposures at or below the final PEL for most of the operations most of the time, workers may encounter higher content beryllium (20 percent or more by weight), or higher temperature processes (Document ID 1662, p. 4.) The application groups in the second category are: (1) Precision turned products and (2) secondary smelting, refining, and alloying. While the median exposures for most jobs in these groups are below the preceding PEL of 2.0 μg/m³, the median exposures for some jobs in these application groups exceed the final PEL of 0.2 μg/m³ when not adequately controlled. For these application groups, additional exposure controls and work practices will be required to reduce exposures to or below the final PEL for most operations most of the time. For example, personal samples collected at a precision turned products facility that machined pure beryllium metal and high beryllium content materials (40–60 percent) measured exposures on two machinists of 2.9 and 6.6 μg/m3 (ERG Beryllium Site 4, 2003). A second survey at this same facility conducted after an upgrade to the ventilation systems in the mill and lathe departments measured PBZ exposures for these machinists of 1.1 and 2.3 μg/m³ (ERG Beryllium Site 9, 2004), and it was noted that not all ventilation was optimally positioned, indicating that further reduction in exposure could be achieved. In 2007, the company reported that after the installation of enclosures on milling machines and additional exhaust, average exposures to mill and lathe operators were reduced to below 0.2 μg/m³ (ICBD, 2007). For secondary smelting operations, several surveys conducted at electronic recycling and precious metal recovery operations indicate that exposures for mechanical processing operators can be controlled to or below 0.2 μg/m³. However, for furnace operations in secondary smelting, the median value in the exposure profile exceeds the preceding PEL. Furnace operations involve high temperatures that produce significant amounts of fumes and particulate that can be difficult to contain. Therefore, the reduction of 8-hour average exposures to or below the final PEL may not be achievable for most furnace operations involved with secondary smelting of beryllium alloys. In these cases, the supplemental use of respiratory protection for specific job tasks will be needed to adequately protect furnace workers for operations where exposures are found to exceed 0.2 μg/m³ despite the implementation of all feasible engineering and work practice controls.

The application groups in category 3 include application groups for which the exposure profiles indicate that exposures in one or more jobs routinely exceed the preceding PEL of 2.0 μg/m³. The three application groups in this category are: (1) Beryllium production, (2) beryllium oxide ceramics production, and (3) nonferrous foundries. For the job groups in which exposures have been found to routinely exceed the preceding PEL, OSHA identifies additional exposure controls and work practices that the Agency has determined can reduce exposures to or below the final PEL, most of the time. For example, OSHA concluded that exposures to beryllium resulting from material transfer, loading, and spray drying of beryllium oxide powders can be reduced to or below 0.2 μg/m3 with process enclosures, ventilation hoods, and diligent housekeeping for material preparation operators working in beryllium oxide ceramics and composites facilities (FEA, Chapter IV–04). However, for furnace operations in primary beryllium production and nonferrous foundries, and shakeout operations at nonferrous foundries, OSHA recognizes that even after installation of feasible controls, supplemental use of respiratory protection may be needed to protect workers adequately (FEA, Chapter IV–03 and IV–05). The evidence in the rulemaking record is insufficient to conclude that these operations would be able to reduce the majority of the exposure to levels below 0.2 μg/m³ most of the time, and therefore some increased supplemental use of respiratory protection may be required for certain tasks in these jobs.

Category 4 includes application groups that encounter exposure to beryllium due to trace levels found in dust or fumes that nonetheless can exceed 0.1 μg/m³ as an 8-hour TWA under foreseeable conditions. The application groups in this category are (1) coal-fired power plants in which exposure to beryllium can occur due to trace levels of beryllium in the fly ash during very dusty maintenance operations, such as cleaning the air pollution control devices; (2) aluminum production in which exposure to beryllium can occur due to naturally occurring trace levels of beryllium found in bauxite ores used to make aluminum; and (3) abrasive blasting using coal and copper slag that can contain trace levels of beryllium. Workers who perform abrasive blasting using either coal or copper slag abrasives are potentially exposed to beryllium due to the high total exposure to the blasting media. Due to the very small amounts of beryllium in these materials, the final PEL for beryllium will be exceeded only during operations that generate excessive amount of visible airborne dust, for which engineering controls and respiratory protection are already required. However, the other workers in the general vicinity do not experience these high exposures if proper engineering controls and work practices, such as temporary enclosures and maintaining appropriate distance during the blasting or maintenance activities, are implemented.

During the rulemaking process, OSHA requested and received comments regarding the feasibility of the PEL of 0.2 μg/m³, as well as the proposed alternative PEL of 0.1 μg/m³ (80 FR 47565, 47780 (Aug. 7, 2015)). OSHA did this because it recognizes that significant risk of beryllium disease is not eliminated at an exposure level of 0.2 μg/m³. As discussed below, OSHA finds that the proposed PEL of 0.2 μg/m³ can be achieved through engineering and work practice controls in most operations most of the time in all the affected industry sectors and application groups, and therefore is feasible for these industries and application groups under the OSH Act. OSHA could not find, however, that the proposed alternative PEL of 0.1 μg/m³ is also feasible for all of the affected industry sectors and application groups.

The majority of commenters, including stakeholders in labor and industry, public health experts, and the general public, explicitly supported the proposed PEL of 0.2 μg/m³ (NIOSH, Document ID 1671, Attachment 1, p. 2; National Safety Council, 1612, p. 3; Beryllium Health and Safety Committee Task Group, 1655, p. 2; Newport News Shipbuilding, 1657, p. 1; National Jewish Health (NJH), 1664, p. 2; the Aluminum Association, 1666, p. 1; the Boeing Company, 1667, p. 1; American Industrial Hygiene Association, 1686, p. 2; United Steelworkers (USW), 1681, p. 7; Andrew Brown, 1636, p. 6; Department of Defense, 1684, p. 1). In addition, Materion Corporation, the sole

primary beryllium production company in the U.S., and USW, jointly submitted a draft proposed rule that included an exposure limit of 0.2 μg/m³ (Document ID 0754, p. 4). In its written comments, Materion explained that it is feasible to control exposure to levels below 0.2 μg/m³ through the use of engineering controls and work practices in most, but not all, operations:

> Based on many years' experience in controlling beryllium exposures, its vigorous product stewardship program in affected operations, and the judgment of its professional industrial hygiene staff, Materion Brush believes that the 0.2 μg/m³ PEL for beryllium, based on median exposures, can be achieved in most operations, most of the time. Materion Brush does recognize that it is not feasible to reduce exposures to below the PEL in some operations, and in particular, certain beryllium production operations, solely through the use of engineering and work practice controls (Document ID 1052).

On the other hand, the Nonferrous Founders' Society (NFFS) asserted that OSHA had not demonstrated that the final PEL of 0.2 μg/m³ was feasible for the nonferrous foundry industry (Document ID 1678, pp. 2–3). NFFS asserted that ''OSHA has failed to meet its burden of proof that a ten-fold reduction to the current two micrograms per cubic meter limit is technologically or economically feasible in the non-ferrous foundry industry'' (Document ID 1678, pp. 2–3; 1756, Tr. 18). In written testimony submitted as a hearing exhibit, NFFS claimed that OSHA's supporting documentation in the PEA had no ''concrete assurance on technologic feasibility either by demonstration or technical documentation'' (Document ID 1732, Appendix A, p. 4).

However, contrary to the NFFS comments, which are addressed at greater length in Section IV–5 of the FEA, OSHA's exposure profile is based on the best available evidence for nonferrous foundries; the exposure data are taken from NIOSH surveys, an ERG site visit, and the California Cast Metals Association (Document ID 1217; 1185; 0341, Attachment 6; 0899). Materion also submitted substantial amounts of monitoring data, process descriptions and information of engineering controls that have been implemented in its facilities to control beryllium exposure effectively, including operations that involve the production of beryllium alloys using the same types of furnace and casting operations as those conducted at nonferrous foundries producing beryllium alloys (Document ID 0719; 0720; 0723). Furthermore, Materion submitted the above-referenced letter to the docket stating that, based on its many years of experience controlling beryllium exposures, a PEL of 0.2 μg/m³ can be achieved in most operations, most of the time (Document ID 1052). Materion's letter is consistent with the monitoring data Materion submitted, and OSHA considers its statement regarding feasibility at the final PEL relevant to nonferrous foundries because Materion has similar operations in its facilities, such as beryllium alloy production. As stated in Section IV–5 of the FEA, the size and configuration of nonferrous foundries may vary, but they all use similar processes; they melt and pour molten metal into the prepared molds to produce a casting, and remove excess metal and blemishes from the castings (NIOSH 85–116, 1985). While the design may vary, the basic operations and worker job tasks are similar regardless of whether the casting metal contains beryllium.

In the NPRM, OSHA requested that affected industries submit to the record any available exposure monitoring data and comments regarding the effectiveness of currently implemented control measures to inform the Agency's final feasibility determinations. During the informal public hearings, OSHA asked the NFFS panel to provide information on current engineering controls or the personal protective equipment used in foundries claiming to have difficulty complying with the preceding PEL, but no additional information was provided (Document ID 1756; Tr. 24–25; 1785, p. 1). Thus, the NFFS did not provide any sampling data or other evidence regarding current exposure levels or existing control measures to support its assertion that a PEL of 0.2 μg/m³ is not feasible, and did not show that the data in the record are insufficient to demonstrate technological feasibility for nonferrous foundry industry.

In sum, while OSHA agrees that two of the operations in the nonferrous foundry industry, furnace and shakeout operations, employing a relatively small percentage of workers in the industry, may not be able to achieve the final PEL of 0.2 μg/m³ most of the time, evidence in the record indicates that the final PEL is achievable in the other six job categories in this industry. Therefore, in the FEA, OSHA finds the PEL of 0.2 μg/m³ is technologically feasible for the nonferrous foundry industry.

OSHA also recognizes that engineering and work practice controls may not be able to consistently reduce and maintain exposures to the final PEL of 0.2 μg/m³ in some job categories in other application groups, due to the processing of materials containing high concentrations of beryllium, which can result in the generation of substantial amounts of fumes and particulate. For example, the final PEL of 0.2 μg/m³ cannot be achieved most of the time for furnace operations in primary beryllium production and for some furnace operation activities in secondary smelting, refining, and alloying facilities engaged in beryllium recovery and alloying. Workers may need supplementary respiratory protection during these high exposure activities where exposures exceed the final PEL of 0.2 μg/m³ or STEL of 2.0 μg/m³ with engineering and work practice controls. In addition, OSHA has determined that workers who perform open-air abrasive blasting using mineral grit (*i.e.,* coal slag) will routinely be exposed to levels above the final PEL (even after the installation of feasible engineering and work practice controls), and therefore, these workers will also be required to wear respiratory protection.

Overall, however, based on the information discussed above and the other evidence in the record and described in Chapter IV of the FEA, OSHA has determined that for the majority of the job groups evaluated exposures are either already at or below the final PEL, or can be adequately controlled to levels below the final PEL through the implementation of additional engineering and work practice controls for most operations most of the time. Therefore, OSHA concludes that the final PEL of 0.2 μg/m³ is technologically feasible.

In contrast, the record evidence does not show that it is feasible for most operations in all affected industries and application groups to achieve the alternative PEL of 0.1 μg/m³ most of the time. As discussed below, although a number of operations can achieve this level, they may be interspersed with operations that cannot, and OSHA sees value in having a uniform PEL that can be enforced consistently for all operations, rather than enforcing different PELs for the same contaminant in different operations.

Several commenters supported a PEL of 0.1 μg/m³. Specifically, Public Citizen; the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO); the International Union, United Automobile, Aerospace, and Agriculture Implement Workers of America (UAW); North America's Building Trades Unions (NABTU); and the American College of Occupational and Environmental Medicine contended that OSHA should adopt this lower level because of the residual risk at 0.2 μg/m³

(Document ID 1689, p. 7; 1693, p. 3; 1670, p. 1; 1679, pp. 6–7; 1685, p. 1; 1756, Tr. 167). Two of these commenters, Public Citizen and the AFL–CIO, also contended that a TWA PEL of 0.1 μg/m3 is feasible (Document ID 1756, Tr. 168–169, 197–198). Neither of those commenters, however, submitted any additional evidence to the record that OSHA could rely on to conclude that a PEL of 0.1 μg/m³ is achievable.

On the other hand, the Beryllium Health and Safety Committee and NJH specifically rejected a PEL of 0.1 μg/m³ in their comments. They explained that they believed the proposed PEL of 0.2 μg/m³ and the ancillary provisions would reduce the prevalence of beryllium sensitization and chronic beryllium disease (CBD) and be the best overall combination for protecting workers when taking into consideration the analytical chemistry capabilities and economic considerations (Document ID 1655, p. 16; 1664, p. 2).

Based on the record evidence, OSHA cannot conclude that the alternative PEL of 0.1 μg/m³ is achievable most of the time for at least one job category in 8 of the 12 application groups or industries included in this analysis: Primary beryllium production; beryllium oxide ceramics and composites; nonferrous foundries; secondary smelting, refining, and alloying, including handling of scrap and recycled materials; precision turned products; dental laboratories; abrasive blasting; and coal-fired electric power generation. In general, OSHA's review of the available sampling data indicates that the alternative PEL of 0.1 μg/m³ cannot be consistently achieved with engineering and work practice controls in application groups that use materials containing high percentages of beryllium or that involve processes that result in the generation of substantial amounts of fumes and particulate. Variability in processes and materials for operations involving the heating or machining of beryllium alloys or beryllium oxide ceramics also makes it difficult to conclude that exposures can be routinely reduced to below 0.1 μg/m³. For example, in the precision turned products industry, OSHA has concluded that exposures for machinists machining pure beryllium or high beryllium alloys can be reduced to or below 0.2 μg/m³, but not 0.1 μg/m³. Additionally, OSHA has determined that job categories that involve high-energy operations will not be able to consistently achieve 0.1 μg/m³ (*e.g.,* abrasive blasting with coal slag in open-air). These operations can cause workers to have elevated exposures even when available engineering and work practice controls are used.

In other cases, paucity of data or other data issues prevent OSHA from determining whether engineering and work practice controls can reduce exposures to or below 0.1 μg/m³ most of the time (see Chapter IV of the FEA). A large portion of the sample results obtained by OSHA for the dental laboratories industry and for two of the job categories in the coal-fired electric power generation industry (operations workers and routine maintenance workers) were below the reported limit of detection (LOD). Because the LODs for many of these samples were higher than 0.1 μg/m³, OSHA could not assess whether exposures were below 0.1 μg/m³. For example, studies of dental laboratories showed that use of well-controlled ventilation can consistently reduce exposures to below the LOD of 0.2 μg/m³. However, without additional information, OSHA cannot conclude that exposures can be reduced to or below 0.1 μg/m³ most of the time. Therefore, OSHA cannot determine if a PEL of 0.1 μg/m³ would be feasible for the dental laboratory industry.

The lack of available data has also prevented OSHA from determining whether exposures at or below of 0.1 μg/m³ can be consistently achieved for machining operators in the beryllium oxide ceramics and composites industry. As discussed in Section IV–4 of the FEA, the exposure profile for dry (green) machining and lapping and plate polishing (two tasks within the machining operator job category) is based on 240 full-shift PBZ samples obtained over a 10-year period (1994 to 2003). The median exposure levels in the exposure profile for green machining and lapping and polishing are 0.16 μg/m³ and 0.29 μg/m³, respectively. While the record indicates that improvements in exposure controls were implemented over time (Frigon, 2005, Document ID 0825; Frigon, 2004 (Document ID 0826)), data showing to what extent exposures have been reduced are not available. Nonetheless, because the median exposures for green machining are already below 0.2 μg/m³, and the median exposures for lapping and polishing are only slightly above the PEL of 0.2 μg/m³, OSHA concluded that the controls that have been implemented are sufficient to reduce exposures to at or below 0.2 μg/m³ most of the time. However, without additional information, OSHA cannot conclude that exposures could be reduced to or below 0.1 μg/m³ most of the time for these tasks.

Most importantly for this analysis, the available evidence demonstrates that the alternative PEL of 0.1 μg/m³ is not achievable in five out of the eight job categories in the nonferrous foundries industry: Furnace operator, shakeout operator, pouring operator, material handler, and molder. As noted above, the first two of these job categories, furnace operator and shakeout operator, which together employ only a small fraction of the workers in this industry, cannot achieve the final PEL of 0.2 μg/m³ either, but evidence in the record demonstrates that nonferrous foundries can reduce the exposures of most of the rest of the workers in the other six job categories to or below the final PEL of 0.2 μg/m³, most of the time. However, OSHA's feasibility determination for the pouring operator, material handler, and molder job categories, which together employ more than half the workers at these foundries, does not allow the Agency to conclude that exposures for those jobs can be consistently lowered to the alternative PEL of 0.1 μg/m³. See Section IV–5 of the FEA. Thus, OSHA cannot conclude that most operations in the nonferrous foundries industry can achieve a PEL of 0.1 μg/m³, most of the time. Accordingly, OSHA finds that the alternative PEL of 0.1 μg/m³ is not feasible for the nonferrous foundries industry.

OSHA has also determined either that information in the rulemaking record demonstrates that 0.1 μg/m³ is not consistently achievable in a number of operations in other affected industries or that the information is insufficient to establish that engineering and work practice controls can consistently reduce exposures to or below 0.1 μg/m³. Therefore, OSHA finds that the proposed alternative PEL of 0.1 μg/m³ is not appropriate, and the rule's final PEL of 0.2 μg/m³ is the lowest exposure limit that can be found to be technologically feasible through engineering and work practice controls in all of the affected industries and application groups included in this analysis.

Because of this inability to achieve 0.1 μg/m³ in many operations, if OSHA were to adopt a PEL of 0.1 μg/m³, a substantial number of employees would be required to wear respirators. As discussed in the Summary and Explanation for paragraph (f), Methods of Compliance, use of respirators in the workplace presents a number of independent safety and health concerns. Workers wearing respirators may experience diminished vision, and respirators can impair the ability of employees to communicate with one another. Respirators can impose physiological burdens on employees due to the weight of the respirator and increased breathing resistance

experienced during operation. The level of physical work effort required, the use of protective clothing, and environmental factors such as temperature extremes and high humidity can interact with respirator use to increase the physiological strain on employees. Inability to cope with this strain as a result of medical conditions such as cardiovascular and respiratory diseases, reduced pulmonary function, neurological or musculoskeletal disorders, impaired sensory function, or psychological conditions can place employees at increased risk of illness, injury, and even death. The widespread, routine use of respirators for extended periods of time that may be required by a PEL of 0.1 μg/m³ creates more significant concerns than the less frequent respirator usage that is required by a PEL of 0.2 μg/m³.

Furthermore, OSHA concludes that it would complicate both compliance and enforcement of the rule if it were to set a PEL of 0.1 μg/m³ for some industries or operations and a PEL of 0.2 μg/m³ for the remaining industries and operations where technological feasibility at the lower PEL is either unattainable or unknown. OSHA may exercise discretion to issue a uniform PEL if it determines that the PEL is technologically feasible for all affected industries (if not for all affected operations) and that a uniform PEL would constitute better public policy. See Pertinent Legal Authority (discussing the Chromium decision). In declining to lower the PEL to 0.1 μg/m³ for any segment of the affected industries, OSHA has made that determination here. Therefore, OSHA has determined that the proposed alternative PEL of 0.1 μg/m³ is not appropriate.

OSHA also evaluated the technological feasibility of the final STEL of 2.0 μg/m³ and the alternative STEL of 1.0 μg/m³. An analysis of the available short-term exposure measurements presented in Chapter IV, Section 15 of the FEA indicates that elevated exposures can occur during short-term tasks such as those associated with the operation and maintenance of furnaces at primary beryllium production facilities, at nonferrous foundries, and at secondary smelting operations. Peak exposures can also occur during the transfer and handling of beryllium oxide powders. OSHA finds that in many cases, the control of peak short-term exposures associated with these intermittent tasks will be necessary to reduce workers' TWA exposures to or below the final PEL. The short-term exposure data presented in the FEA show that the majority (79%) of these exposures are already below 2.0 μg/m³.

A number of stakeholders submitted comments related to the proposed and alternative STELs. Some of these stakeholders supported a STEL of 2.0 μg/m³. Materion stated that a STEL of 2.0 μg/m³ for controlling the upper range of worker short term exposures is sufficient to prevent CBD (Document ID 1661, p. 3). Other commenters recommended a STEL of 1.0 μg/m³ (Document ID 1661, p. 19; 1681, p. 7). However, no additional engineering controls capable of reducing short term exposures to at or below 1.0 μg/m³ were identified by these commenters. OSHA provides a full discussion of the public comments in the Summary and Explanation section of this preamble. OSHA has determined that the implementation of engineering and work practice controls required to maintain full shift exposures at or below a PEL of 0.2 μg/m³ will reduce short term exposures to 2.0 μg/m³ or below, and that a STEL of 1.0 μg/m³ would require additional respirator use. Furthermore, OSHA notes that the combination of a PEL of 0.2 μg/m³ and a STEL of 2.0 μg/m³ would, in most cases, keep workers from being exposed to 15 minute intervals of 1.0 μg/m³. See Table IV.78 of Chapter IV of the FEA.

Therefore, OSHA concludes that the STEL of 2.0 μg/m³ can be achieved for most operations most of the time, given that most short-term exposures are already below 2.0 μg/m³. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the final STEL, even after feasible control measures to reduce TWA exposure to or below the final PEL have been implemented, and therefore, some limited use of respiratory protection will continue to be required for short-term tasks in which peak exposures cannot be reduced to less than 2.0 μg/m³ through use of engineering controls.

After careful consideration of the record, including all available data and stakeholder comments in the record, OSHA has determined that a STEL of 2.0 μg/m³ is technologically feasible. Thus, as explained in the Summary and Explanation for paragraph (c), OSHA has retained the proposed value of 2.0 μg/m³ as the final STEL.

E. Costs of Compliance

In Chapter V, Costs of Compliance, OSHA assesses the costs to general industry, maritime, and construction establishments in all affected application groups of reducing worker exposures to beryllium to an eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 0.2 μg/m³ and to the final short-term exposure limit (STEL) of 2.0 μg/m³, as well as of complying with the final standard's ancillary provisions. These ancillary provisions encompass the following requirements: Exposure monitoring, regulated areas (and competent person in construction), a written exposure control plan, protective work clothing, hygiene areas and practices, housekeeping, medical surveillance, medical removal, familiarization, and worker training. This final cost assessment is based in part on OSHA's technological feasibility analysis presented in Chapter IV of the FEA; analyses of the costs of the final standard conducted by OSHA's contractor, Eastern Research Group (ERG); and the comments submitted to the docket in response to the request for information (RFI) as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, comments submitted to the docket in response to the PEA, comments during the hearings conducted in March 2016, and comments submitted to the docket after the hearings concluded.

Table VIII–4 presents summary of the annualized costs. All costs in this chapter are expressed in 2015 dollars and were annualized using a discount rate of 3 percent. (Costs at other discount rates are presented in the chapter itself). Annualization periods for expenditures on equipment are based on equipment life, and one-time costs are annualized over a 10-year period. Chapter V provides detailed explanation of the basis for these cost estimates.

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
Beryllium Oxide – Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$315,959	$117,793	-
Beryllium Oxide – Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$232,556	$105,595	-
334310	Audio and Video Equipment Manufacturing	$118,084	$99,209	-
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$278,998	$199,642	-
334419	Other Electronic Component Manufacturing	$697,514	$482,652	-
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$209,703	$35,369	-
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$325,494	$218,758	-
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$232,562	$140,444	-
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$2,013,397	-	-
Dental Labs – Substituting*				
339116a	Dental Laboratories	$1,253,495	$1,017,075	$631,145
621210a	Offices of Dentists	$178,968	$168,032	$144,738
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$2,167,822	$1,757,907	$1,090,462
621210b	Offices of Dentists	$309,649	$290,706	$250,457
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$4,426,834	$2,252,945	$109,260
Machining – High				
332721a	Precision Turned Product Manufacturing	$729,198	$640,150	$137,756
Machining – Low				
332721b	Precision Turned Product Manufacturing	$8,049,765	$7,072,180	$1,542,921
Non Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$3,576,462	$2,153,997	$534,414
331524	Aluminum Foundries (except Die-Casting)	$521,441	$419,706	$106,565
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$1,323,804	$955,352	$336,613
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$1,177,254	$599,439	$29,407
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$1,802,392	$1,307,125	$468,335

Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$41,736	$34,100	$26,479
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$114,295	$67,494	$14,331

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$805,282	$527,762	$184,943
Springs				
332613	Spring Manufacturing	$3,702,257	$2,602,479	$666,079
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$904,241	$736,071	$177,472
334417	Electronic Connector Manufacturing	$584,177	$277,415	$74,764
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$1,846,653	$1,070,556	$325,146
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$67,570	$17,445	$6,384
331221	Rolled Steel Shape Manufacturing	$19,960	$16,860	$5,201
331513	Steel Foundries (except Investment)	$16,788	$9,628	$5,852
332117	Powder Metallurgy Part Manufacturing	$12,314	$8,617	$6,564
332216	Saw Blade and Handtool Manufacturing	$38,399	$26,832	$8,395
332312	Fabricated Structural Metal Manufacturing	$581,440	$394,214	$100,387
332313	Plate Work Manufacturing	$233,595	$206,246	$41,748
332322	Sheet Metal Work Manufacturing	$769,001	$629,529	$153,221
332323	Ornamental and Architectural Metal Work Manufacturing	$415,257	$342,102	$133,212
332439	Other Metal Container Manufacturing	$66,574	$38,415	$10,537
332919	Other Metal Valve and Pipe Fitting Manufacturing	$35,290	$19,690	$4,906
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$412,635	$359,345	$92,112
333111a	Farm Machinery and Equipment Manufacturing	$219,739	$119,863	$37,334
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$50,310	$34,014	$9,120
333911	Pump and Pumping Equipment Manufacturing	$75,055	$29,195	$10,276
333922	Conveyor and Conveying Equipment Manufacturing	$109,339	$83,855	$14,647
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$51,556	$24,921	$8,516
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$226,282	$138,069	$39,972
336211	Motor Vehicle Body Manufacturing	$162,264	$104,321	$22,757
336214	Travel Trailer and Camper Manufacturing	$145,158	$61,005	$23,374

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
336390a	Other Motor Vehicle Parts Manufacturing	$68,384	$33,840	$10,605
336510a	Railroad Rolling Stock Manufacturing	$36,795	$12,111	$4,009
336999	All Other Transportation Equipment Manufacturing	$35,556	$16,540	$9,603
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$28,978	$21,921	$6,522
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$1,584,633	$932,053	$611,277
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$526,305	$256,015	$33,706
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$941,303	$328,435	$32,255
335210	Small Electrical Appliance Manufacturing	$170,175	$125,024	$8,227
335221	Household Cooking Appliance Manufacturing	$131,328	$60,983	$4,126
335222	Household Refrigerator and Home Freezer Manufacturing	$40,241	$7,346	$1,310
335224	Household Laundry Equipment Manufacturing	$12,166	$1,369	$1,310
335228	Other Major Household Appliance Manufacturing	$48,304	$7,091	$1,310
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$1,137,535	$398,286	$57,392
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$908,472	$455,773	$39,843
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$328,342	$107,290	$8,454
336340	Motor Vehicle Brake System Manufacturing	$261,342	$112,290	$5,042
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$674,120	$241,333	$16,175
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$533,438	$189,394	$12,131
336370	Motor Vehicle Metal Stamping	$1,036,026	$617,330	$25,234
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$505,883	$332,174	$46,775
336390b	Other Motor Vehicle Parts Manufacturing	$2,020,751	$953,614	$75,178
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$1,448,385	$1,448,385	-
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$6,174,423	$989,185	$27,884
311221	Wet Corn Milling	$198,450	$32,970	-
311313	Beet Sugar Manufacturing	$231,570	$42,324	-
311942	Spice and Extract Manufacturing	$33,064	$19,954	-
312120	Breweries	$33,089	$18,534	-
321219	Reconstituted Wood Product Manufacturing	$16,530	$7,274	-

Table VIII-4 Total Annualized Costs, by Sector and Six-Digit NAICS Industry, for Entities Affected by the Final Beryllium Standard; Results Shown by Size Category (3 Percent Discount Rate, 2015 Dollars) (continued)

Application Group/ NAICS	Industry	All Establishments	Small Entities (SBA-defined)	Very Small Entities (<20 Employees)
322110	Pulp Mills	$16,553	$2,995	-
322121	Paper (except Newsprint) Mills	$182,256	$39,535	-
322122	Newsprint Mills	$397,171	$173,886	-
322130	Paperboard Mills	$264,737	$37,754	-
325211	Plastics Material and Resin Manufacturing	$66,132	$33,457	-
325611	Soap and Other Detergent Manufacturing	$16,537	$7,446	-
327310	Cement Manufacturing	$33,060	$10,073	-
333111b	Farm Machinery and Equipment Manufacturing	$16,538	$8,747	-
336510b	Railroad Rolling Stock Manufacturing	$16,542	$4,748	-
611310	Colleges, Universities, and Professional Schools	$149,175	$11,694	-
Abrasive Blasting – Construction				
238320	Painting and Wall Covering Contractors	$4,416,714	$3,719,871	$2,605,987
238990	All Other Specialty Trade Contractors	$4,092,952	$3,147,411	$2,149,166
Abrasive Blasting – Shipyards***				
336611a	Ship Building and Repairing	$3,316,687	$1,063,477	$557,570
Welding in Shipyards****				
336611b	Ship Building and Repairing	$69,071	$20,244	$11,326
Total				
General Industry Subtotal		$61,972,805	$36,113,291	$8,624,173
Construction Subtotal		$8,509,666	$6,867,282	$4,755,152
Maritime Subtotal		$3,385,759	$1,083,721	$568,896
Total, All Industries		$73,868,230	$44,064,294	$13,948,222

Notes:

Figures in rows may not add to totals due to rounding.

"-" denotes industries where OSHA has preliminarily determined that there are no affected small or very small establishments.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

F. Economic Feasibility and Regulatory Flexibility Determination

In Chapter VI, OSHA investigates the economic impacts of its final beryllium rule on affected employers. This impact investigation has two overriding objectives: (1) To establish whether the final rule is economically feasible for all affected application groups/industries,[31] and (2) to determine if the Agency can certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Table VIII–5 presents OSHA's screening analysis, which shows costs as percentage of revenues and as a percentage of profits. The chapter explains why these screening analysis

[31] As noted in the FEA, OSHA uses the umbrella term ''application group'' to refer either to an industrial sector or to a cross-industry group with a common process. In the industrial profile chapter, because some of the discussion being presented has historically been framed in the context of the economic feasibility for an ''industry,'' the Agency uses the term ''application group'' and ''industry'' interchangeably.

results can reasonably be viewed as economically feasible. Section VIII.j shows similar results for small and very small entities.

Table VIII-5

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
Beryllium Oxide – Primary										
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	655	2	$2,224,322	--	--	--	$157,979	--	--
Beryllium Oxide – Secondary										
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	830	10	$29,075,882	$35,031,183	0.72%	$250,797	$23,256	0.07%	9.27%
334310	Audio and Video Equipment Manufacturing	463	5	$2,944,276	$6,359,128	-0.24%	-$15,180	$23,617	0.37%	-155.58%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	418	12	$3,829,332	$9,161,081	3.95%	$361,417	$23,250	0.25%	6.43%
334419	Other Electronic Component Manufacturing	1,259	30	$11,749,377	$9,332,309	3.95%	$368,172	$23,250	0.25%	6.32%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	749	9	$29,145,680	$38,912,791	4.74%	$1,842,824	$23,300	0.06%	1.26%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	655	14	$2,224,322	$3,395,911	1.57%	$53,418	$23,250	0.68%	43.52%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	10	$21,336,550	$31,469,837	1.51%	$475,965	$23,256	0.07%	4.89%
Beryllium Production										
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	186	1	$15,853,340	--	--	--	$2,013,397	--	--
Dental Labs – Substituting*										
339116a	Dental Laboratories	5,114	1,278	$3,604,997	$704,996	7.33%	$51,693	$981	0.14%	1.90%
621210a	Offices of Dentists	99,830	183	$81,961,314	$821,007	7.24%	$59,424	$980	0.12%	1.65%
Dental Labs - Non-Substituting**										
339116b	Dental Laboratories	1,705	426	$1,201,666	$704,996	7.33%	$51,693	$5,087	0.72%	9.84%
621210b	Offices of Dentists	33,277	61	$27,320,438	$821,007	7.24%	$59,424	$5,087	0.62%	8.56%
Drawing										
331420c	Copper Rolling, Drawing, Extruding, and Alloying	249	45	$24,370,147	$97,872,075	2.08%	$2,037,366	$99,439	0.10%	4.88%
Machining – High										
332721a	Precision Turned Product Manufacturing	3,688	22	$18,818,245	$5,102,561	4.73%	$241,533	$33,512	0.66%	13.87%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
Machining – Low										
332721b	Precision Turned Product Manufacturing	3,688	347	$18,036,209	$4,890,512	4.73%	$231,495	$22,015	0.45%	9.51%
Non-Sand Foundries										
331523	Nonferrous Metal Die-Casting Foundries	434	50	$7,838,073	$18,060,076	4.72%	$853,009	$70,398	0.39%	8.25%
331524	Aluminum Foundries (except Die-Casting)	406	7	$2,830,636	$6,972,010	4.72%	$329,300	$70,535	1.01%	21.42%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	300	18	$2,412,855	$8,042,850	4.72%	$379,878	$70,394	0.88%	18.53%
Rolling										
331420a	Copper Rolling, Drawing, Extruding, and Alloying	249	11	$23,357,388	$93,804,771	2.08%	$1,952,698	$95,071	0.10%	4.87%
Sand Foundries										
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	300	23	$2,412,855	$8,042,850	4.72%	$379,878	$76,605	0.95%	20.17%
Smelting - Beryllium Alloys										
331314	Secondary Smelting and Alloying of Aluminum	114	1	$5,623,100	$49,325,439	2.47%	$1,217,849	$40,853	0.08%	3.35%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	249	4	$23,357,388	$93,804,771	2.08%	$1,952,698	$27,690	0.03%	1.42%
Smelting - Precious Metals										
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	261	30	$14,552,929	$55,758,349	2.08%	$1,160,700	$25,959	0.05%	2.24%
Springs										
332613	Spring Manufacturing	392	296	$3,595,394	$9,171,923	4.73%	$434,159	$11,590	0.13%	2.67%
Stamping										
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	1,499	72	$11,816,815	$7,883,132	3.99%	$314,432	$11,597	0.15%	3.69%
334417	Electronic Connector Manufacturing	234	47	$5,693,396	$24,330,752	3.95%	$959,882	$11,591	0.05%	1.21%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	148	$20,449,859	$30,162,034	1.51%	$456,185	$11,596	0.04%	2.54%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
Welding - Arc and Gas										
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	562	6	$113,226,448	$201,470,548	1.24%	$2,500,783	$10,496	0.01%	0.42%
331221	Rolled Steel Shape Manufacturing	167	2	$5,991,188	$35,875,377	2.08%	$746,804	$12,618	0.04%	1.69%
331513	Steel Foundries (except Investment)	208	1	$4,536,694	$21,811,029	4.72%	$1,030,173	$13,345	0.06%	1.30%
332117	Powder Metallurgy Part Manufacturing	133	1	$2,023,839	$15,216,835	3.99%	$606,949	$11,887	0.08%	1.96%
332216	Saw Blade and Handtool Manufacturing	1,012	3	$7,043,067	$6,959,553	4.20%	$292,270	$11,630	0.17%	3.98%
332312	Fabricated Structural Metal Manufacturing	3,099	54	$27,839,554	$8,983,399	2.72%	$244,507	$10,768	0.12%	4.40%
332313	Plate Work Manufacturing	1,245	22	$7,461,246	$5,992,968	2.72%	$163,115	$10,769	0.18%	6.60%
332322	Sheet Metal Work Manufacturing	4,099	71	$20,892,732	$5,097,031	2.72%	$138,729	$10,768	0.21%	7.76%
332323	Ornamental and Architectural Metal Work Manufacturing	2,214	39	$6,058,633	$2,736,510	2.72%	$74,481	$10,765	0.39%	14.45%
332439	Other Metal Container Manufacturing	346	6	$3,885,743	$11,230,472	3.04%	$341,463	$11,043	0.10%	3.23%
332919	Other Metal Valve and Pipe Fitting Manufacturing	243	3	$5,062,721	$20,834,244	6.09%	$1,268,082	$11,767	0.06%	0.93%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	3,553	38	$15,415,053	$4,338,602	6.09%	$264,070	$10,766	0.25%	4.08%
333111a	Farm Machinery and Equipment Manufacturing	1,124	20	$42,075,186	$37,433,440	5.86%	$2,193,945	$10,772	0.03%	0.49%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	472	4	$5,535,698	$11,728,174	3.21%	$376,991	$11,294	0.10%	3.00%
333911	Pump and Pumping Equipment Manufacturing	539	7	$15,903,209	$29,505,027	3.99%	$1,176,661	$10,961	0.04%	0.93%
333922	Conveyor and Conveying Equipment Manufacturing	799	10	$8,945,712	$11,196,135	3.99%	$446,502	$10,771	0.10%	2.41%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	360	5	$11,772,772	$32,702,145	3.99%	$1,304,162	$11,272	0.03%	0.86%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	1,654	21	$15,726,526	$9,508,178	3.99%	$379,186	$10,769	0.11%	2.84%
336211	Motor Vehicle Body Manufacturing	741	15	$11,773,922	$15,889,234	1.51%	$240,317	$10,773	0.07%	4.48%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
336214	Travel Trailer and Camper Manufacturing	663	13	$10,544,247	$15,903,842	1.51%	$240,538	$10,771	0.07%	4.48%
336390a	Other Motor Vehicle Parts Manufacturing	1,508	6	$60,628,177	$40,204,361	1.51%	$608,070	$11,028	0.03%	1.81%
336510a	Railroad Rolling Stock Manufacturing	234	3	$17,944,334	$76,685,188	1.51%	$1,159,824	$11,708	0.02%	1.01%
336999	All Other Transportation Equipment Manufacturing	397	3	$7,731,109	$19,473,827	4.36%	$848,139	$11,749	0.06%	1.39%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	1,097	2	$6,809,534	$6,207,415	2.91%	$180,835	$12,129	0.20%	6.71%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	21,347	147	$34,529,038	$1,617,512	2.81%	$45,395	$10,763	0.67%	23.71%
Welding - Resistance Welding										
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	491	20	$6,278,849	$12,787,881	3.21%	$411,054	$26,798	0.21%	6.52%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	878	35	$31,852,834	$36,278,855	3.21%	$1,166,148	$26,802	0.07%	2.30%
335210	Small Electrical Appliance Manufacturing	127	6	$3,560,517	$28,035,564	4.28%	$1,200,467	$26,799	0.10%	2.23%
335221	Household Cooking Appliance Manufacturing	98	5	$4,674,297	$47,696,913	4.28%	$2,042,354	$26,802	0.06%	1.31%
335222	Household Refrigerator and Home Freezer Manufacturing	30	2	$3,686,247	$122,874,888	4.28%	$5,261,431	$26,827	0.02%	0.51%
335224	Household Laundry Equipment Manufacturing	9	1	$951,577	$105,730,833	4.28%	$4,527,333	$12,166	0.01%	0.27%
335228	Other Major Household Appliance Manufacturing	36	2	$4,710,323	$130,842,293	4.28%	$5,602,591	$26,836	0.02%	0.48%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	849	42	$33,235,797	$39,146,993	1.51%	$592,078	$26,797	0.07%	4.53%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	678	34	$21,336,550	$31,469,837	1.51%	$475,965	$26,799	0.09%	5.63%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	245	12	$12,290,261	$50,164,329	1.51%	$758,710	$26,803	0.05%	3.53%
336340	Motor Vehicle Brake System Manufacturing	195	10	$10,467,412	$53,679,036	1.51%	$811,868	$26,804	0.05%	3.30%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	503	25	$35,792,318	$71,157,690	1.51%	$1,076,224	$26,804	0.04%	2.49%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	398	20	$23,631,348	$59,375,247	1.51%	$898,020	$26,806	0.05%	2.98%
336370	Motor Vehicle Metal Stamping	773	39	$32,802,040	$42,434,722	1.51%	$641,804	$26,805	0.06%	4.18%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	472	19	$5,535,698	$11,728,174	3.21%	$376,991	$26,795	0.23%	7.11%
336390b	Other Motor Vehicle Parts Manufacturing	1,508	75	$60,628,177	$40,204,361	1.51%	$608,070	$26,800	0.07%	4.41%
Aluminum Production										
331313	Alumina Refining and Primary Aluminum Production	8	6	$370,719	$46,339,915	2.47%	$1,144,136	$224,939	0.49%	19.66%
Coal Fired Utilities										
221112	Fossil Fuel Electric Power Generation	2,716	418	$167,481,521	$123,329,544	0.90%	$553,734	$29,543	0.02%	5.34%
311221	Wet Corn Milling	63	12	$12,894,946	$204,681,680	4.62%	$9,466,006	$16,537	0.01%	0.17%
311313	Beet Sugar Manufacturing	31	14	$4,822,174	$155,553,993	8.23%	$12,796,838	$16,541	0.01%	0.13%
311942	Spice and Extract Manufacturing	383	2	$9,644,849	$25,182,374	4.61%	$1,159,747	$16,532	0.07%	1.43%
312120	Breweries	880	2	$29,912,097	$33,991,019	10.78%	$3,665,509	$16,544	0.05%	0.45%
321219	Reconstituted Wood Product Manufacturing	219	1	$6,708,744	$30,633,533	1.37%	$420,171	$16,530	0.05%	3.93%
322110	Pulp Mills	42	1	$6,842,997	$162,928,496	1.43%	$2,328,331	$16,553	0.01%	0.71%
322121	Paper (except Newsprint) Mills	209	11	$45,144,793	$216,003,795	1.43%	$3,086,804	$16,569	0.01%	0.54%
322122	Newsprint Mills	20	24	$3,218,103	$160,905,142	1.43%	$2,299,416	$16,549	0.01%	0.72%
322130	Paperboard Mills	177	16	$29,706,665	$167,834,268	1.43%	$2,398,437	$16,546	0.01%	0.69%
325211	Plastics Material and Resin Manufacturing	1,161	4	$97,687,597	$84,140,910	5.94%	$4,998,379	$16,533	0.02%	0.33%
325611	Soap and Other Detergent Manufacturing	664	1	$28,371,519	$42,728,192	12.34%	$5,274,306	$16,537	0.04%	0.31%
327310	Cement Manufacturing	240	2	$6,246,422	$26,026,757	1.47%	$382,683	$16,530	0.06%	4.32%
333111b	Farm Machinery and Equipment Manufacturing	1,124	1	$42,075,186	$37,433,440	5.86%	$2,193,945	$16,538	0.04%	0.75%

Table VIII-5, continued

Screening Analysis for Establishments Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate										
				Revenues		Profits		Compliance Costs		
NAICS Code	Industry	Total Establishments	Total Affected Establishments	Total ($1,000)	Per Establishment	Rate	Per Establishment	Per Establishment	As a Percent of Revenues	As a Percent of Profits
336510b	Railroad Rolling Stock Manufacturing	234	1	$17,944,334	$76,685,188	1.51%	$1,159,824	$16,542	0.02%	1.43%
611310	Colleges, Universities, and Professional Schools	4,329	9	$232,517,218	$53,711,531	6.07%	$3,259,004	$16,575	0.03%	0.51%
Abrasive Blasting – Construction										
238320	Painting and Wall Covering Contractors	31,376	1,090	$19,595,278	$624,531	3.47%	$21,663	$4,052	0.65%	18.71%
238990	All Other Specialty Trade Contractors	29,072	1,010	$39,396,242	$1,355,127	3.47%	$46,957	$4,052	0.30%	8.63%
Abrasive Blasting – Shipyards***										
336611a	Ship Building and Repairing	689	689	$26,136,187	$37,933,508	6.13%	$2,324,545	$4,814	0.01%	0.21%
Welding – Shipyards****										
336611b	Ship Building and Repairing	689	7	$26,136,187	$37,933,508	6.13%	$2,324,545	$10,467	0.03%	0.45%
Total										
General Industry Subtotal		226,165	4,538	$1,931,626,954	$8,540,786	3.55%	$303,168	$13,657	0.16%	4.50%
Construction Subtotal		60,448	2,100	$58,991,519	$975,905	3.47%	$33,828	$4,052	0.42%	11.98%
Maritime Subtotal		1,378	696	$52,272,373	$37,933,508	6.13%	$2,324,545	$4,867	0.01%	0.21%
Total, All Industries		**287,991**	**7,333**	**$2,042,890,847**	**$7,617,412**	**3.61%**	**$2,661,541**	**$10,073**	**0.02%**	**0.38%**

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

In Chapter VII, OSHA estimates the benefits and net benefits of the final beryllium rule. The methodology for these estimates largely remains the same as in the PEA. OSHA did not receive many comments challenging any aspect

of the benefits analysis presented in the PEA. There are, however, a few significant alterations, such as: Using an empirical turnover rate as part of the estimation of exposure response functions, full analysis of the population model with varying turnover (a model only briefly presented in the PEA), and presentation of a statistical proportional hazard model in response to comment. The other large change to the benefits analysis is the result of the increase in the scope of the rule to protect workers in the construction and ship-building industries. In the proposed rule, coverage of these latter industries was only presented as an alternative and therefore were not included in the benefits in the PEA, but they are covered by the final rule.

This chapter proceeds in five steps. The first step estimates the numbers of diseases and deaths prevented by comparing the current (baseline) situation to a world in which the final PEL is adopted in a final standard, and in which employees are exposed throughout their working lives to either the baseline or the final PEL. The second step also assumes that the final PEL is adopted, but uses the results from the first step to estimate what would happen under a realistic scenario in which new employees will not be exposed above the final PEL, while employees already at work will experience a combination of exposures below the final PEL and baseline exposures that exceed the final PEL over their working lifetime. The comparison of these steps is given in Table VIII–6. OSHA also presents in Chapter VII similar kinds of results for a variety of other risk assessment and population models.

Table VIII-6

Prevented Mortality and Morbidity by PEL Option at Midpoint Effectiveness (45-Year Working Life Case) (Quartile Model)

Midpoint Estimates

	Baseline Total Cases	PEL Option (μg/m^3) Total Number of Avoided Cases			Baseline Annual Cases	PEL Option (μg/m^3) Annual Number of Avoided Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
Total Cases								
Be S - Total	22,644	9,008	8,742	7,235	503	200.2	194.3	160.8
CBD	15,115	6,122	5,924	3,899	336	136.1	131.6	86.6
Mortality								
Lung Cancer	535	201	187	167	12	4.5	4.2	3.7
CBD-Related	9,863	4,018	3,851	2,534	219	89.3	85.6	56.3
Total Mortality	10,398	4,219	4,038	2,701	231	93.8	89.7	60.0
Morbidity	5,251	2,104	2,073	1,365	117	46.8	46.1	30.3

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

The third step covers the monetization of benefits. Table VIII–7 presents the monetization of benefits at various interest rates and monetization values.

Table VIII-7			
Annual Monetized Benefits Resulting from a Reduction in Exposure to Beryllium to Final PEL of 0.2 μg/m^3 and Alternative PELS of 0.1 μg/m^3 and 0.5 μg/m^3			
Lifetime Risk Model			
	PEL Option (μg/m^3)		
	0.1	0.2	0.5
Discount Rate			
Low Estimates			
Undiscounted (0%)	$280.7	$247.6	$233.7
Discounted at 3%	$152.8	$134.8	$127.2
Discounted at 7%	$58.6	$51.8	$48.8
High Estimates			
Undiscounted (0%)	$2,126.6	$2,100.2	$1,273.9
Discounted at 3%	$1,273.5	$1,257.8	$762.7
Discounted at 7%	$605.2	$597.8	$362.1
Midpoint Estimates			
Undiscounted (0%)	$1,003.4	$968.8	$650.2
Discounted at 3%	$580.9	$560.9	$376.5
Discounted at 7%	$258.0	$249.1	$167.2
Population Model with Varying Tenure			
	PEL Option (μg/m^3)		
	0.1	0.2	0.5
Discount Rate			
Low Estimates			
Undiscounted (0%)	$502.7	$455.6	$404.5
Discounted at 3%	$271.9	$246.2	$218.8
Discounted at 7%	$102.8	$93.0	$82.8
High Estimates			
Undiscounted (0%)	$2,954.5	$2,918.3	$1,852.5
Discounted at 3%	$1,769.8	$1,748.1	$1,109.4
Discounted at 7%	$841.7	$831.4	$527.3
Midpoint Estimates			
Undiscounted (0%)	$1,480.4	$1,431.6	$995.4
Discounted at 3%	$856.8	$828.5	$576.2
Discounted at 7%	$380.5	$367.9	$255.9
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis			

In the fourth step, OSHA estimates the net benefits of the final rule by comparing the monetized benefits to the costs presented in Chapter V of the FEA. These values are presented in Table VIII–8. The table shows that benefits exceed costs for all situations except for the low estimate of benefits using a 7 percent discount rate. The low estimate of benefits reflects the assumption that the ancillary provisions have no independent effect in reducing cases of CBD. OSHA considers this assumption to be very unlikely, based on the available evidence.

Table VIII-8				
Annual Monetized Net Benefits Resulting from a Reduction in Exposure to Beryllium to Final PEL of 0.2 μg/m^3 and Alternative PELS of 0.1 μg/m^3 and 0.5 μg/m^3 ($Millions)				
Lifetime Risk Model				
PEL		0.1	0.2	0.5
Discount Rate	Range			
Undiscounted (0%)	Low	$178.6	$175.1	$176.2
	Midpoint	$901.3	$896.3	$592.8
	High	$2,024.5	$2,027.7	$1,216.5
Discounted at 3%	Low	$49.1	$61.0	$68.6
	Midpoint	$477.2	$487.0	$317.9
	High	$1,169.9	$1,183.9	$704.1
Discounted at 7%	Low	($48.7)	($24.9)	($11.9)
	Midpoint	$150.7	$172.4	$106.5
	High	$497.9	$521.2	$301.4
Population Model with Varying Tenure Model				
Undiscounted (0%)	Low	$421.9	$402.8	$364.6
	Midpoint	$1,443.1	$1,422.2	$982.0
	High	$2,983.4	$2,975.6	$1,877.6
Discounted at 3%	Low	$179.3	$182.8	$169.6
	Midpoint	$790.3	$791.0	$543.0
	High	$1,744.2	$1,751.8	$1,100.2
Discounted at 7%	Low	($0.9)	$20.0	$25.5
	Midpoint	$289.2	$307.2	$206.3
	High	$771.0	$791.5	$489.9
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis				

In the fifth step, OSHA provides a sensitivity analysis to explore the robustness of the estimates of net benefits with respect to many of the assumptions made in developing and applying the underlying models. This is done because the models underlying each step inevitably need to make a variety of assumptions based on limited data. OSHA invited comments on each aspect of the data and methods used in this chapter, and received none specifically on the sensitivity analysis. Because dental laboratories constituted a significant source of both costs and benefits to the proposal, the PEA indicated that OSHA was particularly interested in comments regarding the appropriateness of the model, assumptions, and data for estimating the benefits to workers in that industry. Although the Agency did not receive any comments on this question directly, the American Dental Association's comments relevant to the underlying use of beryllium alloys in dental labs are addressed in Chapter III of the FEA. The Agency has not altered its main estimates of the exposure profile for dental laboratory workers, but provides sensitivity analyses in the FEA to examine the outcome if a lower percentage of dental laboratories were to substitute materials that do not contain beryllium for beryllium-containing materials. OSHA also estimates net benefits with a variety of scenarios in which dental laboratories are not included. All of these results are presented in Chapter VII of the FEA.

H. Regulatory Alternatives

Chapter VIII presents the costs, benefits and net benefits of a variety of regulatory alternatives.

I. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act, (RFA), Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601), requires Federal agencies to consider the economic impact that a final rulemaking will have on small entities. The RFA states that whenever an agency promulgates a final rule that is required to conform to the notice-and-comment rulemaking requirements of section 553 of the Administrative Procedure Act (APA), the agency shall prepare a final regulatory flexibility analysis (FRFA). 5 U.S.C. 604(a).

However, 5 U.S.C. 605(b) of the RFA states that Section 604 shall not apply to any final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. As discussed in Chapter VI of the FEA, OSHA was unable to so certify for the final beryllium rule.

For OSHA rulemakings, as required by 5 U.S.C. 604(a), the FRFA must contain:

1. A statement of the need for, and objectives of, the rule;
2. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. a description of the projected reporting, recordkeeping and other

compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected; and for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

The Regulatory Flexibility Act further states that the required elements of the FRFA may be performed in conjunction with or as part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of the FRFA. 5 U.S.C. 605(a).

In addition to these elements, OSHA also includes in this section the recommendations from the Small Business Advocacy Review (SBAR) Panel and OSHA's responses to those recommendations.

While a full understanding of OSHA's analysis and conclusions with respect to costs and economic impacts on small entities requires a reading of the complete FEA and its supporting materials, this FRFA will summarize the key aspects of OSHA's analysis as they affect small entities.

• The Need for, and Objective of, the Rule

The objective of the final beryllium standard is to reduce the number of fatalities and illnesses occurring among employees exposed to beryllium. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, medical surveillance, and other protective measures necessary to perform their jobs safely. The legal basis for the rule is the responsibility given the U.S. Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act provides that, in promulgating health standards dealing with toxic materials or harmful physical agents, the Secretary ''shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5). See Section II of the preamble for a more detailed discussion.

Chronic beryllium disease (CBD) is a hypersensitivity, or allergic reaction, to beryllium that leads to a chronic inflammatory disease of the lungs. It takes months to years after final beryllium exposure before signs and symptoms of CBD occur. Removing an employee with CBD from the beryllium source does not always lead to recovery. In some cases CBD continues to progress following removal from beryllium exposure. CBD is not a chemical pneumonitis but an immune-mediated granulomatous lung disease. OSHA's final risk assessment, presented in Section VI of the preamble, indicates that there is significant risk of beryllium sensitization and chronic beryllium disease from a 45-year (working life) exposure to beryllium at the current TWA PEL of 2 $\mu g/m^3$. The risk assessment further indicates that there is significant risk of lung cancer to workers exposed to beryllium at the current TWA PEL of 2 $\mu g/m^3$. The final standard, with a lower PEL of 0.2 $\mu g/m^3$, will help to address these health concerns. See the Health Effects and Risk Assessment sections of the preamble for further discussion.

• Summary of Significant Issues Raised by Comments on the Initial Regulatory Flexibility Analysis (IRFA) and OSHA's Assessment of, and Response to, Those Issues

This section of the FRFA focuses only on public comments concerning significant issues raised on the Initial Regulatory Flexibility Analysis (IRFA). OSHA received only one such comment.

The Non-Ferrous Founders' Society claimed that the costs of the rule will disproportionately affect small employers and result in job losses to foreign competition (Document ID 1678, p. 3). This comment is addressed in the FEA in the section on International Trade Effects in Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination. The summary of OSHA's response is that, in general, metalcasters in the U.S. have shortened lead times, improved productivity through computer design and logistics management, expanded design and development services to customers, and provided a higher quality product than foundries in China and other nations where labor costs are low (Document ID 1780, p. 3–12). All of these measures, particularly the higher quality of many U.S. metalcasting products and the ability of domestic foundries to fulfill orders quickly, are substantial advantages for U.S. metalcasters that may outweigh the very modest price increases that might occur due to the final rule. For a more detailed response please see the section on International Trade Effects in Chapter VI of the FEA.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration and OSHA'S Response to Those Comments

The Chief Counsel for Advocacy of the Small Business Administration (''Advocacy'') did not provide OSHA with comments on this rule.

• A Description of, and an Estimate of, the Number of Small Entities To Which the Rule Will Apply

OSHA has analyzed the impacts associated with this final rule, including the type and number of small entities to which the standard will apply. In order to determine the number of small entities potentially affected by this rulemaking, OSHA used the definitions of small entities developed by the Small Business Administration (SBA) for each industry.

OSHA estimates that approximately 6.600 small business entities would be affected by the beryllium standard. Within these small entities, 33,800 workers are exposed to beryllium and would be protected by this final standard. A breakdown, by industry, of the number of affected small entities is provided in Table III–14 in Chapter III of the FEA.

OSHA estimates that approximately 5,280 very small entities—those with fewer than 20 employees—would be affected by the beryllium standard. Within these very small entities, 11,800 workers are exposed to beryllium and would be protected by the standard. A breakdown, by industry, of the number of affected very small entities is provided in Table III–15 in Chapter III of the FEA.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Tables VIII–9 and VIII–10 show the average costs of the beryllium standard and the costs of compliance as a percentage of profits and revenues by NAICS code for, respectively, small entities (classified as small by SBA) and very small entities (those with fewer than 20 employees). The full derivation of these costs is presented in Chapter V. The cost for SBA-defined small entities ranges from a low of $832 per entity for

entities in NAICS 339116a: Dental Laboratories, to a high of about $599,836 for NAICS 331313: Alumina Refining and Primary Aluminum Production.

The annualized cost for very small entities ranges from a low of $542 for entities in NAICS 339116a: Dental Laboratories, to a high of about $34,222 for entities in NAICS 331529b: Other Nonferrous Metal Foundries (except Die-Casting).[32]

[32] The cost of $542 for NAICS 339116a is the sum of a $524 cost to substitute for a non-hazard material and $19 for cost of ancillary provisions. The total cost of $34,222 for NAICS 331529b is the sum of $22,601 for engineering controls, $186 for respirator costs, and $11,435 for ancillary provisions.

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Beryllium Oxide - Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$118,743	--	--
Beryllium Oxide - Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$12,538	0.1%	18.1%
334310	Audio and Video Equipment Manufacturing	$20,325	0.4%	-173.4%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$19,317	0.3%	8.3%
334419	Other Electronic Component Manufacturing	$18,331	0.3%	7.8%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$7,414	0.5%	10.3%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$16,508	1.0%	63.6%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$16,333	0.1%	7.1%
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$0	--	--
Dental Labs Substituting*				
339116a	Dental Laboratories	$832	0.2%	2.1%
621210a	Offices of Dentists	$981	0.1%	1.7%
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$4,315	0.8%	11.0%
621210b	Offices of Dentists	$5,090	0.6%	8.6%
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$79,253	0.1%	6.9%
Machining - High				
332721a	Precision Turned Product Manufacturing	$30,658	0.7%	14.5%
Machining - Low				
332721b	Precision Turned Product Manufacturing	$21,237	0.5%	10.0%
Non-Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$52,387	0.6%	12.1%
331524	Aluminum Foundries (except Die-Casting)	$63,675	1.3%	27.1%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$56,187	1.0%	21.8%
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$82,941	0.1%	7.2%
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$61,501	1.1%	23.8%
Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$36,757	0.1%	5.0%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$26,425	0.0%	2.3%
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$22,398	0.0%	2.2%

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Springs				
332613	Spring Manufacturing	$10,777	0.2%	3.4%
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$11,131	0.2%	4.4%
334417	Electronic Connector Manufacturing	$7,926	0.1%	1.5%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$8,419	0.1%	3.7%
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$4,380	0.0%	0.6%
331221	Rolled Steel Shape Manufacturing	$13,662	0.0%	1.8%
331513	Steel Foundries (except Investment)	$9,473	0.1%	1.9%
332117	Powder Metallurgy Part Manufacturing	$8,783	0.1%	2.4%
332216	Saw Blade and Handtool Manufacturing	$9,018	0.2%	5.5%
332312	Fabricated Structural Metal Manufacturing	$8,243	0.1%	5.1%
332313	Plate Work Manufacturing	$9,998	0.2%	7.1%
332322	Sheet Metal Work Manufacturing	$9,650	0.2%	8.9%
332323	Ornamental and Architectural Metal Work Manufacturing	$9,132	0.4%	15.7%
332439	Other Metal Container Manufacturing	$7,874	0.1%	4.5%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$8,224	0.1%	1.1%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$9,726	0.3%	4.4%
333111a	Farm Machinery and Equipment Manufacturing	$6,431	0.1%	1.1%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$8,622	0.1%	3.4%
333911	Pump and Pumping Equipment Manufacturing	$5,759	0.1%	1.3%
333922	Conveyor and Conveying Equipment Manufacturing	$9,180	0.1%	2.7%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$6,208	0.1%	1.5%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$7,212	0.1%	3.6%
336211	Motor Vehicle Body Manufacturing	$8,159	0.1%	5.1%
336214	Travel Trailer and Camper Manufacturing	$5,388	0.1%	5.7%
336390a	Other Motor Vehicle Parts Manufacturing	$6,784	0.0%	2.3%
336510a	Railroad Rolling Stock Manufacturing	$6,219	0.0%	1.9%
336999	All Other Transportation Equipment Manufacturing	$5,817	0.1%	3.1%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$9,887	0.2%	7.4%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$7,050	0.7%	25.1%
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$16,755	0.2%	7.2%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$11,917	0.1%	2.9%
335210	Small Electrical Appliance Manufacturing	$21,934	0.1%	2.9%
335221	Household Cooking Appliance Manufacturing	$13,257	0.1%	1.5%
335222	Household Refrigerator and Home Freezer Manufacturing	$7,733	0.0%	0.5%

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
335224	Household Laundry Equipment Manufacturing	$1,369	0.0%	0.6%
335228	Other Major Household Appliance Manufacturing	$6,753	0.0%	0.7%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$10,707	0.1%	8.5%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$15,635	0.1%	6.8%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$11,414	0.1%	3.4%
336340	Motor Vehicle Brake System Manufacturing	$16,760	0.1%	4.5%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$12,376	0.1%	3.6%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$13,577	0.1%	4.3%
336370	Motor Vehicle Metal Stamping	$20,274	0.1%	5.4%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$19,867	0.2%	7.7%
336390b	Other Motor Vehicle Parts Manufacturing	$15,723	0.1%	5.3%
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$599,836	0.5%	19.7%
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$41,467	0.0%	3.8%
311221	Wet Corn Milling	$6,657	0.0%	0.3%
311313	Beet Sugar Manufacturing	$10,413	0.0%	0.1%
311942	Spice and Extract Manufacturing	$12,092	0.1%	1.9%
312120	Breweries	$9,720	0.2%	1.5%
321219	Reconstituted Wood Product Manufacturing	$8,314	0.0%	3.4%
322110	Pulp Mills	$3,137	0.0%	0.5%
322121	Paper (except Newsprint) Mills	$7,437	0.0%	0.8%
322122	Newsprint Mills	$11,147	0.0%	0.7%
322130	Paperboard Mills	$7,201	0.0%	1.0%
325211	Plastics Material and Resin Manufacturing	$11,843	0.0%	0.6%
325611	Soap and Other Detergent Manufacturing	$7,622	0.1%	0.9%
327310	Cement Manufacturing	$11,512	0.1%	4.9%
333111b	Farm Machinery and Equipment Manufacturing	$9,096	0.1%	1.5%
336510b	Railroad Rolling Stock Manufacturing	$5,305	0.0%	1.6%
611310	Colleges, Universities, and Professional Schools	$3,773	0.0%	0.6%
Abrasive Blasting - Construction				
238320	Painting and Wall Covering Contractors	$3,430	0.6%	18.7%
238990	All Other Specialty Trade Contractors	$3,175	0.3%	8.8%
Abrasive Blasting Shipyards***				
336611a	Ship Building and Repairing	$1,818	0.0%	0.3%
Welding Shipyards****				
336611b	Ship Building and Repairing	$3,613	0.0%	0.6%
Total				
General Industry Subtotal		**$9,651**	**0.3%**	**8.1%**
Construction Subtotal		**$3,308**	**0.4%**	**12.3%**
Maritime Subtotal		**$1,835**	**0.0%**	**0.3%**
Weighted Average, All Industries		**$6,876**	**0.0%**	**0.9%**

Table VIII-9: Average Costs and Impacts for SBA-Defined Small Entities Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Beryllium Oxide - Primary				
327110a	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$0	--	--
Beryllium Oxide - Secondary				
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	$0	0.00%	0.00%
334310	Audio and Video Equipment Manufacturing	$0	0.00%	0.00%
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	$0	0.00%	0.00%
334419	Other Electronic Component Manufacturing	$0	0.00%	0.00%
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	$0	0.00%	0.00%
327110b	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$0	0.00%	0.00%
336320a	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$0	0.00%	0.00%
Beryllium Production				
331410a	Nonferrous Metal (except Aluminum) Smelting and Refining	$0	--	--
Dental Labs Substituting*				
339116a	Dental Laboratories	$542	0.18%	2.42%
621210a	Offices of Dentists	$872	0.12%	1.67%
Dental Labs - Non-Substituting**				
339116b	Dental Laboratories	$2,812	0.92%	12.54%
621210b	Offices of Dentists	$4,526	0.63%	8.67%
Drawing				
331420c	Copper Rolling, Drawing, Extruding, and Alloying	$9,121	0.26%	12.66%
Machining - High				
332721a	Precision Turned Product Manufacturing	$10,396	0.83%	17.64%
Machining - Low				
332721b	Precision Turned Product Manufacturing	$7,300	0.59%	12.39%
Non-Sand Foundries				
331523	Nonferrous Metal Die-Casting Foundries	$23,395	1.85%	39.11%
331524	Aluminum Foundries (except Die-Casting)	$26,897	3.36%	71.13%
331529a	Other Nonferrous Metal Foundries (except Die-Casting)	$30,747	2.47%	52.38%
Rolling				
331420a	Copper Rolling, Drawing, Extruding, and Alloying	$9,656	0.28%	13.41%
Sand Foundries				
331529b	Other Nonferrous Metal Foundries (except Die-Casting)	$34,222	2.75%	58.30%
Smelting - Beryllium Alloys				
331314	Secondary Smelting and Alloying of Aluminum	$26,479	0.69%	28.12%
331420b	Copper Rolling, Drawing, Extruding, and Alloying	$13,315	0.38%	18.48%
Smelting - Precious Metals				
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$13,081	0.27%	13.12%

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Springs				
332613	Spring Manufacturing	$4,458	0.37%	7.84%
Stamping				
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	$4,587	0.33%	8.19%
334417	Electronic Connector Manufacturing	$3,854	0.34%	8.72%
336320c	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$3,882	0.33%	21.75%
Welding - Arc and Gas				
331110a	Iron and Steel Mills and Ferroalloy Manufacturing	$3,277	0.12%	9.87%
331221	Rolled Steel Shape Manufacturing	$5,201	0.13%	6.14%
331513	Steel Foundries (except Investment)	$5,852	0.48%	10.10%
332117	Powder Metallurgy Part Manufacturing	$6,564	0.31%	7.82%
332216	Saw Blade and Handtool Manufacturing	$3,829	0.51%	12.17%
332312	Fabricated Structural Metal Manufacturing	$3,039	0.21%	7.67%
332313	Plate Work Manufacturing	$3,212	0.28%	10.14%
332322	Sheet Metal Work Manufacturing	$3,372	0.30%	11.06%
332323	Ornamental and Architectural Metal Work Manufacturing	$4,217	0.59%	21.53%
332439	Other Metal Container Manufacturing	$3,287	0.28%	9.33%
332919	Other Metal Valve and Pipe Fitting Manufacturing	$3,936	0.16%	2.70%
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	$3,249	0.38%	6.26%
333111a	Farm Machinery and Equipment Manufacturing	$3,043	0.25%	4.19%
333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	$3,514	0.23%	7.22%
333911	Pump and Pumping Equipment Manufacturing	$3,210	0.12%	3.09%
333922	Conveyor and Conveying Equipment Manufacturing	$3,034	0.18%	4.57%
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	$3,491	0.26%	6.50%
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	$3,040	0.22%	5.49%
336211	Motor Vehicle Body Manufacturing	$3,034	0.20%	13.43%
336214	Travel Trailer and Camper Manufacturing	$3,034	0.25%	16.59%
336390a	Other Motor Vehicle Parts Manufacturing	$3,269	0.19%	12.35%
336510a	Railroad Rolling Stock Manufacturing	$3,877	0.17%	11.02%
336999	All Other Transportation Equipment Manufacturing	$3,924	0.28%	6.47%
337215	Showcase, Partition, Shelving, and Locker Manufacturing	$4,266	0.52%	17.84%
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$4,938	0.76%	27.08%
Welding - Resistance Welding				
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	$3,830	0.25%	7.90%
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	$1,952	0.10%	3.25%
335210	Small Electrical Appliance Manufacturing	$2,165	0.12%	2.70%
335221	Household Cooking Appliance Manufacturing	$1,310	0.11%	2.68%
335222	Household Refrigerator and Home Freezer Manufacturing	$1,310	0.08%	1.82%

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
335224	Household Laundry Equipment Manufacturing	$1,310	0.09%	2.08%
335228	Other Major Household Appliance Manufacturing	$1,310	0.06%	1.41%
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	$1,923	0.20%	13.52%
336320b	Motor Vehicle Electrical and Electronic Equipment Manufacturing	$2,075	0.18%	11.63%
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	$1,470	0.07%	4.62%
336340	Motor Vehicle Brake System Manufacturing	$1,310	0.11%	7.60%
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	$1,315	0.08%	4.98%
336360	Motor Vehicle Seating and Interior Trim Manufacturing	$1,488	0.09%	6.26%
336370	Motor Vehicle Metal Stamping	$2,214	0.10%	6.85%
333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	$4,252	0.28%	8.73%
336390b	Other Motor Vehicle Parts Manufacturing	$1,906	0.11%	7.20%
Aluminum Production				
331313	Alumina Refining and Primary Aluminum Production	$0	0.00%	0.00%
Coal Fired Utilities				
221112	Fossil Fuel Electric Power Generation	$2,626	0.01%	2.39%
311221	Wet Corn Milling	$0	0.00%	0.00%
311313	Beet Sugar Manufacturing	$0	0.00%	0.00%
311942	Spice and Extract Manufacturing	$0	0.00%	0.00%
312120	Breweries	$0	0.00%	0.00%
321219	Reconstituted Wood Product Manufacturing	$0	0.00%	0.00%
322110	Pulp Mills	$0	0.00%	0.00%
322121	Paper (except Newsprint) Mills	$0	0.00%	0.00%
322122	Newsprint Mills	$0	0.00%	0.00%
322130	Paperboard Mills	$0	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	$0	0.00%	0.00%
325611	Soap and Other Detergent Manufacturing	$0	0.00%	0.00%
327310	Cement Manufacturing	$0	0.00%	0.00%
333111b	Farm Machinery and Equipment Manufacturing	$0	0.00%	0.00%
336510b	Railroad Rolling Stock Manufacturing	$0	0.00%	0.00%
611310	Colleges, Universities, and Professional Schools	$0	0.00%	0.00%
Abrasive Blasting - Construction				
238320	Painting and Wall Covering Contractors	$2,504	0.71%	20.34%
238990	All Other Specialty Trade Contractors	$2,289	0.32%	9.28%
Abrasive Blasting Shipyards***				
336611a	Ship Building and Repairing	$1,467	0.10%	1.66%
Welding Shipyards****				
336611b	Ship Building and Repairing	$3,112	0.22%	3.52%
Total				
General Industry Subtotal		$2,956	0.34%	6.06%
Construction Subtotal		$2,402	0.46%	13.22%
Maritime Subtotal		$1,483	0.10%	1.68%

Table VIII-10: Average Costs and Impacts for Very Small Entities (with Fewer than 20 Employees) Affected by the Final Beryllium Standard With Costs Calculated Using a 3 Percent Discount Rate, Continued

Application Group/ NAICS	Industry	Cost Per Entity	Cost to Revenue	Cost to Profit
Total, All Industries		$2,641	0.09%	1.70%

Notes:

Figures in rows may not add to totals due to rounding.

"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 327110a) and Beryllium Oxide (NAICS 331410a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities.

* Application group Dental Labs – Substituting applies to establishments that substitute beryllium-free material for beryllium and incur costs due to the price differential between beryllium-free alloys and alloys that contain beryllium plus the cost of additional training to teach dental technicians how to cast the beryllium-free alloys.

** Application group Dental Labs - Non-Substituting are estabishments with exposures below the PEL that continue to use berylium alloys and incur the cost of the ancillary provisions required by the final standard.

*** Employers in application group Abrasive Blasting – Shipyards are shipyards employing abrasive blasters that use mineral slag abrasives to etch the surfaces of boats and ships.

**** Employers in application group Welding in Shipyards employ welders in shipyards. Some of these employers may do both welding and abrasive blasting.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Description of the Steps OSHA Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes and Statement of the Reasons For Selecting the Alternative Adopted in the Final Rule

OSHA has made a number of changes in the final beryllium rule that will serve to minimize significant impacts on small entities consistent with the objectives of the OSH Act. These changes are explained in more detail in Section XVI: Summary and Explanation in this preamble.

During the SBAR Panel, SERs requested a clearer definition of the triggers for medical surveillance. This concern was rooted in the cost of BeLPTs and the trigger of potential skin contact. For the final rule, the Agency has removed skin contact as a trigger for medical surveillance. OSHA has also reduced the frequency of medical surveillance from annually (in the proposed rule) to biennially in the final rule.

In the final rule, OSHA has added a performance option, as an alternative to scheduled monitoring, to allow employers to comply with exposure assessment requirements. This performance option should allow employers more flexibility, and often lower cost, in complying with the exposure assessment requirements.

Some SERs were already applying many of the protective controls and practices that would be required by the ancillary provisions of the standard. However, many SERs objected to the requirements regarding hygiene facilities. For this final rule, OSHA has concluded that all affected employers currently have hand washing facilities. OSHA has also concluded that no affected employers will be required to install showers. OSHA noted in the PEA that some facilities already have showers. There were no comments challenging the Agency's preliminary determinations regarding the existing availability of shower facilities or the means of preventing contamination, so the Agency concludes that all employers have showers where needed. Therefore, employers will not need to provide any new shower facilities to comply with the standard.[33]

Similarly, in the PEA the Agency included no additional costs for readily accessible washing facilities, under the expectation that employers already have such facilities in place (PEA p. IX–19). Although the abrasive blasters exposed to beryllium in maritime and construction work may not have been expressly addressed in the PEA, OSHA notes that their employers are typically already required to provide readily accessible washing facilities to comply with other OSHA standards such as its sanitation standard at 29 CFR 1926.51(f)(1).[34] In the absence of additional comment, OSHA is not including any costs for washing facilities in the FEA.

OSHA's shipyard standard at 29 CFR 1915.58(e) requires handwashing facilities ''at or adjacent to each toilet facility'' and ''equipped with . . . running water and soap, or with waterless skin-cleansing agents that are capable of . . . neutralizing the contaminants to which the employee may be exposed.'' OSHA's construction standard at 29 CFR 1926.51(f)(1) requires ''adequate washing facilities for employees engaged in . . . operations where contaminants may be harmful to the employees. Such facilities shall be in near proximity to the worksite and shall be so equipped as to enable employees to remove such substances.''

[33] OSHA reached the same conclusion in the PEA (p. V–118). For information purposes, OSHA estimated the initial cost of installing portable showers at $39,687, with an annualized cost of $4,653 per facility (Id.) and did not receive any comments suggesting that shower costs should be included or regarding the cost of installing them. The annual cost per employee for shower supplies, towels, and time required for showering was estimated to be $1,519. However, as indicated above in the text, the Agency believed that employers would be able to comply with the standard by less costly means than the installation of shower facilities.

[34] OSHA's shipyard standard at 29 CFR 1915.58(e) requires handwashing facilities ''at or adjacent to each toilet facility'' and ''equipped with . . . running water and soap, or with waterless skin-cleansing agents that are capable of . . . neutralizing the contaminants to which the employee may be exposed.'' OSHA's construction standard at 29 CFR 1926.51(f)(1) requires ''adequate washing facilities for employees engaged in . . . operations where contaminants may be harmful to the employees. Such facilities shall be in near proximity to the worksite and shall be so equipped as to enable employees to remove such substances.''

The Agency has determined that the long-term rental of modular units was representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.

Finally, in the final rule, OSHA has extended the compliance deadlines for change rooms from one year to two years and for engineering controls from two years to three years.

- Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion presented in Chapter VIII of the FEA, but only for the regulatory alternatives to the final OSHA beryllium standard that would have lowered costs.

Each regulatory alternative presented here is described and analyzed relative to the final rule. Where appropriate, the Agency notes whether the regulatory alternative, to have been a legitimate candidate for OSHA consideration, required evidence contrary to the Agency's final findings of significant risk and feasibility. For this chapter on the Final Regulatory Flexibility Analysis, the Agency is only presenting regulatory alternatives that would have reduced costs for small entities. (See Chapter VIII for the full list of all alternatives analyzed.) There are 14 alternatives that would have reduced costs for small entities (and for all businesses in total). Using the numbering scheme from Chapter VIII of the FEA, these are Regulatory Alternatives #1a, #2a, #2b, #5, #6, #7, #8, #9, #10, #11, #12, #13, #15, #16, #18, and #22. OSHA has organized these 16 cost-reducing alternatives (and a general discussion of considered phase-ins of the rule) into four categories: (1) Scope; (2) exposure limits; (3) methods of compliance; and (4) ancillary provisions.

(1) Scope Alternatives

The scope of the beryllium final rule applies to general industry work, construction and maritime activities. In addition, the final rule provides an exemption for those working with materials containing only trace amounts of beryllium (less than 0.1% by weight) when the employer has objective data that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

The first set of regulatory alternatives would alter the scope of the final standard by differing in coverage of groups of employees and employers. Regulatory Alternatives #1a, #2a, and #2b would decrease the scope of the final standard.

Regulatory Alternative #1a would exclude all operations where beryllium exists only as a trace contaminant; that is, where the materials used contain less than 0.1% beryllium by weight, with no other conditions. OSHA has identified two industries with workers engaged in general industry work that would be excluded under Regulatory Alternative #1a: Primary aluminum production and coal-fired power generation.

Table VIII–11 presents, for informational purposes, the estimated costs, benefits, and net benefits of Regulatory Alternative #1a using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of this alternative relative to the final rule. Table VIII–11 also breaks out costs by provision, and benefits by type of disease and by morbidity/mortality prevented. (Note: ''morbidity'' cases are cases where health effects are limited to non-fatal illness; in these cases there is no further disease progression to fatality).

As shown in Table VIII–11, Regulatory Alternative #1a would decrease the annualized cost of the rule from $73.9 million to $64.6 million using a 3 percent discount rate and from $76.6 million to $67.0 million using a 7 percent discount rate. Annualized benefits in monetized terms would decrease from $560.9 million to $515.7 million, using a 3 percent discount rate, and from $249.1 million to $229.0 million using a 7 percent discount rate. Net benefits would decrease from $487.0 million to $451.1 million using a 3 percent discount rate and from $172.4 million to $162.0 million using a 7 percent discount rate.

Table VIII-11 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Alternative Scope (Regulatory Alternative #1a) (2015 Million Dollars)

	Rule (PEL = 0.2 μg/m³, AL = 0.10 μg/m³)			Alternative 1a (Remove trace contaminants)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$11.6	$12.5		-$0.7	-$0.7
Respirators		$0.3	$0.3		$0.3	$0.3		$0.0	$0.0
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		$0.0	$0.0
Exposure Assessment		$13.7	$14.4		$10.7	$11.1		-$3.1	-$3.2
Regulated Areas		$0.9	$0.9		$0.9	$0.9		$0.0	$0.0
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.1		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$6.4	$6.6		-$1.0	-$1.1
Medical Removal		$1.2	$1.3		$1.0	$1.1		-$0.2	-$0.2
Exposure Control Plan		$2.3	$2.4		$2.1	$2.2		-$0.2	-$0.2
Protective Clothing and Equipment		$2.0	$2.0		$1.8	$1.8		-$0.2	-$0.2
Hygiene Areas and Practices		$2.4	$2.4		$2.4	$2.4		$0.0	$0.0
Housekeeping		$22.8	$23.2		$20.0	$20.4		-$2.8	-$2.9
Training		$8.3	$8.3		$7.3	$7.3		-$1.0	-$1.0
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$64.6**	**$67.0**		**-$9.3**	**-$9.7**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			79			-7		
Beryllium-Related Mortality	90	$558.0	$247.5	83	$513.1	$227.5	-7	-$44.9	-$19.9
Beryllium Morbidity	46	$2.9	$1.6	42	$2.6	$1.5	-4	-$0.2	-$0.1
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$515.7**	**$229.0**		**-$45.2**	**-$20.1**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$451.1**	**$162.0**		**-$35.9**	**-$10.4**

Notes:

Figures in rows may not add to totals due to rounding.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Regulatory Alternative #2a would exclude construction and maritime work from the scope of the final standard. For example, this alternative would exclude abrasive blasters, pot tenders, and cleanup staff working in

construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media.

Table VIII–12 presents the estimated costs, benefits, and net benefits of Regulatory Alternative #2a using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of these alternatives relative to the final rule. Table VIII–12 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As shown in Table VIII–12, Regulatory Alternative #2a would decrease costs from $73.9 million to $62.0 million, using a 3 percent discount rate, and from $76.6 million to $64.4 million using a 7 percent discount rate. Annualized benefits would decrease from $560.9 million to $533.3 million, using a 3 percent discount rate, and from $249.1 million to $236.8 million using a 7 percent discount rate. Net benefits would change from $487.0 million to $471.3 million, using a 3 percent discount rate, and is essentially unchanged at a discount rate of 7 percent, with the final rule having net benefits of $172.4 million while the alternative has $172.5 million. Thus, at a 7 percent discount rate, the costs exceed the benefits for this alternative by $0.1 million per year. However, OSHA believes that for these industries, the cost estimate is severely overestimated because 45 percent of the costs are for exposure monitoring assuming that employers use the periodic monitoring option. Employers in this sector are far more likely to use the performance based monitoring options at considerably reduced costs. If this is the case, benefits would exceed costs even at a 7 percent discount rate.

Regulatory Alternative #2b would eliminate the ancillary provisions in the final rule for the shipyard and construction sectors and for any operations where beryllium exists only as a trace contaminant. Accordingly, only the final TWA PEL and STEL would apply to employers in these sectors and operations (through 29 CFR 1910.1000 Tables Z–1 and Z–2, 1915.1000 Table Z, and 1926.55 Appendix A). Operations in general industry where the ancillary provisions would be eliminated under Regulatory Alternative #2b include aluminum smelting and production and coal-powered utility facilities and any other operations where beryllium is present only as a trace contaminant (in addition to all operations in construction and shipyards).

As shown in Table VIII–13, Regulatory Alternative #2b would decrease the annualized cost of the rule from $73.9 million to $53.5 million using a 3 percent discount rate, and from $76.6 to $55.6 million using a 7 percent discount rate. Annualized benefits would decrease from $560.9 million to $493.3 million, using a 3 percent discount rate, and from $249.1 million to $219.1 million, using a 7 percent discount rate. Net benefits would decrease from $487.0 million to $439.8 million, using a 3 percent discount rate, and from $172.4 million to $163.5 million, using a 7 percent discount rate.

Table VIII-12 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Alternative Scope Excluding Maritime and Construction (Regulatory Alternative #2a) (2015 Million Dollars)

	Rule (PEL = 0.2 μg/m^3, AL = 0.10 μg/m^3)			Alternative 2a (Remove Maritime and Construction Sectors)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$12.2	$13.2		$0.0	$0.0
Respirators		$0.3	$0.3		$0.3	$0.3		$0.0	$0.0
Rule Familiarization		$0.2	$0.2		$0.1	$0.1		-$0.1	-$0.1
Exposure Assessment		$13.7	$14.4		$8.5	$8.9		-$5.3	-$5.4
Regulated Areas		$0.9	$0.9		$0.6	$0.6		-$0.3	-$0.3
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.2		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$6.0	$6.2		-$1.4	-$1.5
Medical Removal		$1.2	$1.3		$0.7	$0.7		-$0.5	-$0.6
Exposure Control Plan		$2.3	$2.4		$2.1	$2.2		-$0.2	-$0.2
Protective Clothing and Equipment		$2.0	$2.0		$1.8	$1.8		-$0.2	-$0.2
Hygiene Areas and Practices		$2.4	$2.4		$0.9	$0.9		-$1.5	-$1.6
Housekeeping		$22.8	$23.2		$21.1	$21.6		-$1.6	-$1.7
Training		$8.3	$8.3		$7.5	$7.6		-$0.8	-$0.8
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$62.0**	**$64.4**		**-$11.9**	**-$12.3**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			81			-4		
Beryllium-Related Mortality	90	$558.0	$247.5	85	$530.6	$235.3	-4	-$27.4	-$12.2
Beryllium Morbidity	46	$2.9	$1.6	44	$2.7	$1.5	-2	-$0.1	-$0.1
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$533.3**	**$236.8**		**-$27.6**	**-$12.3**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$471.3**	**$172.5**		**-$15.7**	**$0.0**

Notes:

Figures in rows may not add to totals due to rounding.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Table VIII-13 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of Updating Z Tables 1910.1000, 1915.1000, and 1926.55 and Requiring Control Costs for Industries with Trace Contaminants (Regulatory Alternative #2b) (2015 Million Dollars)

	Rule (PEL = 0.2 μg/m³, AL = 0.1 μg/m³)			Alternative 2b (Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants)			Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$12.3	$13.3		$0.0	$0.0
Respirators		$0.3	$0.3		$0.3	$0.3		-$0.1	-$0.1
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		$0.0	$0.0
Exposure Assessment		$13.7	$14.4		$5.4	$5.7		-$8.3	-$8.7
Regulated Areas		$0.9	$0.9		$0.6	$0.6		-$0.3	-$0.3
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.1		$0.0	$0.0
Medical Surveillance		$7.4	$7.7		$5.0	$5.1		-$2.4	-$2.6
Medical Removal		$1.2	$1.3		$0.5	$0.5		-$0.7	-$0.8
Exposure Control Plan		$2.3	$2.4		$1.9	$1.9		-$0.5	-$0.5
Protective Clothing and Equipment		$2.0	$2.0		$1.6	$1.6		-$0.4	-$0.4
Hygiene Areas and Practices		$2.4	$2.4		$0.9	$0.9		-$1.6	-$1.6
Housekeeping		$22.8	$23.2		$18.3	$18.7		-$4.4	-$4.5
Training		$8.3	$8.3		$6.5	$6.6		-$1.8	-$1.8
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$53.5**	**$55.6**		**-$20.4**	**-$21.1**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			75			-11		
Beryllium-Related Mortality	90	$558.0	$247.5	79	$490.8	$217.7	-11	-$67.2	-$29.8
Beryllium Morbidity	46	$2.9	$1.6	40	$2.5	$1.4	-6	-$0.4	-$0.2
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$493.3**	**$219.1**		**-$67.5**	**-$30.0**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$439.8**	**$163.5**		**-$47.2**	**-$8.9**

Notes:

Figures in rows may not add to totals due to rounding.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

(2) Exposure Limit (TWA PEL, STEL, and Action Level) Alternatives

Paragraph (c) of the three final standards establishes two PELs for beryllium in all forms, compounds, and mixtures: An 8-hour TWA PEL of 0.2 μg/m³ (paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³ (paragraph (c)(2)). OSHA has defined the action level for the final standard as an airborne concentration of beryllium of 0.1 μg/m³ calculated as an eight-hour TWA (paragraph (b)). In this final rule, as in other standards, the action level has been set at one half of the TWA PEL.

Regulatory Alternative #5 would set a higher TWA PEL at 0.5 μg/m³ and an action level at 0.25 μg/m³. This alternative responds to an issue raised during the Small Business Advocacy Review (SBAR) process conducted in 2007 to consider a draft OSHA beryllium proposed rule that culminated in an SBAR Panel report (SBAR, 2008). That report included a recommendation that OSHA consider both the economic impact of a low TWA PEL and regulatory alternatives that would ease cost burden for small entities. OSHA has provided a full analysis of the economic impact of its final PELs (see Chapter VI of the FEA), and Regulatory Alternative #5 was considered in response to the second half of that recommendation. However, the higher 0.5 μg/m³ TWA PEL is not consistent with the Agency's mandate under the OSH Act to promulgate a lower PEL if it is feasible and could prevent additional fatalities and non-fatal illnesses. The data presented in Table VIII–14 below indicate that the final TWA PEL would prevent additional fatalities and non-fatal illnesses relative to Regulatory Alternative #5.

Table VIII–14 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the final rule under the final TWA PEL of 0.2 μg/m³ and for the regulatory alternative TWA PEL of 0.5 μg/m³ (Regulatory Alternative #5), using alternative discount rates of 3 percent and 7 percent. In addition, the table presents the incremental costs, the incremental benefits, and the incremental net benefits of going from a TWA PEL of 0.5 μg/m³ to the final TWA PEL of 0.2 μg/m³. Table VIII–14 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As Table VIII–14 shows, going from a TWA PEL of 0.5 μg/m³ to a TWA PEL of 0.2 μg/m³ would prevent, annually, an additional 30 beryllium-related fatalities and an additional 16 non-fatal illnesses. This is consistent with OSHA's final risk assessment, which indicates significant risk to workers exposed at a TWA PEL of 0.5 μg/m³; furthermore, OSHA's final feasibility analysis indicates that a lower TWA PEL than 0.5 μg/m³ is feasible. Net benefits of this regulatory alternative versus the final TWA PEL of 0.2 μg/m³ would decrease from $487.0 million to $376.5 million using a 3 percent discount rate and from $172.4 million to $167.2 million using 7 percent discount rate.

Table VIII-14 Annualized Costs, Benefits and Incremental Benefits of OSHA's Final Beryllium Standard of 0.1 µg/m3 and 0.5 µg/m3 PEL Alternative (Regulatory Alternatives #4 and #5) (2015 Million Dollars)

	Rule (PEL = 0.2 µg/m3, AL = 0.10 µg/m3)			Alternative 5 (PEL = 0.5 µg/m3, AL = 0.25 µg/m3)			Alternative 5 Incremental Costs/Benefits		
	Cases	3%	7%	Cases	3%	7%	Cases	3%	7%
Annualized Costs									
Control Costs		$12.3	$13.3		$7.6	$8.2		**$4.7**	**$5.1**
Respirators		$0.3	$0.3		$0.2	$0.2		**$0.1**	**$0.1**
Rule Familiarization		$0.2	$0.2		$0.2	$0.2		**$0.0**	**$0.0**
Exposure Assessment		$13.7	$14.4		$7.8	$8.4		**$5.9**	**$5.9**
Regulated Areas		$0.9	$0.9		$0.5	$0.5		**$0.4**	**$0.4**
Beryllium Work Areas		$0.1	$0.2		$0.1	$0.2		**$0.0**	**$0.0**
Medical Surveillance		$7.4	$7.7		$4.9	$5.1		**$2.5**	**$2.6**
Medical Removal		$1.2	$1.3		$0.3	$0.4		**$0.8**	**$0.9**
Exposure Control Plan		$2.3	$2.4		$2.3	$2.4		**$0.0**	**$0.0**
Protective Clothing and Equipment		$2.0	$2.0		$2.0	$2.0		**$0.0**	**$0.0**
Hygiene Areas and Practices		$2.4	$2.4		$1.6	$1.6		**$0.8**	**$0.8**
Housekeeping		$22.8	$23.2		$22.8	$23.2		**$0.0**	**$0.0**
Training		$8.3	$8.3		$8.3	$8.3		**$0.0**	**$0.0**
Total Costs (Point Estimate)		**$73.9**	**$76.6**		**$58.6**	**$60.7**		**$15.3**	**$15.9**
Annual Benefits: Number of Cases Prevented									
Fatal Lung Cancers (Midpoint Estimate)	4			4			0		
Fatal Chronic Beryllium Disease	86			56			29		
Beryllium-Related Mortality	90	$558.0	$247.5	60	$374.6	$166.2	30	**$183.4**	**$81.3**
Beryllium Morbidity	46	$2.9	$1.6	30	$1.9	$1.1	16	**$1.0**	**$0.5**
Monetized Annual Benefits (Midpoint Estimate)		**$560.9**	**$249.1**		**$376.5**	**$167.2**		**$184.4**	**$81.9**
Net Benefits									
Net Benefits		**$487.0**	**$172.4**		**$376.5**	**$167.2**		**$110.5**	**$5.2**

Notes:

Figures in rows may not add to totals due to rounding.

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Regulatory Alternative With Unchanged PEL But Full Ancillary Provisions

An Informational Analysis: This final regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits that OSHA estimated would come from the ancillary provisions rather than from meeting the PEL solely with engineering controls (see Chapter VII of the FEA for a more detailed discussion). OSHA decided to analyze for informational purposes the effect of retaining the preceding PEL but applying all of the ancillary provisions, including respiratory protection. Under this approach, the TWA PEL would remain at 2.0 micrograms per cubic meter, but all of the other final provisions (including respiratory protection) would be required with their triggers remaining the same as in the final rule—either the presence of airborne beryllium at any level (*e.g.,* initial monitoring, written exposure control plan), at certain kinds of dermal exposure (PPE), at the action level of 0.1 μg/m³ (*e.g.,* periodic monitoring, medical removal), or at 0.2 μg/m³ (*e.g.,* regulated areas, respiratory protection, medical surveillance).

Given the record regarding beryllium exposures, this approach is not one OSHA could legally adopt. The absence of engineering controls would not be consistent with OSHA's application of the hierarchy of controls, in which engineering controls are applied to eliminate or control hazards, before administrative controls and personal protective equipment are applied to address remaining exposures. Section 6(b)(5) of the OSH Act requires OSHA to ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' For that reason, this additional analysis is provided strictly for informational purposes. E.O. 12866 and E.O. 13563 direct agencies to identify approaches that maximize net benefits, and this analysis is purely for the purpose of exploring whether this approach would hold any real promise to maximize net benefits if it was permissible under the OSH Act. It does not appear to hold such promise because an ancillary-provisions-only approach would not be as protective and thus offers fewer benefits than one that includes a lower PEL and engineering controls. Also, OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional final approach.

When examined on an industry-by-industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provision-only approach. Some employers would use engineering controls where they are cheaper, even if they are not mandatory. OSHA does not have sufficient information to do an analysis employer-by-employer of when the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no cost savings to the ancillary-provisions-only approach. However, OSHA estimates an annualized total cost saving of $2.7 million per year for entire industries where the ancillary-provisions-only approach would be less expensive.

The above discussion does not account for the possibility that the lack of engineering controls would result in higher beryllium exposures for workers in adjacent (non-production) work areas due to the increased level of beryllium in the air. Because of a lack of data, and because the issue did not arise in the other regulatory alternatives OSHA considered (all of which have a PEL of less than 2.0 μg/m³), OSHA did not examine exposure levels in non-production areas for either cost or benefit purposes. To the extent such exposure levels would be above the action level, there would be additional costs for respiratory protection and medical surveillance.

If respirators were as effective as engineering controls, the ancillary-provisions-only approach would have benefits comparable to the benefits of the final rule. However, in this alternative most exposed individuals would be required to use respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA also examined what the benefits would be if respirators were not required, were not worn, or were ineffective. OSHA found that, if all of the other aspects of the benefits analysis remained the same, the annualized benefits would be reduced by from $33.2 million using a discount rate of 3 percent, and $22.4 using a discount rate of 7 percent, largely as a result of failing to reduce deaths from lung cancer, which are unaffected by the ancillary provisions. However, there are also other reasons to believe that benefits may be even lower:

(1) As noted above, in the final rule OSHA did not consider benefits caused by reductions in exposure in non-production areas. Unless employers act to reduce exposures in the production areas, the absence of a requirement for such controls would largely negate such benefits from reductions in exposure in the non-productions areas.

(2) OSHA judges that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD for all sectors except for abrasive blasting and coal-fired power plants, and an estimate of 11.25 percent, or one fourth of the percentage for other sectors, for abrasive blasting and coal-fired power plants) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The Agency's high estimate (90 percent for all sectors except abrasive blasting and coal fired power plants, 22.5 percent for abrasive blasting and coal-fired power plants) of the proportion of remaining CBD cases eliminable by ancillary provisions is based on data from a facility with average exposure levels of less than 0.2 μg/m³.

Based on these considerations, OSHA finds that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The cost savings, if any, are estimated to be small, and the difficult-to-measure declines in benefits could be substantial.

(2) A Method-of-Compliance Alternative

Paragraph (f)(2)(i) of the final standards contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in general industry, maritime, and construction. For each operation in a beryllium work area in general industry or where exposures are or can reasonably be expected to be above the action level in shipyards or construction, employers must ensure that one or more of the following are in place to minimize employee exposure: Material and/or process substitution; isolation, such as ventilated partial or full enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using these methods only when they can show that such methods are not feasible or where exposures are below the action level based on two exposure samples taken at least seven days apart.

OSHA believes that the methods outlined in paragraph (f)(2)(i) provide the most reliable means to control variability in exposure levels. However, OSHA also recognizes that the requirements of paragraph (f)(2)(i) are not typical of OSHA standards, which usually require engineering controls

only where exposures exceed the TWA PEL or STEL. The Agency therefore also considered Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the final standard and make conforming edits to paragraphs (f)(2)(ii) and (iii). This regulatory alternative does not eliminate the need for engineering controls to comply with the final TWA PEL and STEL, but does eliminate the requirement to use one or more of the specified engineering or work practice controls where exposures equal or exceed the action level. As shown in Table VIII–15, Regulatory Alternative #6 would decrease the annualized cost of the final rule by $606,706 using a discount rate of 3 percent and by $638,100 using a discount rate of 7 percent.

In the PEA, OSHA had been unable to estimate the benefits of this alternative and invited public comment. The Agency did not receive public comment and therefore has not estimated the change in benefits resulting from Regulatory Alternative #6.

Table VIII-15 Cost of Regulatory Alternative #6 (Eliminate provision (f)(2)) (2015 dollars)

	Total Cost	Increment Relative to Rule
3% Discount Rate		
Rule	$73,868,230	-
Alternative 6: Eliminate (f)(2) controls	$73,261,523	-$606,706
7% Discount Rate		
Rule	$76,637,363	-
Alternative 6: Eliminate (f)(2) controls	$75,999,263	-$638,100
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis		

(4) Regulatory Alternatives That Affect Ancillary Provisions

The final standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, competent person, and regulated areas or access control. As reported in Chapter V of the FEA, these ancillary provisions account for $61.3 million (about 83 percent) of the total annualized costs of the rule ($73.4 million) using a 3 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and exposure monitoring, with annualized costs of $22.8 million and $13.7 million, respectively, at a 3 percent discount rate.

OSHA's reasons for including each of the final ancillary provisions are explained in Section XVI of the preamble, Summary and Explanation of the Standards.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the final ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the final rule are summarized in Table VIII–16 at the end of this section. OSHA has determined that several of these ancillary provisions will increase the benefits of the final rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the final TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for exposure monitoring (#9, #10, and #11), for regulated areas (#12), for personal protective clothing and equipment (#13), for medical surveillance (#14 through #20), and for medical removal protection (#22).

All Ancillary Provisions

The SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider not applying ancillary provisions of the standard where exposure levels are low so as to minimize costs for small businesses (SBAR, 2008). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would apply ancillary provisions of the beryllium standard only where exposures exceed the final TWA PEL of 0.2 μg/m^3 or the final STEL of 2.0 μg/m^3.

Regulatory Alternative #7 would only update 1910.1000 Tables Z–1 and Z–2, so that the final TWA PEL and STEL would apply to all workers in general industry, construction, and maritime. This alternative would eliminate all of the ancillary provisions of the final rule, including exposure assessment, medical surveillance, medical removal protection, PPE, housekeeping, training, competent person, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the final ancillary provisions of the rule (estimated at $61.4 million annually at a 3 percent discount rate) would be eliminated. In order to meet the PELs, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that, under this alternative, many employers would follow the recommendations of Materion and the United Steelworkers to provide medical surveillance, PPE, and other protective measures for their workers (Materion and United Steelworkers, 2012). OSHA has not attempted to estimate the extent to which these ancillary provision costs would be incurred if they were not formally required or whether any of

these costs under Regulatory Alternative #7 would reasonably be attributable to the final rule. The total costs for this alternative are $12.5 million at a 3% discount rate and $13.5 million at a 7% discount rate.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule, presented in Table VIII–16. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 71 percent, relative to the final rule, from $560.9 million to $211.9 million, using a 3 percent discount rate, and from $249.1 million to $94.0 million using a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the FEA, which found that about 68 percent of the benefits of the final rule, evaluated at their mid-point value, were attributable to the combination of the ancillary provisions. As these estimates show, OSHA expects that the benefits estimated under the final rule will not be fully achieved if employers do not implement the ancillary provisions of the final rule.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to beryllium. The stakeholders' recommended standard—that representatives of Materion, the primary beryllium producer, and the United Steelworkers union provided to OSHA—confirms the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and United Steelworkers, 2012). Ancillary provisions such as personal protective clothing and equipment, regulated areas, medical surveillance, hygiene areas, housekeeping requirements, and hazard communication all serve to reduce the risks to beryllium-exposed workers beyond that which the final TWA PEL alone could achieve.

Under Regulatory Alternative #8, several ancillary provisions that the current final rule would require under a variety of exposure conditions (*e.g.,* dermal contact, any airborne exposure, exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL.

Regulatory Alternative #8 affects the following provisions of the final standard:

—*Exposure monitoring:* Whereas the scheduled monitoring option of the final standards requires monitoring every six months when exposure levels are at or above the action level and at or below the TWA PEL and every three months when exposure levels exceed the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring where exposure levels exceed the TWA PEL or STEL;

○ *Written exposure control plan:* Whereas the final standards require written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;

○ *PPE:* Whereas the final standards require PPE when airborne exposure to beryllium exceeds, or can reasonably be expected to exceed, the PEL or STEL, and where there is a reasonable expectation of dermal contact with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;

○ *Medical Surveillance:* Whereas the final standard's medical surveillance provisions require employers to offer medical surveillance to employees exposed above the action level for 30 days per year, showing signs or symptoms of CBD, exposed to beryllium in an emergency, or when recommended by a medical opinion, Alternative #8 would require surveillance only for those employees exposed above the TWA PEL or STEL.

To estimate the cost savings for this alternative, OSHA re-estimated the group of workers that would fall under the above provisions, with results presented in Table VIII–16. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the final rule would decline from $73.9 million to $35.8 million, using a 3 percent discount rate, and from $76.6 million to $37.9 million, using a 7 percent discount rate.

The Agency has not quantified the impact of this alternative on the benefits of the rule. However, ancillary provisions that offer protective measures to workers exposed below the final TWA PEL, such as personal protective clothing and equipment, beryllium work areas, hygiene areas, housekeeping requirements, and hazard communication, all serve to reduce the risks to beryllium-exposed workers beyond that which the final TWA PEL and STEL could achieve.

The remainder of this chapter discusses additional regulatory alternatives that apply to individual ancillary provisions.

Exposure Monitoring

Paragraph (d) of the final standard, Exposure Assessment, allows employers to choose either the performance option or scheduled monitoring. The scheduled monitoring option requires semi-annual monitoring for those workers exposed at or above the action level but at or below the PEL and quarterly exposure monitoring for those workers exposed above the PEL. The rationale for this provision is provided in the preamble discussion of paragraph (a) in Section XVI, Summary and Explanation of the Standards.

OSHA has examined three regulatory alternatives that would modify the requirements of periodic monitoring in the final rule. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring annually when exposures are at or above the action level or above the STEL, but at or below the TWA PEL. As shown in Table VIII–16, Regulatory Alternative #9 would decrease the annualized cost of the final rule by about $4.3 million using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring annually when exposures are at or above the action level. As shown in Table VIII–16, Regulatory Alternative #10 would decrease the annualized cost of the final rule by about $4.9 million using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #11, employers would be required to perform annual exposure monitoring where exposures are at or above the action level but at or below the TWA PEL and STEL. When exposures are above the TWA PEL, no periodic monitoring would be required. As shown in Table VIII–16, Regulatory Alternative #11 would decrease the annualized cost of the final rule by about $5.0 million using either a 3 percent or 7 percent discount rate. OSHA is unable to quantify the effect of this change on benefits but has judged the alternative adopted necessary and protective.

Regulated Areas

Final paragraph (e) for General Industry requires employers to establish and maintain beryllium work areas in any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium, and regulated areas wherever airborne concentrations of beryllium exceed, or can reasonably be expected to

exceed, the TWA PEL or STEL. The Shipyards standard also requires regulated areas. The Construction standard has a comparable competent person requirement. Employers in General Industry and Shipyards are required to demarcate regulated areas and limit access to regulated areas to authorized persons.

The SBAR Panel report recommended that OSHA consider dropping or limiting the provision for regulated areas (SBAR, 2008). In response to this recommendation, OSHA examined Regulatory Alternative #12, which would eliminate the requirement that employers establish regulated areas in the General Industry and Maritime standards, and eliminate the competent person requirement in the Construction standard. This alternative would not eliminate the final requirement to establish beryllium work areas, where required. As shown in Table VIII–16, Regulatory Alternative #12 would decrease the annualized cost of the final rule by about $1.0 million using either a 3 or 7 percent discount rate.

Personal Protective Clothing and Equipment

Regulatory Alternative #13 would modify the requirements for personal protective equipment (PPE) by eliminating the requirement for appropriate PPE whenever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. This alternative would be narrower, and thus less protective, than the PPE requirement in the final standards, which require PPE to be used where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL, or where there is a reasonable expectation of dermal contact with beryllium.

The economic analysis for the final standard already contains costs for protective clothing, namely gloves, for all employees who can reasonably be expected to be have dermal contact with beryllium; thus OSHA estimated the cost of this alternative as the cost reduction from not providing gloves under these circumstances. As shown in Table VIII–16, Regulatory Alternative #13 would decrease the annualized cost of the final rule by about $481,000 using either a 3 percent or 7 percent discount rate.

- Medical Surveillance

The final requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are or are reasonably expected to be exposed to beryllium at or above the action level for more than 30 days per year, who show signs or symptoms of CBD or other beryllium-related health effects, are exposed to beryllium in an emergency, or whose more recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends such surveillance, and (2) low dose CT scans for employees when recommended by the PLCHP. The final standards require biennial medical exams to be provided for eligible employees. The standards also require tests for beryllium sensitization to be provided to eligible employees biennially.

OSHA estimated in Chapter V of the FEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive medical surveillance.[35] In Chapter V of the FEA, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the final standard. The Agency's final analysis indicates that 4 workers with beryllium sensitization and 6 workers with CBD will be referred to a CBD diagnostic center annually as a result of this medical surveillance. Medical surveillance is particularly important for this rule because beryllium-exposed workers, including many workers exposed below the final PELs, are at significant risk of illness.[36]

OSHA has examined four regulatory alternatives (#15, #16, #18, and #22) that would modify the final rule's requirements for employee eligibility, the tests that must be offered, and the frequency of periodic exams. Medical surveillance was a subject of special concern to SERs during the SBAR Panel process, and the SBAR Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been partially addressed in this final rule, which was modified since the SBAR Panel was convened (see the preamble at Section XVI, Summary and Explanation of the Standards, for more detailed discussion). Regulatory Alternative #16 also responds to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements.

OSHA has determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the final TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see the preamble at Section V, Health Effects, and Section VII, Significance of Risk). The Agency therefore anticipates that more employees would develop adverse health effects without receiving the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see section XVI of this preamble, the Summary and Explanation for paragraph (k)).

Regulatory Alternative #15 would decrease eligibility for medical surveillance to employees who are exposed to beryllium above the final PEL

To estimate the cost of Regulatory Alternative #15, OSHA assumed that all workers exposed above the PEL before the final rule would continue to be exposed after the standard is promulgated. Thus, this alternative eliminates costs for medical exams for the number of workers exposed between the action level and the TWA PEL. As shown in Table VIII–16, Regulatory Alternative #15 would decrease the annualized cost of the final rule by about $4.5 million using a discount rate of 3 percent, and by about $4.8 million using a discount rate of 7 percent.

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA considered two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. As shown in Table VIII–16, this alternative would decrease the annualized cost of the final rule by about $2.4 million using either a 3 percent or 7 percent discount rate.

Regulatory Alternative #18 would eliminate the CT scan requirement from the final rule. This alternative would decrease the annualized cost of the final rule by about $613,000 using a discount rate of 3 percent, and by about $643,000 using a discount rate of 7 percent.

- Medical Removal

Under paragraph (l) of the final standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they provide their employers with a written medical report indicating they are diagnosed with CBD or confirmed positive for beryllium sensitization, or if a written medical opinion recommends medical removal

[35] See baseline compliance rates for medical surveillance in Chapter III of the FEA, Table III–20.

[36] OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

in accordance with the medical surveillance paragraph of the standards. When an employee chooses removal, the employer is required to remove the employee to comparable work in an environment where beryllium exposure is below the action level if such work is available and the employee is either already qualified or can be trained within one month. If comparable work is not available, the employer must place the employee on paid leave for six months or until comparable work becomes available (whichever comes first). Or, rather than choosing removal, an eligible employee could choose to remain in a job with exposure at or above the action level, in which case the employer would have to provide, and the employee would have to use, a respirator.

The SBAR Panel report included a recommendation that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (SBAR, 2008). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would remove the final requirement that employers offer MRP. As shown in Table VIII–16, this alternative would decrease the annualized cost of the final rule by about $1.2 million using a discount rate of 3 percent, and by about $1.3 million using a discount rate of 7 percent.

Table VIII-16 Cost of Regulatory Alternatives Affecting Ancillary Provisions (2015 dollars)				
	Total Cost	Incremental Cost Relative to Rule	Benefits	Incremental Benefits Relative to Rule
3% Discount Rate				
Rule	$73,868,230	-	$560,873,424	-
Alternative 7: Update Z table 1910.1000 only (No ancillary provisions)	$12,516,905	-$61,351,325	$211,870,162	-$349,003,262
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$35,794,047	-$38,074,183		
Alternative 9: Annual periodic monitoring between AL/STEL and PEL	$69,544,910	-$4,323,319		
Alternative 10: Annual periodic monitoring AL/STEL to PEL and > PEL.	$69,021,502	-$4,846,728		
Alternative 11: Annual periodic monitoring when exposure above AL/STEL, biannual monitoring when exposure above PEL	$68,847,033	-$5,021,197		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$72,854,475	-$1,013,754		
Alternative 13: No PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$73,387,012	-$481,217		
Alternative 15: Medical surveillance applies to workers above the PEL post-rule	$69,405,421	-$4,462,809		
Alternative 16: No BeLPTs in medical surveillance	$71,492,837	-$2,375,392		
Alternative 17: BeLPTs part of annual exam, rather than biennially.	$76,666,395	$2,798,166		
Alternative 18: No CT Scans	$73,236,886	-$631,343		
Alternative 22: No medical removal protection	$72,717,171	-$1,151,058		
7% Discount Rate				
Rule	$76,637,363	-	$249,078,679	-
Alternative 7: Update Z table 1910.1000 only (No ancillary provisions)	$13,541,714	-$63,095,649	$94,023,516	-$155,055,163
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	$37,894,318	-$38,743,045		
Alternative 9: Annual periodic monitoring between AL/STEL and PEL	$72,314,044	-$4,323,319		
Alternative 10: Annual periodic monitoring AL/STEL to PEL and > PEL.	$71,790,636	-$4,846,728		
Alternative 11: Annual periodic monitoring when exposure above AL/STEL, biannual monitoring when exposure above PEL	$71,616,166	-$5,021,197		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	$75,594,292	-$1,043,071		
Alternative 13: No PPE wherever there is contact with beryllium or beryllium contaminated surfaces	$76,156,146	-$481,217		
Alternative 15: Medical surveillance applies to workers above the PEL post-rule	$71,882,838	-$4,754,525		
Alternative 16: No BeLPTs in medical surveillance	$74,214,979	-$2,422,384		
Alternative 17: BeLPTs part of annual exam, rather than biennially.	$79,356,557	$2,719,194		
Alternative 18: No CT Scans	$75,994,175	-$643,188		
Alternative 22: No medical removal protection	$75,338,041	-$1,299,322		
Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis				

SBAR Panel

Table VIII–17 lists all of the SBAR Panel recommendations and OSHA's response to those recommendations.

• Table VIII–17: SBAR Panel Recommendations and OSHA Responses

Panel recommendation	OSHA response
The Panel recommends that OSHA evaluate carefully the costs and technological feasibility of engineering controls at all PEL options, especially those at the lowest levels.	OSHA has reviewed its cost estimates and the technological feasibility of engineering controls at various PEL levels. These issues are discussed in the Regulatory Alternatives Chapter.
The Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations with exposures far below the PEL. The Panel also recommends that OSHA consider explaining more clearly how employers may use ''objective data'' to estimate exposures. Although the draft proposal contains a provision allowing employers to initially estimate exposures using ''objective data'' (e.g., data showing that the action level is unlikely to be exceeded for the kinds of process or operations an employer has), the SERs did not appear to have fully understood how this alternative may be used.	OSHA has removed the initial exposure monitoring requirement for workers likely to be exposed to beryllium by skin or eye contact through routine handling of beryllium powders or dusts or contact with contaminated surfaces. The periodic monitoring requirement presented in the SBAR Panel report required monitoring every 6 months for airborne levels at or above the action level but below the PEL, and every 3 months for exposures at or above the PEL. The final standard, in line with OSHA's normal practice, requires exposure monitoring every three months for levels above the PEL or STEL and every six months for exposures between the action level and the PEL. In the preamble to the final standard, OSHA provides further explanation on the use of objective data, which would exempt employers from the requirements of the final rule. These issues are discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (d): Exposure Monitoring.
The Panel recommends that OSHA consider providing some type of guidance to describe how to use objective data to estimate exposures in lieu of conducting personal sampling. Using objective data could provide significant regulatory relief to several industries where airborne exposures are currently reported by SERs to be well below even the lowest PEL option. In particular, since several ancillary provisions, which may have significant costs for small entities may be triggered by the PEL or an action level, OSHA should consider encouraging and simplifying the development of objective data from a variety of sources.	In the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of estimating the cost of this rule, the Agency is assuming that no establishments will use objective data. The Agency recognizes that this will overestimate costs. The use of objective data is discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (d): Exposure Monitoring.
The Panel recommends that OSHA revisit its analysis of the costs of regulated areas if a very low PEL is proposed. Drop or limit the provision for regulated areas: SERs with very low exposure levels or only occasional work with beryllium questioned the need for separating areas of work by exposure level. Segregating machines or operations, SERs said, would affect productivity and flexibility. Until the health risks of beryllium are known in their industries, SERs challenged the need for regulated areas.	SERs with very low exposure levels or only occasional work with beryllium will not be required to have regulated areas unless exposures are above the final PEL of 0.2 $\mu g/m^3$. The final standards for general industry and maritime require the employer to establish and maintain a regulated area wherever employees are, or can be expected to be, exposed to airborne beryllium at levels above the PEL of 0.2 $\mu g/m^3$. There is no regulated area requirement in Construction.
The Panel recommends that OSHA revisit its cost model for hygiene areas to reflect SERs' comments that estimated costs are too low and more carefully consider the opportunity costs of using space for hygiene areas where SERs report they have no unused space in their physical plant for them. The Panel also recommends that OSHA consider more clearly defining the triggers (skin exposure and contaminated surfaces) for the hygiene areas provisions. In addition, the Panel recommends that OSHA consider alternative requirements for hygiene areas dependent on airborne exposure levels or types of processes. Such alternatives might include, for example, hand washing facilities in lieu of showers in particular cases or different hygiene area triggers where exposure levels are very low.	In General industry employers must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In General Industry, although there is a shower requirement, OSHA has determined that establishments required to have showers will already have them, and employers will not have to install showers to comply with the beryllium standard (Please see the Hygiene Areas and Practices section in Chapter V of the FEA). In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. For Construction and Maritime, language involving showers has been removed but employers are still required to provide change rooms. Where personal protective clothing or equipment must be used, the employer must provide washing facilities. The standards do not require that eating and drinking areas be provided, but impose requirements when the employer chooses to have eating and drinking areas. Change rooms have been costed in general industry for employees who work in a beryllium work area and in construction and maritime for employees who required to use personal protective clothing or equipment. The Agency has determined that the long-term rental of modular units is representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.

Panel recommendation	OSHA response
The Panel recommends that OSHA consider clearly explaining the purpose of the housekeeping provision and describing what affected employers must do to achieve it. For example, OSHA should consider explaining more specifically what surfaces need to be cleaned and how frequently they need to be cleaned. The Panel recommends that the Agency consider providing guidance in some form so that employers understand what they must do. The Panel also recommends that once the requirements are clarified that the Agency re-analyze its cost estimates. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.	In the preamble to the final rule, OSHA has clarified the purpose of the housekeeping provision. However, due to the variety of work settings in which beryllium is used, OSHA has concluded that a highly specific directive in the preamble on what surfaces need to be cleaned, and how frequently, would not provide effective guidance to businesses. Instead, at the suggestion of industry and union stakeholders (Materion and USW, 2012), OSHA's final standards include a more flexible requirement for employers to develop a written exposure control plan specific to their facilities. In general industry, the employer must establish procedures to maintain all surfaces in beryllium work areas as free as practicable of beryllium as required by the written exposure control plan. Other than requirements pertaining to eating and drinking areas, there are no requirements to maintain surface cleanliness in construction or maritime. These issues are discussed in the preamble at Section XVI, Summary and Explanation of the Standards, (f) Methods of Compliance and (j) Housekeeping. The adoption of Regulatory Alternative #20 in the PEA reduced the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in the final rule. These alternatives for medical surveillance are discussed in the Regulatory Alternatives Chapter, Chapter VIII and in the preamble at section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance.
The Panel recommends that OSHA consider that small entities may lack the flexibility and resources to provide alternative jobs to employees who test positive for the BeLPT, and whether medical removal protection (MRP) achieves its intended purpose given the course of beryllium disease. The Panel also recommends that if MRP is implemented, that its effects on the viability of very small firms with a sensitized employee be considered carefully.	Under the final standards, skin exposure is not a trigger for medical removal (unlike the draft version used for the SBAR Panel). Employees are only eligible for medical removal if they are in a job with airborne exposure at or above the action level and provide the employer with a written medical report confirming that they are sensitized or have been diagnosed with CBD, or that the physician recommends removal, or if the employer receives a written medical opinion recommending removal of the employee. After becoming eligible for medical removal an employee may choose to remain in a job with exposure at or above the action level, provided that the employer provides and the employee wears a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134). If the employee chooses removal, the employer is only required to place the employee in comparable work with exposure below the action level if such work is available; if such work is not available, the employer may place the employee on paid leave for six months or until such work becomes available, whichever comes first. OSHA discusses the basis of the provision in the preamble at Section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the FEA in Chapter V and Chapter VI, respectively.
The Panel recommends that OSHA consider more clearly defining the trigger mechanisms for medical surveillance and also consider additional or alternative triggers—such as limiting the BeLPT to a narrower range of exposure scenarios and reducing the frequency of BeLPT tests and physical exams. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.	As stated above, the triggers for medical surveillance in the final standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented at the SBAR Panel required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—the final standard ties medical surveillance to exposures at or above the action level for more than 30 days per year (or signs or symptoms of beryllium-related health effects, emergency exposure, or a medical opinion recommending medical surveillance on the basis of a CBD or sensitization diagnosis). Thus, small businesses with exposures below the final action level would not need to provide or manage medical surveillance for their employees unless employees develop signs or symptoms of beryllium-related health effects or are exposed in emergencies. These issues are discussed in the preamble at section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance.
The Panel recommends that the Agency, in evaluating the economic feasibility of a potential regulation, consider not only the impacts of estimated costs on affected establishments, but also the effects of the possible outcomes cited by SERs: Loss of market demand, the loss of market to foreign competitors, and of U.S. production being moved abroad by U.S. firms. The Panel also recommends that OSHA consider the potential burdens on small businesses of dealing with employees who have a positive test from the BeLPT. OSHA may wish to address this issue by examining the experience of small businesses that currently provide the BeLPT test.	OSHA has reviewed the possible effects of the final regulation on market demand and/or foreign production, in addition to the Agency's usual measures of economic impact (costs as a fraction of revenues and profits). This discussion can be found in Chapter VI of the FEA (entitled Economic Feasibility Analysis and Regulatory Flexibility Determination).

Panel recommendation	OSHA response
The Panel recommends that OSHA consider seeking ways of minimizing costs for small businesses where the exposure levels may be very low. Clarifying the use of objective data, in particular, may allow industries and establishments with very low exposures to reduce their costs and involvement with many provisions of a standard. The Panel also recommends that the Agency consider tiering the application of ancillary provisions of the standard according to exposure levels and consider a more limited or narrowed scope of industries.	The provisions in the standard presented in the SBAR panel report applied to all employees, whereas the final standard's ancillary provisions are only applied to employees in work areas who are, or can reasonably be expected to be, exposed to airborne beryllium. In addition, the scope of the final standard includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the final standard (1) does not apply to beryllium-containing articles that the employer does not process; and (2) does not apply to materials that contain less than 0.1% beryllium by weight if the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. In the preamble to the final standard, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVI, Summary and Explanation of the Standards, (d) Exposure Monitoring). OSHA also considered two Regulatory Alternatives that would reduce the impact of ancillary alternatives on employers, including small businesses. Regulatory Alternative #7, a PEL-only standard, would drop all ancillary provisions from the standard. Regulatory Alternative #8 would limit the application of several ancillary provisions, including Exposure Monitoring, the written exposure control plan section of Method of Compliance, PPE, Housekeeping, and Medical Surveillance, to operations or employees with exposure levels exceeding the TWA PEL or STEL. These alternatives are discussed in the Regulatory Alternatives, Chapter VIII of the FEA.
The Panel recommends that OSHA provide an explanation and analysis for all health outcomes (and their scientific basis) upon which it is regulating employee exposure to beryllium. The Panel also recommends that OSHA consider to what extent a very low PEL (and lower action level) may result in increased costs of ancillary provisions to small entities (without affecting airborne employee exposures). Since in the draft proposal the PEL and action level are critical triggers, the Panel recommends that OSHA consider alternate action levels, including an action level set at the PEL, if a very low PEL is proposed.	The explanation and analysis for all health outcomes (and their scientific basis) are discussed in the preamble to the final standard at Section V, Health Effects, and Section VI, Risk Assessment. They are also reviewed in the preamble to the final standard at Section VII, Significance of Risk, and the Benefits Chapter of the FEA. As discussed above, OSHA considered Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in Chapter VIII of the FEA.
The Panel recommends that OSHA consider more clearly and thoroughly defining the triggers for ancillary provisions, particularly the skin exposure trigger. In addition, the Panel recommends that OSHA clearly explain the basis and need for small entities to comply with ancillary provisions. The Panel also recommends that OSHA consider narrowing the trigger related to skin and contamination to capture only those situations where surfaces and surface dust may contain beryllium in a concentration that is significant enough to pose any risk—or limiting the application of the trigger for some ancillary provisions.	OSHA has removed skin exposure as a trigger for several ancillary provisions in the final standard, including Exposure Assessment and Medical Surveillance. For each employee working in a beryllium work area in general industry, and for each employee required to use personal protective clothing or equipment in construction and maritime, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition, the potential for dermal contact with beryllium triggers requirements related to beryllium work areas, the written exposure control plan, washing facilities, housekeeping and training: For some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or dermal contact with beryllium. In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. For Construction and Maritime, language involving showers has been removed and employers are required to provide change rooms for employees required to use personal protective clothing or equipment and required to remove their personal clothing. Where dermal contact occurs, employers must provide washing facilities. These requirements are discussed in the preamble at Section XVI, Summary and Explanation of the Standards. The Agency has also explained the basis and need for compliance with ancillary provisions in the preamble at Section XVI, Summary and Explanation of the Standards.

Panel recommendation	OSHA response
Several SERs said that OSHA should first assume the burden of describing the exposure level in each industry rather than employers doing so. Others said that the Agency should accept exposure determinations made on an industry-wide basis, especially where exposures were far below the PEL options under consideration.	In the Technological Feasibility Analysis presented in the FEA, OSHA has described the baseline exposure levels in each industry or application group.
As noted above, the Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations or processes with exposures far below the PEL. The use of objective data is a principal method for industries with low exposures to satisfy compliance with a proposed standard. The Panel recommends that OSHA consider providing some guidance to small entities in the use of objective data.	In the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of the economic analysis, the Agency is choosing to assume that no establishments will use objective data. The Agency recognizes that this will overestimate costs.
The Panel recommends that OSHA consider more fully evaluating whether the BeLPT is suitable as a test for beryllium sensitization in an OSHA standard and respond to the points raised by the SERs about its efficacy. In addition, the Agency should consider the availability of other tests under development for detecting beryllium sensitization and not limit either employers' choices or new science and technology in this area. Finally, the Panel recommends that OSHA re-consider the trigger for medical surveillance where exposures are low and consider if there are appropriate alternatives.	OSHA has provided discussion of the BeLPT in the preamble to the final rule at section V, Health Effects; and in the preamble at section XVI, Summary and Explanation of the Standards, (b) Definitions and (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed.
	As stated above, the triggers for medical surveillance in the final standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented during the SBREFA process required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—the final standard ties medical surveillance to exposures above the final action level of 0.1 $\mu g/m^3$ (or signs or symptoms of beryllium-related health effects, emergency exposure, or a medical opinion recommending medical surveillance on the basis of a CBD or sensitization diagnosis). The triggers for medical surveillance are discussed in the preamble at section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance.
	OSHA has considered Regulatory Alternative #16, where employers would not be required to offer employees a BeLPT that tests for beryllium sensitization. from the final standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in the preamble at Section XVI, Summary and Explanation of the Final Standard, (k) Medical Surveillance.
Seeking ways of minimizing costs to low-risk processes and operations: OSHA should consider alternatives for minimizing costs to industries, operations, or processes that have low exposures. Such alternatives may include, but not be limited to: Encouraging the use of objective data by such mechanisms as providing guidance for objective data; assuring that triggers for skin exposure and surface contamination are clear and do not pull in low-risk operations; providing guidance on least-cost ways for low risk facilities to determine what provisions of the standard they need to comply with; and considering ways to limit the scope of the standard if it can be ascertained that certain processes do not represent a significant risk.	The standard presented in the SBAR panel report had skin exposure as a trigger. The final standards require PPE when there is a reasonable expectation of dermal contact with beryllium. The employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. OSHA uses an exposure profile to determine which workers will be affected by the standards. As a result, in General Industry and Maritime, the final standards require regulated areas where exposures can exceed the PEL or STEL. In General Industry, beryllium work areas must be established in areas that contain a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.
	In Construction, the written exposure control plan must contain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, and the competent person must implement the plan.
	In addition, the scope of the final standards includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the final standard (1) does not apply to beryllium-containing articles that the employer does not process; and (2) does not apply to materials that contain less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. In the preamble to the final standards, OSHA discusses the issue of objective data. While OSHA recognizes that some establishments will have objective data, for purposes of this rule, the Agency is choosing to assume that no establishments will use objective data. The Agency recognizes that this will overestimate costs.

Panel recommendation	OSHA response
PEL-only standard: One SER recommended a PEL-only standard. This would protect employees from airborne exposure risks while relieving the beryllium industry of the cost of the ancillary provisions. The Panel recommends that OSHA, consistent with its statutory obligations, analyze this alternative.	OSHA considered Regulatory Alternative #7, a PEL-only standard. This alternative is discussed in Chapter VIII of the FEA.
Alternative triggers for ancillary provisions: The Panel recommends that OSHA clarify and consider eliminating or narrowing the triggers for ancillary provisions associated with skin exposure or contamination. In addition, the Panel recommends that OSHA should consider trying ancillary provisions dependent on exposure rather than have these provisions all take effect with the same trigger. If OSHA does rely on a trigger related to skin exposure, OSHA should thoroughly explain and justify this approach based on an analysis of the scientific or research literature that shows a risk of sensitization via exposure to skin. If OSHA adopts a relatively low PEL, OSHA should consider the effects of alternative airborne action levels in pulling in many low risk facilities that may be unlikely to exceed the PEL—and consider using only the PEL as a trigger at very low levels.	OSHA has removed skin exposure as a trigger for several ancillary provisions in the final standard, including Exposure Monitoring and Medical Surveillance. In General Industry, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In Construction and Maritime, for each employee required to use personal protective clothing or equipment, the employer must ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition, the language of the final standard regarding skin exposure has changed: For some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or skin contact with beryllium compounds. These requirements are discussed in the preamble at Section XVI, Summary and Explanation of the Standards. OSHA has explained the scientific basis for minimizing skin exposure to beryllium in the preamble to the final rule at Section V, Health Effects, and explains the basis for specific ancillary provisions related to skin exposure in the preamble at Section XVI, Summary and Explanation of the Standards. In the final standards, the application of ancillary provisions is dependent on exposure, and not all provisions take effect with the same trigger. A number of requirements are triggered by exposures (or a reasonable expectation of exposures) above the PEL or action level (AL). As discussed above, OSHA considered Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in Chapter VIII of the FEA.
Revise the medical surveillance provisions, including eliminating the BeLPT: The BeLPT was the most common complaint from SERs. The Panel recommends that OSHA carefully examine the value of the BeLPT and consider whether it should be a requirement of a medical surveillance program. The Panel recommends that OSHA present the scientific evidence that supports the use of the BeLPT as several SERs were doubtful of its reliability. The Panel recommends that OSHA also consider reducing the frequency of physicals and the BeLPT, if these provisions are included in a proposal. The Panel recommends that OSHA also consider a performance-based medical surveillance program, permitting employers in consultation with physicians and health experts to develop appropriate tests and their frequency.	After considering comments from SERs, OSHA has revised the medical surveillance provision and removed the skin exposure trigger for medical surveillance. As a result, OSHA estimates that the number of small-business employees requiring a BELPT will be substantially reduced. OSHA has provided discussion of the BeLPT in the preamble to the final rule at section V, Health Effects; and in the preamble at section XVI, Summary and Explanation of the Standards, (b) Definitions and (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed. The frequency of periodic BeLPT testing in the final standard is biennial, whereas annual testing was included in the draft standard presented to the SBAR Panel. Regulatory Alternative #20 would reduce the frequency of physical examinations from biennial to annual, matching the frequency of BeLPT testing in the final rule. In response to the suggestion to allow performance-based medical surveillance, OSHA considered two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Regulatory Alternative #16 would eliminate BeLPT testing requirements from the final standard. Regulatory Alternative #18 would eliminate the CT scan requirement from the final standard. These alternatives are discussed in the Regulatory Alternatives Chapter and in the preamble at Section XVI, Summary and Explanation of the Standards, (k) Medical Surveillance.

Panel recommendation	OSHA response
No medical removal protection (MRP): OSHA's draft proposed standard did not include any provision for medical removal protection, but OSHA did ask the SERs to comment on MRP as a possibility. Based on the SER comments, the Panel recommends that if OSHA includes an MRP provision, the agency provide a thorough analysis of why such a provision is needed, what it might accomplish, and what its full costs and economic impacts on those small businesses that need to use it might be.	The final standard includes an MRP provision. OSHA discusses the basis of the provision in the preamble at Section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the FEA in Chapter V and Chapter VI, respectively. The Agency considered Alternative #22, which would eliminate the MRP requirement from the standard. This alternative is discussed in the Regulatory Alternatives Chapter and in the preamble at section XVI, Summary and Explanation of the Standards, (l) Medical Removal Protection.

IX. OMB Review Under the Paperwork Reduction Act of 1995

Introduction

The three final beryllium standards (collectively ''the standards'') for occupational exposure to beryllium—general industry (29 CFR 1910.1024), construction (29 CFR 1926.1124), and shipyard (29 CFR 1915.1024)—contain collection of information (paperwork) requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq,* and OMB's regulations at 5 CFR part 1320. The PRA requires that agencies obtain approval from OMB before conducting any collection of information (44 U.S.C. 3507). The PRA defines ''collection of information'' to mean ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format'' (44 U.S.C. 3502(3)(A)).

In accordance with the PRA (44 U.S.C. 3506(c)(2)), OSHA solicited public comments on the Beryllium Standard for General Industry (29 CFR 1910.1024*),* Information Collection Request (ICR) (paperwork burden hour and cost analysis) for the proposed rule (80 FR 47555). The Department submitted this ICR to OMB for review in accordance with 44 U.S.C. 3507(d) on August 7, 2015. A copy of this ICR is available to the public at *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=1218-0267*).

On October 21, 2015, OMB issued a Notice of Action (NOA) assigning Beryllium Standard for General Industry new OMB Control Number 1218–0267 to use in future paperwork submissions involving this rulemaking. OMB requested that, ''Prior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates.''

The proposed rule invited the public to submit comments to OMB, in addition to OSHA, on the proposed collections of information with regard to the following:

- Whether the proposed collections of information are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the collections of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information (78 FR 56438).

No public comments were received specifically in response to the proposed ICR submitted to OMB for review. However, several public comments submitted in response to the Notice of Proposed Rulemaking (NPRM), described earlier in this preamble, substantively addressed provisions containing collections of information and contained information relevant to the burden hour and costs analysis. These comments are addressed in the preamble, and OSHA considered them when it developed the revised ICR associated with these final standards.

The Department of Labor submitted the final ICR January 9, 2017 containing a full analysis and description of the burden hours and costs associated with the collections of information of the standards to OMB for approval. A copy of the ICR is available to the public at *http://www.reginfo.gov.* OSHA will publish a separate notice in the **Federal Register** that will announce the results of OMB's review. That notice will also include a list of OMB approved collections of information and total burden hours and costs imposed by the new standards.

Under the PRA, Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and the collection of information notice displays a currently valid OMB control number (44 U.S.C. 3507(a)(3)). Also, notwithstanding any other provision of law, no employer shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512). The major collections of information found in the standards are listed below.

Summary of Information Collection Requirements

The Beryllium standards contain collection of information requirements which are essential components of the occupational safety and health standards that will assist both employers and their employees in identifying the exposures to beryllium and beryllium compounds, the medical effects of such exposures, and the means to reduce the risk of overexposures to beryllium and beryllium compounds. In the final ICR, OSHA has expanded its coverage to include the construction and shipyard industries—in order to tailor the collection of information requirements to the circumstances found in these sectors. The decision to include standards for construction and shipyards is based on information and comment submitted in response to the NPRM request for comment, and during the informal public hearing.

1. *Title:* Beryllium (29 CFR 1910.1024; 29 CFR 1915.1024; 29 CFR 1926. 1124).
2. *Type of Review:* New.
3. *OMB Control Number:* 1218–0267.
4. *Affected Public:* Business or other for-profit. This standard applies to employers in general industry, shipyard, and construction who have employees that may have occupational exposures to any form of beryllium, including compounds and mixtures, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of the Final standard.

5. *Number of Respondents:* 5,872 affected employers.

6. *Frequency of Responses:* On occasion; quarterly, semi-annually, annual; biannual.

7. *Number of Responses:* 246,433.

8. *Average Time per Response:* Varies from 5 minutes (.08 hours) for a clerical worker to generate and maintain an employee medical record, to more than 8 hours for a human resource manager to develop and implement a written exposure control plan.

9. *Estimated Total Burden Hours:* 196,894.

10. *Estimated Cost* (capital-operation and maintenance): $46,158,266.

Discussion of Significant Changes in the Collections of Information Requirements

Below is a summary of the collection of information requirements contained in the final rule, and a brief description of the most significant changes between the proposal and the final rule portions of the regulatory text containing collection of information requirements. One of the most significant changes between the NPRM and this final rule is that OSHA extended the scope of the rule so that the most of the provisions now also apply to construction and shipyard work. As a result, while most of the provisions are identical across all three standards (general industry, construction, and shipyards), there are technically more collections of information. However, for purposes of the review and explanation that follows, OSHA has focused on the changes to the general industry provisions and has not separately identified the additions to the construction and shipyard standard unless they deviate from the requirements in the general industry standard. A more detailed discussion of all the changes made to the proposed rule, including the requirements that include identified collection of information, is in Section XVIII: *Summary and Explanation.* The impact on information collections is also discussed in more detail in Item 8 of the ICR.

Exposure Assessment

Paragraph (d) sets forth requirements for assessing employee exposures to beryllium. Consistent with the definition of ''airborne exposure'' in paragraph (b) of these standards, exposure monitoring results must reflect the exposure to airborne beryllium that would occur if the employee were not using a respirator.

Proposed paragraph (d) used the term ''Exposure monitoring.'' In the final rule, this term was changed to ''Exposure assessment'' throughout the paragraph. This change in the final standards was made to align the provision's purpose with the broader concept of exposure assessment beyond conducting air monitoring, including the use of objective data.

OSHA added a paragraph (d)(2) as an alternative exposure assessment method to the scheduled monitoring requirements in the proposed rule. Under this option employers must assess 8-hour TWA exposure and the 15-minute short term exposure for each employee using any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

Proposed paragraph (d)(3), *Periodic Exposure Monitoring,* would have required employers whose initial monitoring results indicated that employee's exposures results are at or above the action level and at or below the TWA PEL to conduct periodic exposure monitoring at least annually. Final paragraph (d)(3), *Scheduled Monitoring Option,* increased the frequency schedule for periodic monitoring and added a requirement to perform periodic exposure monitoring when exposures are above the PEL, paragraph (d)(3)(vi) and when exposures are above the STEL in paragraph (d)(3)(viii).

Proposed paragraph (d)(4) would have required employers to conduct exposure monitoring within 30 days after a change in production processes, equipment, materials, personnel, work practices, or control methods that could reasonably be expected to result in new or additional exposures. OSHA changed the proposed requirement to require that employers perform reassessment of exposures when there is a change in ''production, process, control equipment, personnel, or work practices'' that may reasonably be expected to result in new or additional exposures at or above the action level or STEL. In addition, OSHA added ''at or above the action level or STEL'' to final paragraph (d)(4). In summary, the final rule requires that employers must perform reassessment of exposures when there is a change in production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures at or above the action level or STEL.

Proposed paragraph (d)(5)(i), Employee Notification of Monitoring Results, would have required employers in general industry to inform their employees of results within 15 working days after receiving the results of any exposure monitoring completed under this standard. Final paragraph (d)(6), *Employee Notification of Assessment Results,* requires that employers in general industry, construction and shipyards inform their employees of results within 15 working days after completing an exposure assessment.

Proposed paragraph (d)(5)(ii) (paragraph (d)(6)(ii) of the final standards) would have required that whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must include in the written notification the suspected or known sources of exposure and the corrective action(s) the employer has taken or will take to reduce exposure to or below the PELs, where feasible corrective action exists but had not been implemented when the monitoring was conducted. Final paragraph (d)(6)(ii) removes the requirement that employers include suspected or known sources of exposure in the written notification.

Methods of Compliance

Proposed paragraph (f)(1)(i) would have required employers to establish, implement and maintain a written control plan for beryllium work areas. OSHA has retained the requirement for a written exposure control plan and incorporated most provisions of the proposed paragraph (f)(1)(i) into the final standards for construction and shipyards, with certain modifications due to the work processes and worksites particular to these sectors.

Paragraph (f)(1)(i) differs from the proposal in that it requires a written exposure control plan for each facility, whereas the proposal would have required a written exposure control plan for beryllium work areas within each facility. OSHA has modified the requirement of a list of operations and job titles reasonably expected to have exposure to include those operations and job titles that are reasonably expected to have dermal contact with beryllium. Finally, OSHA modified the proposed requirement to inventory engineering and work practice controls required by paragraph (f)(2) of this standard to include respiratory protection.

Paragraph (f)(1)(ii) of the final standards requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it when: (A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in additional or new airborne exposure to beryllium; (B) the employer is notified that an employee is eligible for medical removal in accordance with paragraph

(l)(1) of this standard, referred for evaluation at a CBD Diagnostic Center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or (C) the employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

OSHA made several changes to that paragraph. First, OSHA added a requirement to review and evaluate the effectiveness of each written exposure control plan at least annually. Second, OSHA changed the proposed language of (f)(1)(ii)(B) to reflect other changes in the standard, including a change to ensure that employers are not automatically notified of cases of sensitization or CBD among their employees. Third, OSHA modified (f)(1)(ii)(B) to clarify the Agency's understanding that signs and symptoms of beryllium exposure may be related to inhalation or dermal exposure. Finally, OSHA modified the wording of (f)(1)(ii) to require the employer to update ''each'' written exposure control plan rather than ''the'' written exposure control plan, since an employer who operates multiple facilities is required to establish, implement and maintain a written exposure control plan for each facility.

Paragraph (f)(1)(iii) of the proposed rule would have required the employer to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)). OSHA did not receive comments specific to this provision, and has retained it in the final standard for general industry and included the paragraph in the final standards for construction and shipyards.

Respiratory Protection

Proposed Paragraph (g) of the standard would have established the requirements for the use of respiratory protection. OSHA added language to paragraph (g) to clarify that both the selection and use of respiratory protection must be in accordance with the Respiratory Protection standard 29 CFR 1910.134, which is cross-referenced, and to provide a powered air-purifying respirator (PAPR) when requested by an employee. The Respiratory protection standard contains collection of information requirements, include a written respiratory protection program and fit-testing records (29 CFR 1910.134(c)). The collection of information requirements contained in the Respiratory Protection Program standard are approved under OMB Control Number 1218–0099.

Personal Protective Equipment

Final paragraph (h)(3)(iii), like proposed paragraph (h)(3), requires employers to inform in writing the persons or the business entities who launder, clean or repair the protective clothing or equipment required by this standard of the potentially harmful effects of exposure to airborne beryllium and contact with soluble beryllium compounds and how the protective clothing and equipment must be handled in accordance with the standard.

Housekeeping

Paragraph (j)(3) requires warning labels in accordance with the requirements in paragraph (m) when employer transfer materials containing beryllium. *Medical Surveillance* Final paragraph (k) sets forth requirements for the medical surveillance provisions. The paragraph specifies which employees must be offered medical surveillance, as well as the frequency and content of medical examinations. It also sets forth the information that the licensed physician and CBD diagnostic center is to provide to the employee and employer.

In paragraphs (k)(1)(i)(A)–(D) of the proposal, OSHA specified that employers must make medical surveillance required by this paragraph available for each employee: (1) Who has worked in a regulated area for more than 30 days in the last 12 months; (2) showing symptoms or signs of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue; or (3) exposed to beryllium during an emergency; and (4) who was exposed to airborne beryllium above .2 $\mu g/m^3$ for more than 30 days in a 12-month period for 5 years or more, limited to the procedures described in paragraph (k)(3)(ii)(F) of this section unless the employee also qualifies for an examination under paragraph (k)(1)(i)(A), (B), or (C) of this section. OSHA revised the first proposed medical surveillance trigger to require the offering of medical surveillance based on exposures at or above the action level, rather than the PEL. In addition, OSHA revised the proposed trigger to require employers to make medical surveillance available to each employee who is or is reasonably expected to be exposed at or above the action level for more than 30 days a year, rather than waiting for the 30th day of exposure to occur.

Paragraph (k)(1)(i)(B) has been revised to include signs or symptoms of other beryllium-related health effects.

Proposed paragraph (k)(1)(i)(C) required employers to offer medical surveillance to employees exposed during an emergency. No revisions were made to this paragraph.

OSHA added final paragraph (k)(1)(i)(D), which requires that medical surveillance be made available when the most recent written medical opinion to the employer recommends continued medical surveillance. Under final paragraphs (k)(6) and (k)(7), the written opinion must contain a recommendation for continued periodic medical surveillance if the employee is confirmed positive or diagnosed with CBD, and the employee provides written authorization.

Frequency: Proposed paragraph (k)(2) specified when and how frequently medical examinations were to be offered to those employees covered by the medical surveillance program. Under proposed paragraph (k)(2)(i)(A), employers would have been required to provide each employee with a medical examination within 30 days after making a determination that the employee had worked in a regulated area for more than 30 days in the past 12 months, unless the employee had received a medical examination provided in accordance with this standard within the previous 12 months. OSHA made several changes to this requirement. First, OSHA revised the medical surveillance trigger of employees working in a regulated area to a determination that employee is or is reasonably expected to be exposed at or above the action level for more than 30 days of year; or who shows signs or symptoms of CBD or other beryllium-related health effects. Second, the Agency changed the extended the length of time from within the last 12 months to within the last two years.

Proposed paragraph (k)(2)(ii) required employers to provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of proposed paragraph (k)(1)(i)(A) or (B). OSHA revised the paragraph to specify that medical examinations were to be made available ''at least'' every two years and to include employees who continue to meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. Under the final standards, employees exposed in an

emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the biennial examination requirement unless they also meet the criteria of paragraphs (k)(1)(i)(A) or (B) or (D). Final paragraph (k)(2)(i)(A) also differs from the proposal in that in the proposed paragraph the employer did not have to offer an examination if the employee had received an equivalent examination within the last 12 months. In the final rule, this was increased to within two years to align that provision with the frequency of periodic examinations, which is every two years in the final rule.

Proposed paragraph (k)(2)(iii) required the employer to offer a medical examination at the termination of employment, if the departing employee met any of the criteria of proposed paragraphs (k)(1) at the termination of employment for each employee who met the criteria of paragraphs (k)(1)(i)(A), (B), or (C), unless an examination has been provided in accordance with the standard during the 6 months prior to the date of termination.

Final paragraph (k)(2)(iii) requires the employer to make a medical examination available to each employee who meets the criteria of final paragraph (k)(1)(i) at the termination of employment, unless the employee received an exam meeting the requirements of the standards within the last 6 months. OSHA extended the requirement to employees who meet the criteria of final paragraph (k)(1)(i)(D).

Contents of Examination. Paragraph (k)(3) details the contents of the examination. Paragraph (k)(3)(i) requires the employer to ensure that the PLHCP advised the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

Paragraphs (k)(3)(ii)(A)–(D) detail the content of the medical examination. The final rule made several changes to the content of the employee medical examination including, but not limited to, revising paragraphs: (k)(3)(ii)(A), to include emphasis on past and present airborne exposure to or dermal contact with beryllium; (k)(3)(ii)(C) to require a physical examination for skin rashes, rather than an examination for breaks and wounds; (k)(3)(ii)(E) to require the BeLPT test to be offered ''at least'' every two years, rather than every two years; (k)(3)(ii)(F) to include an LDCT scan when recommended by the PLHCP. With these changes, final paragraphs (k)(3)(ii)(A)–(D) require the medical examination to include: (1) Medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, any history of respiratory dysfunction and smoking history, and; (2) a physical examination with emphasis on the respiratory system; (3) a physical examination for skin rashes; and (4) a pulmonary function test, performed in accordance with guidelines established by the ATS including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV1). A more detailed discussion regarding all of the changes to the content of the Medical examinations may be found in section XVI, *Summary and Explanation of the Standards,* under (k) *Medical Surveillance.*

Information Provided to the PLHCP

Proposed paragraph (k)(4) detailed which information must be provided to the PHLCP. Specifically, the proposed standard required the employer to provide to the examining PLHCP the following information, if known to the employer: A description of the employee's former and current duties that relate to the employee's occupational exposure ((k)(4)(i)); the employee's former and current levels of occupational exposure ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that clothing and equipment ((k)(4)(iii)); and information the employer has obtained from previous medical examinations provided to the employee, that is currently within the employer's control, if the employee provides a medical release of the information ((k)(4)(iv)). OSHA made several changes to this paragraph. First, OSHA updated paragraph (k)(4)(i) to require the employer to provide a description of the employee's former and current duties that relate to both the employee's airborne exposure to and dermal contact with beryllium, instead of merely requiring the provision of information related to occupational exposure. Second, OSHA changed the requirement that the employer obtain a ''medical release'' from the employee to ''written consent'' before providing the PLHCP with information from records of employment-related medical examinations. Third, OSHA revised the provision to require that the employer ensure that the same information provided to the PLHCP is also provided to the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of the standard.

Licensed Physician's Written Medical Opinion

Paragraph (k)(5) of the proposed standard provided for the licensed physician to give a written medical opinion to the employer, but relied on the employer to give the employee a copy of that opinion; thus, there was no difference between information the employer and employee received. The final standards differentiate the types of information the employer and employee receive by including two separate paragraphs within the medical surveillance section that require a written medical report to go to the employee, and a more limited written medical opinion to go to the employer. The requirement to provide the medical opinion to the employee is in paragraph (k)(5) of the final standards; the requirement for providing documentation to the employer is in paragraph (k)(6) of the final standards. Most significantly, OSHA removed the requirement that the medical opinion pass through the employer to the employee.

Licensed Physician's Written Medical Report for the Employee

Final paragraphs (k)(5)(i)–(v) provide the contents of the licensed physician's written medical report for the employee. They include: The results of the medical examination, including any medical condition(s), such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as is defined in paragraph (b) of the standard), that may place the employee at increased risk from further airborne exposure; any medical conditions related to airborne exposure that require further evaluation or treatment (this requirement was not expressly included in the proposal); any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on airborne beryllium exposure.

Paragraph (k)(5) also provides that if the employee is confirmed positive or diagnosed with CBD, or if the physician otherwise deems it appropriate, the written medical report must also contain a referral to a CBD diagnostic center, a recommendation for continued medical surveillance, and a recommendation for medical removal from airborne beryllium exposures above the action level, as described in paragraph (l) of the standard. Proposed paragraph (k)(6) also addressed information provided to employees who were confirmed positive or diagnosed with CBD, but simply required a consultation with the physician.

Licensed Physician's Written Medical Opinion for the Employer

Paragraph (k)(6)(i) requires employers to obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under (k)(3)(ii)(E)). In proposed (k)(5), the physician would have been required to share most of the information identified now provided directly to the employee per final (k)(5) with the employer, but in the final rule OSHA limited the information that could be shared with the employer. In final (k)(6) the written medical opinion for the employer must contain only the date of the examination, a statement that the examination has met the requirements of this standard, and any recommended limitations on the employee's use of respirators, protective clothing, and equipment; and a statement that the PLHCP explained the results of the examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment.

Paragraph (k)(6)(ii) states that if the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. The requirement for written authorization was not in the proposal. Paragraphs (k)(6)(iii)–(v) state that if an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a referral for evaluation at a CBD diagnostic center and recommendations for continued medical surveillance and medical removal from airborne exposure to beryllium as described in paragraph (l).

Paragraph (k)(6)(vi) requires the employer to ensure that employees receive a copy of the written medical opinion for the employer within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee. A similar requirement was included in proposed (k)(5)(iii), but the time period was two weeks.

Beryllium Sensitization Test Results Research (Removed)

Proposed paragraph (k)(7) would have required employers to convey the results of beryllium sensitization tests to OSHA for evaluation and analysis at the request of OSHA. Based on comments received during the comment period, OSHA decided not to include the proposed paragraph (k)(7) in the final standard.

Referral to a Diagnostic Center

Final paragraph (k)(7) requires that if the employee wants a clinical evaluation at a CBD diagnostic center, the employer must provide the examination at no cost to the employee. OSHA made several changes to final paragraph (k)(7) as compared to similar provisions in paragraph (k)(6) of the proposal. First, OSHA changed the trigger for referral to a CBD diagnostic center to include both confirmed positive and a CBD diagnosis for consistency with final paragraphs (k)(5)(iii) and (k)(6)(iii). Second, OSHA removed the requirement for a consultation between the physician and employee. However, final paragraph (k)(7)(i) requires that employers provide a no-cost evaluation at a CBD-diagnostic center that is mutually agreed upon by the employee and employer.

Final paragraph (k)(7) requires the employer to ensure that the employee receives a written medical report form the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv) and (v) and that the PLHCP explains the results of the examination of the employee within 30 days of the examination.

Communication of Hazards

Proposed paragraph (m)(1)(i) required chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS (29 CFR 1910.1200) for beryllium. No substantive changes were made to this paragraph.

Proposed paragraph (m)(1)(ii) would have required employers to address at least the following, in classifying the hazards of beryllium: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation. According to the HCS, employers must classify hazards if they do not rely on the classifications of chemical manufacturers, importers, and distributors (see 29 CFR 1910.1200(d)(1)). OSHA revised the language to bring it into conformity with other substance specific standards so it is clear that chemical manufacturers, importers, and distributors are among the entities required to classify the hazards of beryllium. OSHA has chosen not to include an equivalent requirement in the final standards for construction and shipyards since employers in construction and shipyards are generally downstream users of beryllium products (blasting media) and would not therefore be classifying chemicals.

Proposed paragraph (m)(1)(iii) would have required employers to include beryllium in the hazard communication program established to comply with the HCS, and ensure that each employee has access to labels on containers and safety data sheets for beryllium and is trained in accordance with the HCS and the training paragraph of the standard. The final paragraph (m)(1)(iii) applies to the general industry, shipyards, and construction. The final provisions are substantively unchanged from the proposal.

Recordkeeping

Paragraph (n) of the final standards sets forth the employer's obligation to comply with requirements to maintain records of air monitoring data, objective data, medical surveillance, and training.

Proposed paragraph (n)(1)(i) required employers to maintain records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard. OSHA made one minor modification in the final standard: OSHA added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records.

Proposed paragraph (n)(1)(ii) required that records of all measurements taken to monitor employee exposure include at least the following information: The date of measurement for each sample taken; the operation being monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored. OSHA has made one editorial modification to paragraph (n)(1)(ii)(B), which is to change ''operation'' to ''task.'' Proposed paragraph (n)(1)(iii) required employers to maintain employee exposure monitoring records in accordance with 29 CFR 1910.1020(d)(1)(ii). OSHA has changed the requirement that the employer ''maintain this record as required by'' OSHA's Records Access standard to ''ensure that exposure records are maintained and made available in accordance with'' that standard.

Proposed Paragraph (n)(2) Historical Monitoring Data (Removed)

Proposed paragraph (n)(2) contained the requirement to retain records of any historical monitoring data used to satisfy the proposed standard's the initial monitoring requirements. OSHA deleted the separate recordkeeping requirement for historical data.

Final (n)(2)(i), (ii), and (iii) Objective Data

As a result of deleting paragraph (n)(2) Historical Data, OSHA has included proposed paragraph (n)(3) as paragraph (n)(2) in the final standards, with minor alterations. Paragraph (n)(2) contains the requirements to keep accurate records of objective data. Paragraph (n)(2)(i) requires employers to establish and maintain accurate records of the objective data relied upon to satisfy the requirement for initial monitoring in paragraph (d)(2). Under paragraph (n)(2)(ii), the record is required to contain at least the following information: (A) The data relied upon; (B) the beryllium-containing material in question; (C) source of the data; (D) description of the process, task, or activity on which the objective data were based; (E) other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based. These requirements included minor changes in the description of the last two changes, but were not substantively different.

Paragraph (n)(2)(iii) of the final standard (paragraph (n)(3)(iii) in the proposal) requires the employer to maintain a record of objective data relied upon as required by the Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)).

Paragraph (n)(3)(i), (ii), & (iii) Medical Surveillance Records

Paragraph (n)(3) of the final standards (paragraph (n)(4) in the proposal), addresses medical surveillance records. Employers must establish and maintain medical surveillance records for each employee covered by the medical surveillance requirements in paragraph (k). Paragraph (n)(3)(ii) lists the categories of information that an employer was required to record: The employee's name, social security number, and job classification; a copy of all licensed physicians' written medical opinions; and a copy of the information provided to the PLHCP. OSHA has moved the requirement that the record include copies of all licensed physicians' written opinions from proposed paragraph (n)(4)(ii)(B) to paragraph (n)(3)(ii)(B) of the final standards.

Proposed paragraph (n)(4)(iii) required the employer to maintain employee medical records in accordance with OSHA's Records Access Standard at 29 CFR 1910.1020. OSHA has added ''and made available'' after ''maintained'' in final paragraph (n)(3)(iii) of the standards, but the requirement is otherwise unchanged.

Paragraph (n)(4)(i) and (ii) Training Records

Paragraph (n)(4) of the final standards (paragraph (n)(5) of the proposal) requires employers to preserve training records, including records of annual retraining or additional training, for a period of three years after the completion of the training. At the completion of training, the employer is required to prepare a record that includes the name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. This record maintenance requirement also applied to records of annual retraining or additional training as described in paragraph (m)(4). This paragraph is substantively unchanged from the proposal.

Paragraph (n)(5) Access to Records

Paragraph (n)(5) of the final standards (paragraph (n)(6) of the proposal), requires employers to make all records mandated by these standards available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative as stipulated by OSHA's Records Access standard (29 CFR 1910.1020). This paragraph is substantively unchanged from the proposal.

Paragraph (n)(6) Training Records

Paragraph (n)(6) of the final standards (paragraph (n)(6) in the proposal), requires that employers comply with the Records Access standard regarding the transfer of records, 29 CFR 1910.1020(h), which instructs employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business. This paragraph is substantively unchanged from the proposal.

X. Federalism

OSHA reviewed the final beryllium rule according to the most recent Executive Order (''E.O.'') on Federalism, E.O. 13132, 64 FR 43255 (Aug. 10, 1999). The E.O. requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The E.O. allows Federal agencies to preempt State law only with the expressed consent of Congress. In such cases, Federal agencies must limit preemption of State law to the extent possible.

Under Section 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act''), 29 U.S.C. 667, Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to States that obtain Federal approval for such plans as ''State-Plan States.'' 29 U.S.C. 667. Occupational safety and health standards developed by State-Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State-Plan States are free to develop and enforce their own occupational safety and health standards.

While OSHA wrote this final rule to protect employees in every State, Section 18(c)(2) of the OSH Act permits State-Plan States to develop and enforce their own standards, provided those standards require workplaces to be at least as safe and healthful as this final rule requires. Additionally, standards promulgated under the OSH Act do not apply to any worker whose employer is a state or local government. 29 U.S.C. 652(5).

This final rule complies with E.O. 13132. In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, this rule limits State policy options in the same manner as every standard promulgated by the Agency. In States with OSHA-approved State plans, this rulemaking does not significantly limit State policy options to adopt stricter standards.

XI. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the States and U.S. territories with their own OSHA-approved occupational safety and health plans (''State-Plan

States'') must revise their standards to reflect the new standard or amendment. The State standard must be at least as effective as the Federal standard or amendment, and must be promulgated within six months of the publication date of the final Federal rule. 29 CFR 1953.5(a). Currently, there are 28 State-Plan States.

A State-Plan State may demonstrate that a standard change is not necessary because the State standard is already the same as or at least as effective as the new or amended Federal standard. In order to avoid delays in worker protection, the effective date of the State standard and any of its delayed provisions must be the date of State promulgation or the Federal effective date, whichever is later. The Assistant Secretary may permit a longer time period if the State makes a timely demonstration that good cause exists for extending the time limitation. 29 CFR 1953.5(a).

Of the 28 States and territories with OSHA-approved State plans, 22 cover public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. The remaining six states and territories cover only public-sector employees: Connecticut, Illinois, New Jersey, Maine, New York, and the Virgin Islands.

This beryllium rule applies to general industry, construction, and shipyards. This rule requires that all State-Plan States revise their standards appropriately within six months of the date of this notice.

XII. Unfunded Mandates Reform Act

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA''), 2 U.S.C. 1532, an agency must prepare a written ''qualitative and quantitative assessment'' of any regulation creating a mandate that ''may result in the expenditure by the State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation)'' in any one year before promulgating a final rule. OSHA's rule does not place a mandate on State or local governments, for purposes of the UMRA, because OSHA cannot enforce its regulations or standards on State or local governments. 29 U.S.C. 652(5). Under voluntary agreement with OSHA, some States require public sector entities to comply with State standards, and these agreements specify that these State standards must be at least as protective as OSHA standards. The OSH Act does not cover tribal governments in the performance of traditional governmental functions, though it does cover tribal governments when they engage in commercial activity. However, the final rule will not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, the final rule does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Final Economic Analysis (see Section VIII above), OSHA concludes that the rule would not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year. As noted below, OSHA also reviewed this final rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (Nov. 9, 2000), and determined that it does not have ''tribal implications'' as defined in that Order.

XIII. Protecting Children From Environmental Health and Safety Risks

E.O. 13045, 66 FR 19931 (Apr. 23, 2003), requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (''OIRA'') for review pursuant to E.O. 12866, 58 FR 51735 (Oct. 4, 1993), must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. E.O. 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under E.O. 12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.,* through air, food, water, soil, or product use).

The final beryllium rule is economically significant under E.O. 12866 (see Section IX of this preamble). However, after reviewing the rule, OSHA has determined that it will not impose environmental health or safety risks to children as set forth in E.O. 13045. The final rule will require employers to limit employee exposure to beryllium and take other precautions to protect employees from adverse health effects associated with exposure to beryllium. OSHA is not aware of any studies showing that exposure to beryllium in workplaces disproportionately affects children, who typically are not allowed in workplaces where such exposure exists. OSHA is also not aware that there are a significant number of employees under 18 years of age who may be exposed to beryllium, or that employees of that age are disproportionately affected by such exposure. One commenter, Kimberly-Clark Professional, noted that children may be subject to secondary beryllium exposure due to beryllium particles being carried home on their parents' work clothing, shoes, and hair (Document ID 1962, p. 2). Commenter Evan Shoemaker also noted that ''beryllium can collect on surfaces such as shoes, clothing, and hair as well as vehicles leading to contamination of the family and friends of workers exposed to beryllium'' (Document ID 1658, p. 3). However, OSHA does not believe beryllium exposure disproportionately affects children or that beryllium particles brought home on work clothing, shoes, and hair result in exposures at or near the action level. Furthermore, Kimberly-Clark Professional also noted that potential secondary exposures can be controlled through the use of personal protective equipment in the workplace (Document ID 1676, p. 2). The final standards contain ancillary provisions, such as personal protective clothing and hygiene areas, which are specifically designed to minimize the amount of beryllium leaving the workplace. Therefore, OSHA believes that the final beryllium rule does not constitute a covered regulatory action as defined by E.O. 13045.

XIV. Environmental Impacts

OSHA has reviewed the final beryllium rule according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). OSHA made a preliminary determination that the proposed

standard would have no significant impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. No comments to the record questioned this determination, nor has the Agency found other evidence to invalidate it. Therefore, OSHA concludes that the final beryllium standard will have no significant environmental impacts.

XV. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this final rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (Nov. 9, 2000), and determined that it does not have ''tribal implications'' as defined in that order. The OSH Act does not cover tribal governments in the performance of traditional governmental functions, so the rule will not have substantial direct effects on one or more Indian tribes in their sovereign capacity, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. On the other hand, employees in commercial businesses owned by tribes or tribal members will receive the same protections and benefits of the standard as all other covered employees.

XVI. Summary and Explanation of the Standards

OSHA proposed a standard for occupational exposure to beryllium and beryllium compounds in general industry and proposed regulatory alternatives to address beryllium exposures in the construction and maritime industries. The proposed standard for general industry was structured according to OSHA's traditional approach, with permissible exposure limits, and ancillary provisions such as exposure assessment, methods of compliance, and medical surveillance. As discussed below, OSHA based the proposal substantively on a joint industry and labor stakeholders' draft occupational health standard developed and submitted to OSHA by Materion Corporation (Materion) and the United Steelworkers (USW). The final rule, however, is based on the entirety of the rulemaking record.

In the final rule, OSHA is expanding coverage to include the construction and shipyard industries and establishing separate final standards for occupational exposure to beryllium in general industry, construction, and shipyards. In the NPRM, OSHA discussed Regulatory Alternative 2a to include both the construction and shipyard industries in the final rule (80 FR 47732–47734), presented estimated costs and benefits associated with extending the scope of the final rule, and requested comment on the alternative. The decision to include standards for construction and shipyards is based on information and comment submitted in response to this request for comment and evaluated by OSHA during the public comment periods and the informal public hearing. OSHA decided to issue three separate standards because there are some variations in the standards for each industry, although the structure of the final standards for general industry, construction, and shipyards remains generally consistent with other OSHA health standards. The most significant change is in the standard for construction where paragraph (e) Competent person, replaces paragraph (e) Beryllium work areas and regulated areas in general industry and paragraph (e) Regulated areas in shipyards.

All three final standards have a provision for methods of compliance, although in the standard for construction this provision has an additional requirement to describe procedures used by the designated competent person to restrict access to work areas, when necessary, to minimize the number of employees exposed to airborne beryllium above the PEL or STEL. This requirement allows the competent person to perform essentially the same role as the requirement governing regulated areas in general industry and shipyards, which is to regulate and minimize the number of workers exposed to hazardous levels of beryllium. OSHA decided to include a competent person provision in the final standard for construction because of the industry's familiarity with this concept and its past successful use in many OSHA construction standards and documents. ''Competent person'' is defined in OSHA's Safety and Health Regulations for Construction (29 CFR 1926.32(f)) as being a person who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them. This generally applicable definition corresponds well with the definition for ''competent person'' in the standard for construction: In this context, ''competent person'' means an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of this standard.

OSHA has retained, in modified form, the scope exemption from the proposed standard for materials containing less than 0.1 percent beryllium by weight in the standard for general industry and included it in the standards for construction and shipyards. The scope exemption has been modified in the final standards with the additional requirement that the employer must have objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. The 0.1 percent exemption was generally supported by commenters from general industry and shipyards; construction employers did not comment. Other commenters, especially those representing workers or public health organizations, expressed concern that these materials, in some cases, could expose workers to hazardous levels of beryllium. As discussed in more detail in the summary and explanation for Scope and application, the objective data requirement addresses these concerns and ensures the protection of workers who experience significant exposures from materials containing trace amounts of beryllium. Employers who have objective data showing that employees will not be exposed at or above the action level under any foreseeable conditions when processing materials containing less than 0.1 percent beryllium by weight are exempt from the standard.

OSHA decided to add a performance option in paragraph (d), Exposure assessment, as an alternative exposure assessment method to the scheduled monitoring requirements in the proposed rule, based on public comment received from industry and labor. OSHA believes the performance option, which encompasses either exposure monitoring or assessments based on objective data, gives employers flexibility in determining employee exposure to beryllium based on to their unique workplace circumstances. OSHA has provided this performance option in recent health standards such as respirable crystalline silica (29 CFR 1910.1053(d)(2)) and chromium VI (29 CFR 1910.1026(d)(3)).

OSHA also received comments about other provisions in the proposed standard, and in some cases, OSHA responded with changes from the

proposed rule that were based on the evidence provided in the record. Any changes made to the provisions in the final standards are described in detail in their specific summary and explanation sections.

Although details of the final standards for general industry, construction, and shipyards differ slightly, most of the requirements are the same or similar in all three standards. Therefore, the summary and explanation is organized according to the main requirements of the standards, but includes paragraph references to the standards for general industry, construction, and shipyards. The summary and explanation uses the term ''standards'' or ''final standards'' when referring to all three standards. Generally, when the summary and explanation refers to the term ''standards,'' it is referring to the final standards. To avoid confusion, the term ''final rule'' is sometimes used when making a comparison to or clarifying a change from the proposed rule.

The proposed rule applied to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by proposed paragraphs (a)(2) and (a)(3) of the proposed standard. The final standards are identical in their application to occupational exposures to beryllium. In the summary and explanation sections, OSHA has changed ''beryllium and beryllium compounds'' or anything specifying soluble beryllium to just ''beryllium.'' OSHA intends the term ''beryllium'' to cover all forms of beryllium, including compounds and mixtures, both soluble and poorly soluble, throughout the summary and explanation sections. Other global changes in the regulatory text include changing ''shall'' to ''must'' to make it clear when a provision is a requirement and adding ''personal'' to ''protective clothing or equipment'' and ''protective clothing and equipment'' consistently. OSHA has changed ''exposure'' to ''airborne exposure'' to make it clear when referring to just airborne exposure, and specifically noting when OSHA intends to cover dermal contact.

As noted above, OSHA's proposed rule was based, in part, upon a draft occupational health standard submitted to the Agency by Materion, the leading producer of beryllium and beryllium products in the United States, and USW, an international labor union representing workers who manufacture beryllium alloys and beryllium-containing products in a number of industries (Document ID 0754). Materion and USW worked together to craft a model beryllium standard that OSHA could adopt and that would have support from both labor and industry. They submitted their joint draft standard to OSHA in February 2012.

Like the proposal, many of the provisions in the final rules are identical or substantively similar to those contained in Materion and USW's draft standard. For example, the final rule for general industry and the Materion/USW draft standard both include an exclusion for materials containing less than 0.1 percent beryllium; both contain many similar definitions; both contain a time weighted average (TWA) PEL of 0.2 μg/m^3; both include exposure monitoring provisions, including provisions for scheduled monitoring, employee notification of results, methods of sample analysis, and observation of monitoring; both contain similar requirements for beryllium work areas and regulated areas; both mandate a written exposure control plan and engineering and work practice controls that follow OSHA's traditional hierarchy of controls; and both include similar provisions related to respiratory protection, protective clothing and equipment, hygiene areas and practices, housekeeping, medical surveillance, medical removal protection, training and communication of hazards, recordkeeping, and compliance dates.

(a) Scope and Application

Separate standards for general industry, construction, and shipyards. OSHA proposed a standard addressing occupational exposure to beryllium in general industry and regulatory alternatives to address exposures in the construction and maritime industries.[37] The proposal was modeled on a suggested rule that was crafted by two major stakeholders in general industry, Materion Corporation (Materion) and the United Steelworkers (USW) (Document ID 0754). Materion and USW provided OSHA with data on exposure and control measures and information on their experiences with handling beryllium in general industry settings (80 FR 47774). At the time, the information available to OSHA on beryllium exposures outside of general industry was limited. Therefore, the Agency preliminarily decided to limit the scope of its beryllium rule proposal to general industry but propose regulatory alternatives that would expand the scope of the proposed standard to also include employers in construction and maritime if it turned out the record evidence warranted it. Specifically, OSHA requested comment on Regulatory Alternative #2a, which would expand the scope of the proposed standard to also include employers in construction and maritime, and Regulatory Alternative #2b, which would update 29 CFR 1910.1000 Tables Z–1 and Z–2, 1915.1000 Table Z, and 1926.55 Appendix A so that the proposed TWA PEL and STEL would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. OSHA also requested stakeholder comment and data on employees in construction or maritime, or in general industry, not covered in the scope of the proposed standard, who deal with beryllium only as a trace contaminant, who may be at significant risk from occupational beryllium exposures.

OSHA did not receive any additional exposure data for construction or shipyards in response to OSHA's request in the NPRM. However, since the proposal, OSHA reviewed its OIS compliance exposure database and identified personal exposure sample results on beryllium for abrasive blasting workers in construction, general industry and maritime, which can be found broken out by sector in FEA Table IV.68.

The vast majority of stakeholders who submitted comments on this issue supported extending the scope of the proposed rule to cover workers in the construction and maritime industries who are exposed to beryllium (*e.g.,* Document ID 1592; 1625, p. 3; 1655, p. 15; 1658, p. 5; 1664, pp. 1–2; 1670, p. 7; 1671, Attachment 1, p. 5; 1672, p. 1; 1675, p. 2; 1676, p. 1; 1677, p. 1; 1679, p. 2; 1681, pp. 5, 16; 1683, p. 2; 1684, Attachment 2, p. 3; 1685, p. 2; 1686, p. 2; 1689, p. 6; 1690, p. 2; 1693, p. 3; 1703, p. 2; 1705, p. 1). For example, the National Council for Occupational Safety and Health (National COSH) urged that OSHA should ensure greater

[37] The proposed rule did not cover agricultural employers because OSHA had not found any evidence indicating that beryllium is used or handled in agriculture in a way that might result in beryllium exposure. OSHA's authority is also restricted in this area; since 1976, an annual rider in the Agency's Congressional appropriations bill has limited OSHA's use of funds with respect to farming operations that employ fewer than ten employees (Consolidated Appropriations Act, 1976, 94, 90 Stat. 1420, 1421 (1976) (and subsequent appropriations acts)). In the Notice of Proposed Rulemaking (NPRM), the Agency requested information on whether employees in the agricultural sector are exposed to beryllium in any form and, if so, their levels of exposure and what types of exposure controls are currently in place (80 FR 47565, 47775). OSHA did not receive comment on beryllium and the agriculture industry or information that would support coverage of agricultural operations. Therefore, agriculture employers and operations are not covered by the rule.

protections to beryllium exposed workers by extending the scope of the proposed standard to workers in the construction and maritime industries. National COSH explained: ''In the proposed preamble, OSHA recognizes that these workers are exposed to beryllium during abrasive blasting and clean-up of spent material. The risks that construction and maritime workers face when exposed to beryllium particulate is the same as the risk faced at similar exposures by general industry workers'' (Document ID 1690, p. 2). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) agreed, adding that ''[a]vailable data in the construction and maritime sector shows that there is a significant risk of sensitization and CBD among these workers'' (Document ID 1689, p. 6). Similarly, the American Industrial Hygiene Association (AIHA) warned that the ''[p]otential for exposure, especially in the construction industry, is very high'' (Document ID 1686, p. 2).

OSHA also heard testimony during the public hearing from Dr. Lee Newman of the American College of Occupational and Environmental Medicine (ACOEM), Peggy Mroz of National Jewish Health (NJH), Emily Gardner of Public Citizen, Mary Kathryn Fletcher of AFL–CIO, and Mike Wright of the USW that supported covering workers in the construction and maritime industries (Document ID 1756, Tr. 81; 1756, Tr. 97–98; 1756, Tr. 172–175; 1756, Tr. 198–199; 1755, Tr. 181). Peggy Mroz of NJH testified that ''[b]ased on the data presented, [NJH] support[s] expanding the scope of the proposed standard to include . . . employers in construction and maritime'' (Document ID 1756, Tr. 98). Emily Gardner of Public Citizen argued that ''the updated standard cannot leave construction and shipyard workers vulnerable to the devastating effects of beryllium'' (Document ID 1756, Tr. 175). She added that ''Public Citizen urges OSHA to revise the proposed rule to cover these workers'' (Document ID 1756, Tr. 175).

Several commenters specifically supported Regulatory Alternative #2a. For example, the International Union, United Automobile, Aerospace, and Agriculture Implement Workers of America (UAW) indicated its support for this alternative (Document ID 1693, p. 3 (pdf)). UAW added that Alternative #2a would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media (Document ID 1693, p. 3 (pdf)). Kimberly-Clark Professional (KCP) similarly indicated that it favored the adoption of this alternative (Document ID 1676, p. 1). KCP explained that ''[h]azardous exposures are equally dangerous to workers regardless of whether the worker is in a factory or on a construction site, and the worker protection provided by OSHA regulations should also be equal'' (Document ID 1676, p. 1). In addition, 3M Company also observed that Regulatory Alternative #2a is a more protective alternative (Document ID 1625, p. 3 (pdf)).

However, other commenters argued in favor of keeping the proposed scope unchanged (*e.g.,* Document ID 1583; 1661, Attachment 2, pp. 6–7; 1673, pp. 12–23). Some of these stakeholders contended that adding construction and maritime was not necessary (*e.g.,* Document ID 1673, pp. 20–22). For example, Materion opined that ''the requirements of [29 CFR] 1910.94 provide sufficient protections for the construction and maritime industries and accordingly, [Materion and USW] did not include construction and maritime within [their] assessment of technological feasibility or the scope of the standard'' (Document ID 1661, Attachment 2, p. 7). Materion added that ''it is [its] understanding that in the absence of a specific maritime standard, OSHA applies general industry standards to the maritime industries'' (Document ID 1661, Attachment 2, p. 7). While this may be the general practice of the industry, OSHA does not enforce general industry standards where the shipyard standards apply unless they are specifically cross referenced in the shipyard standards.

Some of these commenters offered specific concerns with covering the construction and maritime industries, or with covering abrasive blasting in general. For instance, Jack Allen, Inc. argued against extending the proposed rule to cover the use of coal slag in the sandblasting industry because the industry already has processes and controls in place to prevent exposures to all dusts during operations (Document ID 1582). The Abrasive Blasting Manufacturers Alliance (ABMA) presented a number of arguments against the coverage of abrasive blasting. ABMA argued that regulating the trace amounts of beryllium in abrasive blasting will increase the use of silica-based blasting agents ''despite OSHA's longstanding recommendation of substitution for silica-based materials'' (Document ID 1673, p. 14). ABMA added that scoping in abrasive blasting would increase the amount of coal slag materials ''going to landfills rather than being used for beneficial purpose'' (Document ID 1673, p. 14). ABMA also cited to technological feasibility issues in sampling and analysis, noted that the proposed standard was not appropriately tailored to construction and maritime worksites, and argued that it is not appropriate to regulate abrasive blasting on a chemical-by-chemical basis (Document ID 1673, pp. 8, 21–23).

After careful consideration of these comments and those relating to Regulatory #2b discussed below, OSHA has decided to adopt Regulatory Alternative #2a to expand the proposal's scope to cover construction and shipyards. As noted by commenters like the AFL–CIO, record evidence shows that exposures above the new action level and PEL, primarily from abrasive blasting operations, occur in both the construction and shipyard industries (*see* Chapter IV of the Final Economic Analysis and Regulatory Flexibility Analysis (FEA)). As discussed in Section V, Health Effects, and Section VII, Significance of Risk, employees exposed to airborne beryllium at these levels are at significant risk of developing adverse health effects, primarily chronic beryllium disease (CBD) and lung cancer. And under the OSH Act, and specifically section 6(b)(5), the Agency is required to set health standards which most adequately assure, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standards for the period of his working life. Therefore, OSHA finds it would be inappropriate to exclude construction and shipyard employers from coverage under this rule.

OSHA disagrees with Materion's assertion that existing standards render it unnecessary to have this standard cover construction and shipyard employers whose employees are exposed to beryllium during abrasive blasting operations. The OSHA Ventilation standard referenced by Materion (29 CFR 1910.94) applies only to general industry and does not cover construction and shipyard workers. The OSHA Ventilation standard in construction (1926.57) and Mechanical paint removers standard in shipyards (1915.34) provide some general protections for abrasive blasting workers but do not provide the level of protection provided by the ancillary provisions contained in the final standards such as medical surveillance, personal protective clothing and equipment, and beryllium-specific training.

OSHA also disagreed with Jack Allen, Inc.'s assertion that the employers conducting abrasive blasting already have sufficient processes and controls in place to prevent exposures to all dusts during operations. OSHA's examination of the record identifies data on beryllium exposure in the abrasive blasting industry showing beryllium exposure above the action level and TWA PEL when beryllium-containing slags are used (*e,g.,* Document ID 1166; 1815, Attachment 35; 1880). And even in abrasive blasting operations where all available controls and work processes to reduce beryllium exposure are used, additional ancillary provisions are still as necessary to protect workers from the harmful effects of exposure to beryllium as in general industry. OSHA also finds unsubstantiated ABMA's assertion that regulating the trace amounts of beryllium in abrasive blasting will increase the use of silica-based blasting agents and result in an increase in the amount of coal slag materials going to landfills. OSHA has identified several controls for abrasive blasting in its technological feasibility analysis (see Chapter IV of the FEA). OSHA also noted that substitution is not always feasible and employers should be cautious to not introduce additional hazards when switching to an alternate media. The Agency is certainly not encouraging employers to increase the use of silica sand as a blasting media. However, workers using silica-based blasting materials are protected under a new comprehensive silica standard (29 CFR 1910.1053, 29 CFR 1926.1153). Employers are in the best position to determine which blasting material to use and how to weigh the costs of compliance with the two rules. A 1998 NIOSH-funded study on substitute materials for silica sand in abrasive blasting provides comprehensive information on alternative media and can be used by employers seeking to identify appropriate abrasive blasting media alternatives (Document ID 1815, Attachment 85–87). In fact, exploring the use of alternative media for safer abrasive blasting media is already underway (Document ID 1741, p. 2). OSHA anticipates that the amount of slag material being deposited in landfills will remain constant regardless of its use prior to disposal, as the spent slag material used in abrasive blasting will still need to be disposed of. OSHA is also not persuaded by ABMA's technological feasibility argument that regulating trace amounts of beryllium would require testing below the limit of detection and that it is not technologically feasible to measure beryllium exposures in abrasive blasting. As explained in sections 2 and 12 of Chapter IV of the Final Economic Analysis, there are a number of available sampling and analytical methods that are capable of detecting beryllium at air concentrations below the action level of 0.1 μg/m^3, as well as existing exposure data for beryllium in abrasive blasting operations. And finally, OSHA disagrees with ABMA's assertion that regulating abrasive blasting on a chemical-by-chemical basis is inappropriate. The beryllium rule is typical of OSHA substance-specific health standards that have been promulgated for the construction and shipyard industries and include abrasive blasting operations, such as the Lead standard for construction (1926.62) and the Lead standard for general industry (1910.1025), which applies to the shipyard industry.

However, OSHA does agree with ABMA's observation that many of the conditions in the construction and shipyard industries are distinct from those in general industry, and agrees that the standard as proposed was not tailored to construction and shipyard worksites. The Agency has long recognized a distinction between the construction and general industry sectors and has issued standards specifically applicable to construction and shipyard work under 29 CFR part 1926 and 29 CFR part 1915, respectively. OSHA's understanding of the differences between these industries is why OSHA specifically asked stakeholders with experience and knowledge of the construction or shipyard industries to opine on whether coverage of those industries is appropriate and, if so, how the proposal should be revised to best protect workers in those industries. As discussed throughout the rest of this Summary and Explanation section, many stakeholders responded to OSHA's request.

After careful consideration of the record, OSHA finds that the unique needs of, conditions in, and challenges posed by the construction and maritime sectors, particularly concerning abrasive blasting operations at construction sites and shipyards, warrant different requirements from general industry. Therefore, OSHA is issuing three separate standards—one for each of these sectors. OSHA judges that the primary source of beryllium exposure at construction worksites and in shipyards is from abrasive blasting operations when using abrasives that contain trace amounts beryllium.

Abrasive blasters and their helpers are exposed to beryllium from coal slag and other abrasive blasting material like copper slag that may contain beryllium as a trace contaminant. The most commonly used abrasives in the construction industry include coal slag and steel grit, which are used to remove old coatings and etch the surfaces of outdoor structures, such as bridges, prior to painting (Document ID 1815, Attachment 93, p. 80). Shipyards are large users of mineral slag abrasives. In a recent survey conducted for the Navy, the use of coal slag abrasives accounted for 68 percent and copper slag accounted for 20 percent of abrasive media usage as reported by 26 U.S. shipyards and boatyards (Document ID 0767). The use of coal and copper slag abrasives has increased in recent years as industries have sought substitutes for silica sand blasting abrasives to avoid health risks associated with respirable crystalline silica (Document ID 1671, Attachment 3; 1681, Attachment 1, pp. 1–2).

OSHA's exposure profile for abrasive blasters, pot tenders/helpers, and abrasive material cleanup workers is found in Section 12 of Chapter IV in the FEA. The exposure profile for abrasive blasters shows a median of 0.2 μg/m^3, a mean of 2.18 μg/m^3, and a range from 0.004 μg/m^3 to 66.5 μg/m^3. The mean level of 2.18 μg/m^3 is above the preceding PEL for beryllium. For pot tenders/helpers, the exposure profile shows a median of 0.09 μg/m^3, a mean of 0.10 μg/m^3, and a range from 0.04 to 0.20 μg/m^3. Beryllium exposure for workers engaged in abrasive material cleanup shows a median of 0.18 μg/m^3, a mean of 1.76 μg/m^3, and a range from 0.04 μg/m^3 to 7.4 μg/m^3 (*see* Section 12 of Chapter IV in the FEA). OSHA concludes that abrasive blasters, pot tenders/helpers, and cleanup workers have the potential for significant airborne beryllium exposure during abrasive blasting operations and during cleanup of spent abrasive material. Accordingly, these workers require protection under the beryllium standards. To address high concentrations of various hazardous chemicals in abrasive blasting, employers are already required to use engineering and work practice controls to limit workers' exposures and supplement these controls with respiratory protection when necessary. For example, abrasive blasters in the construction industry fall under the protection of the Ventilation standard (29 CFR 1926.57). The Ventilation standard includes an abrasive blasting subsection (29 CFR 1926.57(f)), which requires that abrasive blasting respirators be worn by all abrasive

blasting operators when working inside blast-cleaning rooms (29 CFR 1926.57(f)(5)(ii)(A)), when using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure (29 CFR 1926.57(f)(5)(ii)(B)), or when needed to protect workers from exposures to hazardous substances in excess of the limits set in § 1926.55 (29 CFR 1926.57(f)(5)(ii)(C)). For the shipyard industry, paragraph (c) of the Mechanical paint removers standard (29 CFR 1915.34) also has respiratory protection requirements for abrasive blasting operations. Because of these requirements, OSHA believes that employers already have those controls in place and provide respiratory protection during abrasive blasting operations. Nonetheless, the construction and shipyard standards' new ancillary provisions such as medical surveillance, personal protective clothing and equipment, housekeeping, and beryllium-specific training will provide increased protections to workers in these industries.

OSHA also received comment and heard testimony on potential beryllium exposure from other sources. NIOSH commented that construction workers may be exposed to beryllium when demolishing buildings or building equipment, based on a study of workers demolishing oil-fired boilers (Document ID 1671, Attachment 1, pp. 5, 15; 1671, Attachment 21). Peggy Mroz of NJH testified that ''[n]umerous studies have documented beryllium exposure sensitization and chronic beryllium disease in construction industries, demolition and decommissioning, and among workers who use non-sparking tools'' (Document ID 1756, Tr. 98). Many such cases were discovered among trade workers at Department of Energy sites from the National Supplemental Screening Program (Document ID 1756, Tr. 81–82). Ashlee Fitch from the USW testified that in addition to abrasive blasting using beryllium-contaminated slags, workers in the maritime industry use non-sparking tools that are composed of beryllium alloys. Ms. Fitch stated that these tools can create beryllium particulate when they are dressed (*e.g.,* sharpening, grinding, straightening). She also noted that shipyards may use beryllium for other tasks in the future. Ms. Fitch alluded to a 2000 Navy survey of potential exposure to beryllium in shipyards which identified potential beryllium sources in welding, abrasive blasting, and metal machining (Document ID 1756, Tr. 242–243). Mr. Wright of the USW testified that shipyard management told a USW representative ''that most of the beryllium that they're aware of comes in in the form of articles . . . . That is to say, it might be part of some assembly . . . [a]nd it comes in and it's sealed and closed'' (Document ID 1756, Tr. 270). However, Mr. Wright stated that beryllium is a high-tech material and that ''there is nothing more high-tech than an aircraft carrier or a nuclear submarine'' so exposure from beryllium-containing alloys cannot be ruled out in these operations (Document ID 1756, Tr. 270).

Despite requesting information both in the NPRM and during the public hearing, OSHA does not have sufficient data on beryllium exposures in the construction and shipyard industries to characterize exposures of workers in application groups other than abrasive blasting with beryllium-containing slags. OSHA could not develop exposure profiles for construction and shipyard workers engaged in activities involving non-sparking tools, demolition of beryllium-contaminated buildings or equipment, and working with beryllium-containing alloys. However, OSHA acknowledges the USW's concerns about future beryllium use and recognizes that there is potential for exposure to beryllium in construction and shipyard operations other than abrasive blasting. As such, workers engaged in such operations are exposed to the same hazard of developing CBD and other beryllium-related disease, and therefore deserve the same level of protection as do workers who are engaged in abrasive blasting or covered in the general industry final rule. Therefore, although at this time OSHA cannot specifically quantify exposures in construction or shipyard operations outside of abrasive blasting, OSHA has determined that it is necessary for the final standards for construction and maritime to cover all occupational exposures to beryllium in those industries in order to ensure that the standard is broadly effective and addresses all potential harmful exposures.

Three commenters representing the maritime industry supported Regulatory Alternative #2b—adopting the new PELs for construction and maritime by updating the existing Z tables to incorporate them, but not applying the other ancillary provisions of this standard to construction and maritime (Document ID 1595, p. 2; 1618, p. 2; 1657. p. 1). The Shipbuilders Council of America (SCA) supported lowering the PEL for beryllium from 2.0 μ/m^3 to 0.2 μ/m^3 in 29 CFR 1915.1000 Table Z, but argued that a new beryllium standard would prove to be redundant. SCA contended that many shipyards maintain a comprehensive industrial hygiene program focused on exposure assessments and protective measures for a variety of metals in shipyard tasks, and that shipyards encounter beryllium only at trace contaminant levels in materials involved in the welding and abrasive blasting processes. SCA stated that the potential hazards inherent in and unique to abrasive blasting in shipyards are already effectively controlled through existing regulations (Document ID 1618, pp. 2–4). General Dynamics' Bath Iron Works expressed similar views in their comments on this issue, as did Newport News Shipbuilding (Document 1595, p. 2; 1657, p. 1).

In addition to the commenters representing the maritime industry, Ameren, an electric and natural gas public utility, also supported applying the proposed TWA PEL and STEL to all employers in general industry, construction, and maritime even where beryllium exists only as a trace contaminant (Document ID 1675, p. 3). However, not all commenters endorsed Alternative #2b. The Department of Energy's National Supplemental Screening Program (NSSP) did not support this alternative because the other provisions of the standard would only cover employers and employees within the scope of the proposed general industry rule (Document ID 1677, p. 2). Furthermore, many commenters supported extending the full protections of the standard to the construction and maritime industries as set forth in Regulatory Alternative #2a, discussed earlier, which implicitly rejects Regulatory Alternative #2b (see, *e.g.,* Document ID 1756, Tr. 81; 1756, Tr. 97–98; 1756, Tr. 172–175; 1756, Tr. 198–199; 1755, Tr. 181).

OSHA is not persuaded by the maritime industry commenters' assertions that the ancillary provisions of the beryllium standard would be redundant. While OSHA acknowledges that shipyards encounter beryllium only at trace levels in materials involved in the welding and abrasive blasting processes, OSHA disagrees with their contention that updating the PEL and STEL will provide adequate protection to shipyard workers. OSHA agrees with NSSP and all the commenters supporting Regulatory Alternative #2a that a comprehensive standard specific to beryllium will provide the important protection of ancillary provisions, such as medical surveillance and medical removal protection. OSHA intends to

ensure that workers exposed to beryllium in the construction and shipyard industries are provided with protection that is comparable to the protection afforded workers in general industry. Therefore, OSHA has set an identical PEL and STEL and, where no meaningful distinctions are identified in the record, included substantially the same or approximately equivalent ancillary provisions in all three standards. For further discussion of the differences among the standards, see the provision-specific sections included in this Summary and Explanation.

Therefore, OSHA declines to adopt Regulatory Alternative #2b, which, as noted above, would have updated 29 CFR 1910.1000 Tables Z–1 and Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A so that the new TWA PEL and STEL, but not the standard's ancillary provisions, would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. The Agency intends for employers that are exempt from the scope of these comprehensive standards in accordance with paragraph (a) to comply with the preceding TWA PEL and STEL in 29 CFR 1910.1000 Table Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A, as applicable. Given that the Agency is issuing separate beryllium standards for the construction and shipyard industries, OSHA is also adding to these tables a cross-reference to the new standards and clarifying that if the new standards are stayed or otherwise not in effect, the preceding PEL and short-term ceiling limit apply.

Paragraph (a)(1). Proposed paragraph (a)(1) applied the standard to occupational exposures to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of the standards. As OSHA explained in the proposal, the Agency preliminarily chose to treat beryllium generally, instead of individually addressing specific compounds, forms, and mixtures. This decision was based on the Agency's preliminary determination that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium (80 FR 47774).

Several commenters offered opinions on this approach. The Non-Ferrous Founders' Society (NFFS) expressed concern that beryllium metal was being treated the same as soluble beryllium compounds, such as salts, even though NFFS believes these soluble compounds are more hazardous and suggested that OSHA establish a bifurcated standard for insoluble beryllium versus soluble beryllium compounds (Document ID 1732, p. 3; 1678, p. 2; 1756, Tr. 18). In related testimony, NIOSH's Dr. Aleks Stefaniak discussed the dermal exposure mechanisms of poorly soluble beryllium through particle penetration and particle dissolving (Document ID 1755, pp. 35–39). Dr. Stefaniak testified that while ''intact skin naturally has a barrier . . . [v]ery few people actually have fully intact skin, especially in an industrial environment'' (Document ID 1755, p. 36). He added:

> in fact, beryllium particles, beryllium oxide, beryllium metal, beryllium alloys, all these sort of what we call insoluble forms actually do in fact dissolve very readily in analog of human sweat. And once beryllium is in an ionic form on the skin, it's actually very easy for it to cross the skin barrier (Document ID 1755, pp. 36–37).

NIOSH also provided additional information on beryllium solubility and the development of CBD in its post-hearing brief, labeling as untrue NFFS's assertion that insoluble beryllium does not cause CBD (Document ID 1960, Attachment 2, pp. 8–10), citing studies showing that workers exposed to insoluble forms of beryllium have developed sensitization and CBD (Kreiss, *et al.,* 1997, Document ID 1360; Schuler *et al.,* 2005 (1349); Schuler *et al.,* 2008 (1291); Wegner *et al.,* 2000, (1960, Attachment 7)).

After careful consideration of the various comments on this issue, OSHA is not persuaded that there are differences in workers' health risks that justify treating poorly soluble beryllium differently than soluble compounds. The Agency is persuaded by NIOSH that poorly soluble beryllium presents a significant risk of beryllium-related disease to workers and discusses this topic further in Section V of this preamble, Health Effects. OSHA has determined that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium. Therefore, the Agency concludes that the record supports issuing standards that apply to beryllium in all forms, compounds, and mixtures. Final paragraph (a)(1) is therefore substantively unchanged from the proposal in all three standards.

Paragraph (a)(2). Proposed paragraph (a)(2) excluded from the standard's scope articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. As OSHA explained in the proposal (80 FR 47775), the HCS defines an ''article'' as

> a manufactured item other than a fluid or particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.,* minute or trace amounts of a hazardous chemical . . ., and does not pose a physical hazard or health risk to employees.

OSHA preliminarily found that items or parts containing beryllium that employers assemble where the physical integrity of the item is not compromised are unlikely to release beryllium that would pose a physical or health hazard for workers. Therefore, OSHA proposed to exempt such articles from the scope of the standard. This proposed provision was intended to ease the burden on employers by exempting items from coverage where they are unlikely to pose a risk to employees.

Commenters generally supported this proposed exemption. For example, NFFS stated that the exemption was ''important and practical'' (Document ID 1678, p. 2; Document ID 1756, Tr. 35–36)). However, two commenters requested minor amendments to the exemption. First, ORCHSE Strategies (ORCHSE) asked OSHA to ''clarify'' that proposed paragraph (a)(2) ''exempts 'articles' even if they are processed, unless the processing releases beryllium to an extent that negates the definition of an 'article' '' (Document ID 1691, Attachment 1, p. 16). ORCHSE asserted that the standard should not apply in a workplace when ''the item actually meets OSHA's definition of an article'' and that OSHA should change the regulation's language accordingly (Document ID 1691, Attachment 1, pp. 16–17). Second, the American Dental Association (ADA) asked that OSHA clarify the article exemption, specifically that employers who use but do not process articles are fully exempt from all requirements of the proposed rule, including those established for recordkeeping (Document ID 1597, p. 1).

In contrast, Public Citizen objected to the inclusion of this exemption because exempting articles that are not processed does not take into consideration dermal exposure from handling articles containing beryllium (Document ID 1670, p. 7). Public Citizen pointed to OSHA's proposed rule in which OSHA acknowledged that beryllium absorbed through the skin can induce a sensitization response that is a necessary first step toward CBD and that there is evidence that the risk is not limited to soluble forms. However, during follow-up questioning at the beryllium public hearings, Dr. Almashat

of Public Citizen was unable to provide any examples of dermal exposure from articles through their handling, as opposed to when processing beryllium materials (Document ID 1756, Tr. 178–180). And, in its post-hearing comments, Public Citizen did not provide evidence of dermal exposure to workers handling beryllium materials that would fall under the definition of article (Document ID 1964). In the final standard, OSHA has decided not to alter the proposed exemption of articles. OSHA is not persuaded by ORCHSE's argument that OSHA should change the regulation's language to exempt articles even if they are processed, unless the processing releases beryllium to an extent that negates the definition of an article. The HCS defines an article as

> a manufactured item other than a fluid or particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.,* minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees. (29 CFR 1910.1200(c)).

Whether a particular item is an ''article'' under the HCS depends on the physical properties and intended use of that item. However, employers may use and process beryllium-containing items in ways not necessarily intended by the manufacturer. Therefore, OSHA has decided not to link the processing limitation to the definition of an ''article'' and is retaining the language of proposed (a)(2) to comport with the intention of the exemption.

In response to the ADA's request for clarification that employers who use but do not process articles are fully exempt from all requirements of the rule, OSHA notes that paragraph (a)(2) of the final standards states that the ''standard does not apply'' to those articles. Furthermore, the recordkeeping requirement for objective data in paragraph (n)(2) of the standards states that it applies to objective data used to satisfy exposure assessment requirements, but does not mention any data used to determine coverage under paragraph (a). Therefore, OSHA has determined that no further clarification in the regulatory text is necessary.

In response to the comment from Public Citizen, OSHA did not receive any evidence on the issue of beryllium exposure through dermal contact with unprocessed articles. Therefore, OSHA cannot find that such contact poses a risk.

Paragraph (a)(2) of the final standards therefore remains unchanged from the proposed standard. The final standards do not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process.

Paragraph (a)(3). Proposed paragraph (a)(3) exempted from coverage materials containing less than 0.1 percent beryllium by weight. Requesting comment on this exemption (80 FR 47776), OSHA presented Regulatory Alternative #1a, which would have eliminated the proposal's exemption for materials containing less than 0.1 percent beryllium by weight, and #1b, which would have exempted operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. The Agency asked whether it is appropriate to include an exemption for operations where beryllium exists only as a trace contaminant, but some workers can nevertheless be significantly exposed. And the Agency asked whether it should consider dropping the exemption, or limiting it to operations where exposures are below the proposed action level and STEL. In addition, OSHA requested additional data describing the levels of airborne beryllium in workplaces that fall under this exemption. Some stakeholders supported keeping the 0.1 percent exemption as proposed (Document ID 1661, p. 6; 1666, p. 2; 1668, p. 2; 1673, p. 8; 1674, p. 3; 1687, Attachment 2, p. 8; 1691, Attachment 1, p. 3; 1756, Tr. 35–36, 63). For example, the Edison Electric Institute (EEI) strongly supported the exemption and asserted ''that abandoning the exemption would result in no additional benefits from a reduction in the beryllium permissible exposure limit (PEL) or from ancillary provisions similar to those already in place for the arsenic and other standards'' (Document ID 1674, p. 3). Mr. Weaver of NFFS also opposed eliminating the exemption, testifying that without the 0.1 percent exemption, 900 to 1,100 foundries would come under the scope of the rule (Document ID 1756, Tr. 55–56).

ABMA also supported the proposed 0.1 percent exemption, suggesting that there is a lack of evidence of significant risk from working with material containing beryllium in trace amounts and that OSHA needs substantial evidence that it is ''at least more likely than not'' that exposure to beryllium in trace amounts presents significant risk of harm, under court decisions concerning the Benzene rule (Document ID 1673, pp. 8–9). ABMA further argued that significant risk does not exist even below the previous PEL of 2.0 μg/m^3 (Document ID 1673, pp. 8–9, 11). ABMA added that its members collectively have over 200 years of experience producing coal and/or copper slag abrasive material and have employed thousands of employees in this production process. ABMA explained:

> Through the years, Alliance members have worked with and put to beneficial use over 100 million tons of slag material that would otherwise have been landfilled. Despite this extensive history, the Alliance members have no history of employees with beryllium sensitization or beryllium-related illnesses. Indeed, the Alliance members are not aware of a single documented case of beryllium sensitization or beryllium-related illness associated with coal or copper slag abrasive production among their employees, or their customers' employees working with the products of Alliance members (Document ID 1673, p. 9).

OSHA is not persuaded by these arguments. The lack of anecdotal evidence of sensitization or beryllium-related illness does not mean these workers are not at risk. As noted by Representative Robert C. ''Bobby'' Scott, Ranking Member of the U.S. House of Representatives Committee on Education and the Workforce the U.S. House of Representatives, ''medical surveillance has not been required for beryllium-exposed workers outside of the U.S. Department of Energy. The absence of evidence is not evidence of absence'' (Document ID 1672). As discussed in Section II of this preamble, Pertinent Legal Authority, courts have not required OSHA ''to support its finding that a significant risk exists with anything approaching scientific certainty'' (*Benzene,* 448 U.S. 607, 656 (1980)). Rather, OSHA may rely on ''a body of reputable scientific thought'' to which ''conservative assumptions in interpreting the data . . .'' may be applied, ''risking error on the side of overprotection'' (*Benzene,* 448 U.S. at 656). OSHA may thus act with a ''pronounced bias towards worker safety'' in making its risk determinations (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988). Where, as here, the Agency has evidence indicating that a certain operation can result in exposure levels that the Agency knows can pose a significant risk—such as evidence that workers that have been exposed to beryllium at the final PEL of 0.2 μg/m^3 in primary beryllium production and beryllium machining operations have developed CBD (see this preamble at section V, Risk assessment)—OSHA need not wait until it has specific evidence that employees in that

particular industry are suffering. A number of commenters supported Regulatory Alternative #1a, proposing to eliminate the proposal's exemption for materials containing less than 0.1 percent beryllium by weight (Document ID 1655, p. 15; 1664, p. 2; 1670, p. 7; 1671, Attachment 1, p. 5; 1672, pp. 4–5; 1683, p. 2; 1686, p. 2; 1689, pp. 6–7; 1690, p. 3; 1693, p. 3; 1720, pp. 1, 4). Public Citizen expressed concern with the proposed exemption and pointed out that OSHA identified studies in its proposal unequivocally demonstrating that beryllium sensitization and CBD occur in multiple industries utilizing products containing trace amounts of beryllium and that such an exemption would expose workers in such industries to the risks of beryllium toxicity (Document ID 1670, p. 7). The American Association for Justice, the AFL–CIO, and the UAW were all concerned that the proposed standard's 0.1 percent exemption would result in workers being exposed to significant amounts of beryllium from abrasive blasting (Document ID 1683, p. 2; 1689, pp. 6–7, 10–11; 1693, p. 3). Both Dr. Sammy Almashat and Emily Gardner of Public Citizen testified that they support inclusion of work processes that involve materials containing less than 0.1 percent of beryllium because the beryllium can become concentrated in air, even when using materials with only trace amounts (Document ID 1756, Tr. 174, 177–178, 185–186). Similarly, the AFL–CIO stated that ''there are known over-exposures among industries that use materials with less than 0.1% beryllium by weight, including an estimated 1,665 workers in primary aluminum production and 14,859 coal-fired electric power generation workers'' (Document ID 1689, p. 7). Mary Kathryn Fletcher of the AFL–CIO further explained that the AFL–CIO supported eliminating the exemption because these employees are at significant risk for developing sensitization, chronic beryllium disease (CBD), and lung cancer (Document ID 1756, Tr. 198–199). The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) recommended that OSHA remove the exemption (Document ID 1655, p. 15). AIHA also recommended eliminating or reducing the percentage content exemption until data is available to demonstrate that materials with very low beryllium content will not result in potential exposure above the proposed PEL (Document ID 1686, p. 2).

Both NIOSH and North America's Building Trades Unions (NABTU) expressed concern that the 0.1 percent exemption would expose construction and shipyard workers conducting abrasive blasting with coal slags to beryllium in concentrations above the final PEL. NIOSH and NABTU cited a study by the Center for Construction Research and Training, and NIOSH also cited one of its exposure assessment studies of a coal slag blaster showing beryllium air concentrations exceeding the preceding OSHA PEL (Document ID 1671, Attachment 1, p. 5; 1679, pp. 3–4). In addition, NIOSH points out that although the abrasive blasting workers may use personal protective equipment that limits exposure, supervisors and other bystanders may be exposed. NIOSH gave other examples where the 0.1 percent exemption could result in workers being exposed to beryllium, such as building or building equipment demolition and work in dental offices that fabricate or modify beryllium-containing dental alloys, but did not provide reference material or exposure data for these examples (Document ID 1671, pp. 5–6). In its post-hearing brief, NIOSH also specifically disagreed with EEI's contention that compliance with the arsenic and asbestos standards satisfies the proposed regulatory requirements of the beryllium rule. NIOSH argued that, unlike arsenic and lead, beryllium is a sensitizer, and as such, necessary and sufficient controls are required to protect workers from life-long risk of beryllium sensitization and disease (Document ID 1960, Attachment 2, p. 6).

OSHA also received comment and heard testimony from Dr. Weissman of NIOSH recommending that the scope of the standard be based on employee exposures and not the concentration of beryllium in the material (Document ID 1671, pp. 5–6; Document ID 1755, Tr. 17–18). NIOSH identified coal-fired electric power generation and primary aluminum production as industries that could fall under the 0.1 percent exemption (Document ID 1671, Attachment 1, p. 6). Stating it was not aware of any medical screening of utility workers exposed to fly ash, NIOSH recommended that OSHA include coal-fired electric power generation in the scope of the standard unless and until available data can demonstrate that there is no risk of sensitization to those workers (Document ID 1671, p. 6). NIOSH did not offer specifics on the magnitude of beryllium exposure in the aluminum production industry. In its post-hearing brief, NIOSH recommended that OSHA remove the 0.1 percent exemption from the rule, allowing the rule to cover a broad range of construction, shipyard, and electric utility power generation activities that are associated with beryllium exposure, such as abrasive blasting with coal or copper slag, repairing and maintaining structures contaminated with fly ash, and remediation or demolition (Document ID 1960, Attachment 2, p. 2). And Peggy Mroz of NJH testified that beryllium sensitization and CBD have been reported in the aluminum industry and that NJH has continued to see cases of severe CBD in workers exposed to beryllium through medical recycling and metal reclamation (Document ID 1756, Tr. 98–99).

Other commenters suggested limiting the exemption, as OSHA proposed in Regulatory Alternative #1b, to require employers to demonstrate, using objective data, that the materials, when processed or handled, cannot release beryllium in concentrations at or above the action level as an 8-hour TWA under any foreseeable conditions (Document ID 1597, p. 1; 1681, pp. 5–6). For example, the Materion-USW proposed standard included the 0.1 percent exemption unless objective data or initial monitoring showed exposures could exceed the action level or STEL. USW asserted that not including this requirement in the rule would be a mistake (Document ID 1681, pp. 5–6). The AFL–CIO also supported the joint USW-Materion scope provision (Document ID 1756, Tr. 212). Mike Wright of the USW asserted that maintaining the 0.1 percent exemption would leave thousands of workers unprotected, including those performing abrasive blasting operations in general industry, ship building, and construction (Document ID 1755, Tr. 111–114). Mr. Wright argued that in the 1,3 Butadiene standard OSHA recognized that the 0.1 percent exemption would not protect some workers and therefore included additional language limiting the exemption where objective data showed ''that airborne concentrations generated by such mixtures can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release'' (Document ID 1755, Tr. 113; 29 CFR 1910.1051(a)(2)(ii)). Mr. Wright urged OSHA to include similar language in the beryllium standard (Document ID 1755, Tr. 113–114).

Some commenters endorsed a modified version of Alternative #1b. For example, the Department of Defense (DOD) supported Alternative #1b, but also suggested limiting the exemption if exposures ''could present a health risk

to employees'' (Document ID 1684, Attachment 2, pp. 1, 3). Boeing suggested adding a different exemption to the scope of the standard:

> where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release dusts, fumes, or mists of beryllium in concentrations at or above 0.02 μg/m³ as an 8-hour time-weighted average (TWA) or at or above 0.2 μg/m³ as determined over a sampling period of 15 minutes under any expected conditions of use (Document ID 1667, p. 12).

Other commenters, like ABMA, criticized Regulatory Alternative #1b, insisting that the rulemaking record contained no evidence to support expanding the scope, but that if the scope was expanded to cover trace beryllium, a significant exemption would be needed. ABMA argued that such an exemption would need to go considerably beyond that of using the action level or STEL because of the substantial costs, particularly on small businesses, that would be incurred where there is no evidence of benefit. However, ABMA did not specify what such an exemption would look like (Document ID 1673, p. 11). Similarly, the National Rural Electric Cooperative Association (NRECA) objected to Regulatory Alternative #1b as being unnecessary to protect employees from CBD in coal fired power plants (Document ID 1687, p. 2).

Ameren did not agree with the objective data requirement in Regulatory Alternative #1b because it would be difficult to perform sampling in a timely manner for the many different maintenance operations that occur infrequently. This would include in the scope of the rule activities for which exposures are difficult to measure, but are less likely to cause exposure than other operations (Document ID 1675, p. 2). The NSSP also does not support Regulatory Alternative #1b because without first expanding the scope of the rule to cover the construction and maritime sectors, employers in construction and maritime would still be excluded (Document ID 1677, p. 1).

OSHA agrees with the many commenters and testimony expressing concern that materials containing trace amounts of beryllium (less than 0.1 percent by weight) can result in hazardous exposures to beryllium. We disagree, however, with those who supported completely eliminating the exemption because this could have unintended consequences of expanding the scope to cover minute amounts of naturally occurring beryllium (Ex 1756 Tr. 55). Instead, we believe that alternative #1b—essentially as proposed by Materion and USW and acknowledging that workers can have significant beryllium exposures even with materials containing less than 0.1%—is the most appropriate approach. Therefore, in the final standard, it is exempting from the standard's application materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

As noted by NIOSH, NABTU, and the AFL–CIO, and discussed in Chapter IV of the FEA, workers in abrasive blasting operations using materials that contain less than 0.1 percent beryllium still have the potential for significant airborne beryllium exposure during abrasive blasting operations and during cleanup of spent abrasive material. NIOSH and the AFL–CIO also identified coal-fired electric power generation and primary aluminum production as industries that could fall under the 0.1 percent exemption but still have significant worker exposure to beryllium. Furthermore, OSHA agrees with NIOSH that the Agency should regulate based on the potential for employee exposures and not the concentration of beryllium in the material being handled. However, OSHA acknowledges the concerns expressed by ABMA and EEI that processing materials with trace amounts of beryllium may not necessarily cause significant exposures to beryllium. OSHA does not have evidence that all materials containing less than 0.1 percent beryllium by weight can result in significant exposure to beryllium, but the record contains ample evidence that there are significant exposures in operations using materials with trace amounts of beryllium, such as abrasive blasting, coal-fired power generation, and primary aluminum production. As discussed in Section VII of this preamble, Significance of Risk, preventing airborne exposures at or above the action level reduces the risk of beryllium-related health effects to workers. OSHA is also not persuaded by comments that claim obtaining this exposure data is too difficult for infrequent or short-term tasks because employers must be able to establish their eligibility for the exemption before being able to take advantage of it. If an employer cannot establish by objective data, including actual monitoring data, that exposures will not exceed the action level, then the beryllium standards apply to protect that employer's workers.

As pointed out by commenters such as the USW, similar exemptions are included in other OSHA standards, including Benzene (29 CFR 1910.1028), Methylenedianiline (MDA) (29 CFR 1910.1050), and 1,3-Butadiene (BD) (29 CFR 1910.1051). These exemptions were established because workers in the exempted industries or workplaces were not exposed to the subject chemical substances at levels of significant risk. In the preamble to the MDA standard, OSHA states that the Agency relied on data showing that worker exposure to mixtures or materials of MDA containing less than 0.1 percent MDA did not create any hazards other than those expected from worker exposure beneath the action level (57 FR 35630, 35645–46). The exemption in the BD standard does not apply where airborne concentrations generated by mixtures containing less than 0.1 percent BD by volume can exceed the action level or STEL (29 CFR 1910.1051(a)(2)(ii)). The exemption in the Benzene standard was based on indications that exposures resulting from substances containing trace amounts of benzene would generally be below the exposure limit and on OSHA's determination that the exemption would encourage employers to reduce the concentration of benzene in certain substances (43 FR 27962, 27968).

OSHA's decision to maintain the 0.1 percent exemption and require employers to demonstrate, using objective data, that the materials, when processed or handled, cannot release beryllium in concentrations at or above the action level as an 8-hour TWA under any foreseeable conditions, is a change from proposed paragraph (a)(3) that specified only that the standard did not apply to materials containing less than 0.1 percent beryllium by weight. This is also a change from Regulatory Alternative #1b in another respect, insofar as it proposed requiring objective data demonstrating that employee exposure to beryllium will remain below both the proposed action level and STEL. OSHA removed the STEL requirement as largely redundant because if exposures exceed the STEL of 2.0 μg/m³ for more than one 15-minute period per 8-hour shift, even if exposures are non-detectable for the remainder of the shift, the 8-hour TWA would exceed the action level of 0.1 μg/m³.

Further, OSHA added the phrase ''under any foreseeable conditions'' to paragraph (a)(3) of the final standards to make clear that limited sampling results indicating exposures are below the

action level would be insufficient to take advantage of this exemption. When using the phrase ''any foreseeable conditions,'' OSHA is referring to situations that can reasonably be anticipated. For example, annual maintenance of equipment during which exposures could exceed the action level would be a situation that is generally foreseeable.

In sum, the proposed standard covered occupational exposures to beryllium in all forms, compounds, and mixtures in general industry. It did not apply to articles, as defined by the HCS, or to materials containing less than 0.1 percent beryllium by weight. After a thorough review of the record, OSHA has decided to adopt Regulatory Alternative #2a and include the construction and shipyard sectors within the scope of the final rule. This decision was in response to the majority of comments recommending that OSHA protect workers in these sectors under the final rule and the exposure data in these sectors contained in the record. OSHA has also decided to adopt a modified version of Regulatory Alternative #1b and limit the 0.1 percent exemption to those employers who have objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

Therefore, the final rule contains three standards—one each for general industry, construction, and shipyard. The article exemption has remained unchanged, and the 0.1 percent exemption has been limited to protect workers with significant exposures despite working with materials with trace amounts of beryllium.

(b) Definitions

Paragraph (b) includes definitions of key terms used in the standard. To the extent possible, OSHA uses the same terms and definitions in the standard as the Agency has used in other OSHA health standards. Using similar terms across health standards, when possible, makes them more understandable and easier for employers to follow. In addition, using similar terms and definitions helps to facilitate uniformity of interpretation and enforcement.

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air ($\mu g/m^3$) calculated as an 8-hour time-weighted average (TWA). Exposures at or above the action level trigger requirements for periodic exposure monitoring when the employer is following the scheduled monitoring option (see paragraph (d)(3)). In addition, paragraph (f)(1)(i)(B) requires employers to list as part of their written exposure control plan the operations and job titles reasonably expected to have exposure at or above the action level. Paragraph (f)(2) requires employers to ensure that at least one of the controls listed in paragraph (f)(2)(i) is in place unless employers can demonstrate for each operation or process either that such controls are not feasible, or that employee exposures are below the action level based on at least two representative personal breathing zone samples taken at least seven days apart. In addition, under paragraph (k)(1)(i)(A), employee exposure at or above the action level for more than 30 days per year triggers requirements for medical surveillance. The medical surveillance provision triggered by the action level allows employees to receive exams at least every two years at no cost to the employee. The action level is also relevant to the medical removal requirements. Employees eligible for removal can choose to remain in environments with exposures at or above the action level, provided they wear respirators (paragraph (l)(2)(ii)). These employees may also choose to be transferred to comparable work in environments with exposures below the action level (if comparable work is not available, the employer must maintain the employee's earnings and benefits for six months or until comparable work becomes available (paragraph (l)(3)).

OSHA's risk assessment indicates that significant risk remains at and below the TWA PEL (see this preamble at section VII, Significance of Risk). When there is significant risk remaining at the PEL, the courts have ruled that OSHA has the legal authority to impose additional requirements, such as action levels, on employers to further reduce risk when those requirements will result in a greater than minimal incremental benefit to workers' health (*Asbestos II,* 838 F.2d at 1274). OSHA concludes that an action level for beryllium exposure will result in a further reduction in risk beyond that provided by the PEL alone.

Another important reason to set an action level involves the variable nature of employee exposures to beryllium. Because of this fact, OSHA concludes that maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to beryllium above the TWA PEL on days when no exposure measurements are made. This consideration is discussed later in this section of the preamble regarding paragraph (d)(3).

The United Steelworkers (USW) commented in support of the action level, noting that it is typical in OSHA standards to have an action level at one half of the PEL (Document ID 1681, p. 11). The USW also commented that the ''action level will further reduce exposure to beryllium by workers and will incentivize employers to implement best practice controls keeping exposures at a minimum as well as reducing costs of monitoring and assessments'' (Document ID 1681, p. 11). National Jewish Health (NJH) also supported OSHA's proposal for a more comprehensive standard and noted that the action level in the Department of Energy's beryllium standard has been ''very effective at reducing exposures and rates of beryllium sensitization and chronic beryllium disease in those facilities'' (Document ID 1756, p. 90).

As noted by the commenters, OSHA's decision to set an action level of one-half of the TWA PEL is consistent with previous standards, including those for inorganic arsenic (29 CFR 1910.1018), chromium (VI) (29 CFR 1910.1026), benzene (29 CFR 1910.1028), ethylene oxide (29 CFR 1910.1047), methylene chloride (29 CFR 1910.1052), and respirable crystalline silica (29 CFR 1910.1053).

The definition of ''action level'' is therefore unchanged from the proposal. Some of the ancillary provisions triggered by the action level have changed since the proposal. Those changes are discussed in more detail in the Summary and Explanation sections for those provisions.

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

OSHA included a definition for the terms ''exposure'' and ''exposure to beryllium'' in the proposed rule, and defined the terms to mean ''the exposure to airborne beryllium that would occur if the employee were not using a respirator.'' In the final rule, the word ''airborne'' is added to the terms to make clear that they refer only to airborne beryllium, and not to dermal contact with beryllium. The modified terms replace ''exposure'' and ''exposure to beryllium'' in the rule, and the terms ''exposure'' and ''exposure to beryllium'' are no longer defined.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee. OSHA received no comments on this definition, and it is unchanged from the proposal.

Beryllium lymphocyte proliferation test (BeLPT) means the measurement of blood lymphocyte proliferation in a

laboratory test when lymphocytes are challenged with a soluble beryllium salt. For additional explanation of the BeLPT, see the Health Effects section of this preamble (section V). Under paragraph (f)(1)(ii)(B), an employer must review and evaluate its written exposure control plan when an employee is confirmed positive. The BeLPT could be used to determine whether an employee is confirmed positive (see definition of ''confirmed positive'' in paragraph (b) of this standard). Paragraph (k)(3)(ii)(E) requires the BeLPT unless a more reliable and accurate test becomes available.

NJH supported OSHA's definition of the BeLPT in the NPRM (Document ID 1664, p. 5). However, OSHA has made one change from the proposed definition of the BeLPT in the NPRM to the final definition to provide greater clarity. The Agency has moved the characterization of a confirmed positive result from the BeLPT definition to the ''confirmed positive'' definition because it was more appropriate there.

Beryllium work area means any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is potential for dermal contact with beryllium. The definition of ''beryllium work area'' has been changed from the proposed definition to reflect stakeholder concerns regarding the overlap between a beryllium work area and regulated area, and to include the potential for dermal exposure. The definition only appears in the general industry standard because the requirement for a beryllium work area only applies to the general industry standard. Beryllium work areas are areas where employees are or can reasonably be expected to be exposed to airborne beryllium at any level, whereas an area is a regulated area only if employees are or can reasonably be expected to be exposed above the TWA PEL or STEL; the regulated area, therefore, is either a subset of the beryllium work area or, less likely, identical to it, depending on the configuration and circumstances of the worksite. Dermal exposure has also been included in the final definition to address the potential for sensitization from dermal contact. Therefore, while not all beryllium work areas are regulated areas, all regulated areas are beryllium work areas because they are areas with employee exposure to beryllium. Accordingly, all requirements for beryllium work areas also apply in all regulated areas, but requirements specific to regulated areas apply only to regulated areas and not to beryllium work areas where exposures do not exceed the TWA PEL or STEL. For further discussion, see this section of the preamble regarding paragraph (e), Beryllium work areas and regulated areas.

The presence of a beryllium work area triggers a number of the requirements in the general industry standard. Under paragraph (d)(3)(i), employers must determine exposures for each beryllium work area. Paragraphs (e)(1)(i) and (e)(2)(i) require employers to establish, maintain, identify, and demarcate the boundaries of each beryllium work area. Under paragraph (f)(1)(i)(D), employers must minimize cross-contamination by preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within a beryllium work area. Paragraph (f)(1)(i)(F) states that employers must minimize migration of beryllium from the beryllium work area to other locations within and outside the workplace. Paragraph (f)(2) requires employers to implement at least one of the controls listed in (f)(2)(i)(A) through (D) for each operation in a beryllium work area unless one of the exemptions in (f)(2)(ii) applies. Paragraph (i)(1) requires employers to provide readily accessible washing facilities to employees working in a beryllium work area, and to ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. In addition employers must ensure that these areas comply with the Sanitation standard (29 CFR 1910.141) (paragraph (i)(4)). Employers must maintain surfaces in all beryllium work areas as free as practicable of beryllium (paragraph (j)(1)(i)). Paragraph (j)(2) requires certain practices and prohibits other practices for cleaning surfaces in beryllium work areas. Under paragraph (m)(4)(ii)(B), employers must ensure workers demonstrate knowledge of the written exposure control plan with emphasis on the location(s) of beryllium work areas.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results. For purposes of these standards, the term ''CBD diagnostic center'' refers to any medical facility that meets these criteria, whether or not the medical facility formally refers to itself as a CBD diagnostic center. For example, if a hospital has all of the capabilities required by this standard for CBD diagnostic centers, the hospital would be considered a CBD diagnostic center for purposes of these standards.

OSHA received comments from NJH and ORCHSE Strategies (ORCHSE) regarding the definition of the ''CBD diagnostic center.'' NJH commented that CBD diagnostic centers do not need to be able to perform the BeLPT but should be able to process the BAL appropriately and ship samples within 24 hours to a facility that can perform the BeLPT. NJH also indicated that CBD diagnostic centers should be able to perform CT scans, pulmonary function tests with DLCO (diffusing capacity of the lungs for carbon monoxide), and measure gas exchange abnormalities. NJH further indicated that CBD diagnostic centers should have a medical doctor who has experience and expertise, or is willing to obtain such expertise, in the diagnosis and treatment of chronic beryllium disease (Document ID 1664, pp. 5–6). ORCHSE argued that CBD diagnostic centers should be allowed to rely on off-site interpretation of transbronchial biopsy pathology, reasoning that this change would broaden the accessibility of CBD diagnostic centers to more affected employees (Document ID 1691, p. 3).

OSHA evaluated these recommendations and included the language regarding sample processing and removed the proposal's requirement that BeLPTs be performed on-site. The Agency also changed the requirement that pulmonary specialist perform testing as outlined in the proposal to the final definition which requires that a pulmonary specialist be on-site. This requirement addresses the concerns ORCHSE raised about accessibility of CBD diagnostic centers by increasing the number of facilities that would qualify as centers. This also preserves the expertise required to diagnose and treat CBD as stated by NJH (Document 1664, p. 6).

Paragraph (k)(7) includes provisions providing for an employee who has been confirmed positive to receive an initial clinical evaluation and subsequent medical examinations at a CBD diagnostic center.

Chronic beryllium disease (CBD) means a chronic lung disease associated

with exposure to airborne beryllium. The Health Effects section of this preamble, section V, contains more information on CBD. CBD is relevant to several provisions of this standard. Under paragraph (k)(1)(i)(B), employers must make medical surveillance available at no cost to employees who show signs and symptoms of CBD. Paragraph (k)(3)(ii)(B) requires medical examinations conducted under this standard to include a physical examination with emphasis on the respiratory system, in order to identify respiratory conditions such as CBD. Under paragraph (k)(5)(i)(A), the licensed physician's report must advise the employee on whether or not the employee has any detected medical condition that would place the employee at an increased risk of CBD from further exposure to beryllium. Furthermore, CBD is a criterion for medical removal under paragraph (l)(1). Under paragraph (m)(1)(ii), employers must address CBD in classifying beryllium hazards under the hazard communication standard (HCS) (29 CFR 1910.1200). Employers must also train employees on the signs and symptoms of CBD (see paragraph (m)(4)(ii)(A) of the general industry and shipyard standards and paragraph (m)(3)(ii)(A) of the construction standard).

Competent person means an individual on a construction site who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the standard for construction. This definition appears only in the standard for construction.

The competent person concept has been broadly used in OSHA construction standards (*e.g.,* 29 CFR 1926.32(f) and 1926.20(b)(2)), including in the recent health standard for respirable crystalline silica (29 CFR 1926.1153). Under 29 CFR 1926.32(f), competent person is defined as ''one capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees and who is authorized to take prompt corrective measures to eliminate them.'' OSHA has adapted this definition for the beryllium construction standard by specifying ''foreseeable beryllium hazards in the workplace'' instead of ''predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees.'' The Agency also replaced the word ''one'' with ''an individual.'' The Agency revised the phrase ''to eliminate them'' to read ''to eliminate or minimize them'' to denote there may be cases where complete elimination would not be feasible. The definition of competent person also indicates that the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard, in order to ensure that the competent has appropriate training, education, or experience. See the discussion of ''competent person'' in the summary and explanation of paragraphs (e), Beryllium work areas and regulated areas, and (f), Methods of compliance, in this section.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two (either consecutive or non-consecutive) abnormal BeLPT test results, an abnormal and borderline test result, or three borderline test results. The definition of ''confirmed positive'' also includes a single result of a more reliable and accurate test indicating that a person has been identified as sensitized to beryllium if the test has been validated by repeat testing to have more accurate and precise diagnostic capabilities within a single test result than the BeLPT. OSHA recognizes that diagnostic tests for beryllium sensitization could eventually be developed that would not require a second test to confirm sensitization. Alternative test results would need to have comparable or increased sensitivity, specificity and positive predictive value (PPV) in order to replace the BeLPT as an acceptable test to evaluate beryllium sensitization (see section V.D.5.b of this preamble).

OSHA received comments from NJH, the American Thoracic Society (ATS) and ORCHSE regarding the requirement for consecutive test results within a two year time frame, and the inclusion of borderline test results (Document ID 1664, p.5; 1668, p. 2; 1691, p. 20). NJH and ATS submitted similar comments regarding the requirement of two abnormal BeLPT test results to be consecutive and within two years. According to NJH, ''the definition of 'confirmed positive' [should] include two abnormals, an abnormal and a borderline test result, and/or three borderline tests. This recommendation is based on studies of Middleton *et al.* (2008, and 2011), which showed that these other two combinations result in a PPV similar to two abnormal test results and are an equal predictor of CBD.'' (Document ID 1664, p. 5). In addition, the ATS stated:

> These test results need not be from consecutive BeLPTs or from a second abnormal BeLPT result within a two-year period of the first abnormal result. These recommendations are based on the many studies cited in the docket, as well as those of Middleton, *et al.* (2006, 2008, and 2011), which showed that an abnormal and a borderline result provide a positive predictive value (PPV) similar to that of two abnormal test results for the identification of both beryllium sensitization and for CBD (Document ID 1668, p. 2).

Materion Corporation (Materion) opposed changing the requirement for two abnormal BeLPT results and opposed allowing two or three borderline results to determine sensitization (Document ID 1808, p. 4). Without providing scientific studies or other bases for its position, Materion argued that ''[m]aking a positive BeS determination for an individual without any confirmed abnormal test result is not warranted and clearly is not justifiable from a scientific, policy or legal perspective'' (Document ID 1808, p. 4).

OSHA evaluated these comments and modified the definition of ''confirmed positive'' accordingly for reasons described more fully within the Health Effects section of this preamble, V.D.5.b, including reliance on the Middleton studies (2008, 2011). The original definition for ''confirmed positive'' in the proposed standard was adapted from the model standard submitted to OSHA by Materion and the USW in 2012. Having carefully considered all these comments and their supporting evidence, where provided, the Agency finds the arguments from NJH, ATS, and ORCHSE persuasive. In particular ATS points out the Middleton *et al.* studies ''. . . showed that an abnormal and a borderline result provide a positive predictive value (PPV) similar to that of two abnormal test results for the identification of both beryllium sensitization and for CBD.'' (Document ID. 1688 p. 3). Therefore, the Agency recognizes that a borderline BeLPT test result when accompanied by an abnormal test result, or three separate borderline test results, should also be considered ''confirmed positive.''

In addition, ORCHSE commented on the use of a single test result from a more reliable and accurate test (Document ID 1691, p. 20). Specifically, ORCHSE recommended revising the language to include ''the result of a more reliable and accurate test such that beryllium sensitization can be confirmed after one test, indicating a person has been identified as having beryllium sensitization'' (Document ID 1691, p. 20). In response to the comment from ORCHSE, the Agency has included

additional language regarding the results from an alternative test (Document ID 1691, p. 20). OSHA inserted additional language clarifying that the alternative test has to be validated by repeat testing indicating that it has comparable or increased sensitivity, specificity and PPV than the BeLPT. The Agency finds that this language provides more precise direction for acceptance of an alternative test.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee. The recordkeeping requirements mandate that, upon request, employers make all records required by this standard available to the Director (as well as the Assistant Secretary) for examination and copying (see paragraph (n)(6)). Typically, the Assistant Secretary sends representatives to review workplace safety and health records. However, the Director may also review these records while conducting studies such as Health Hazard Evaluations of workplaces, or for other purposes. OSHA received no comments on this definition, and it is unchanged from the proposal.

Emergency means any uncontrolled release of airborne beryllium. An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.

An emergency triggers several requirements of this standard. Under paragraph (g)(1)(iv), respiratory protection is required during emergencies to protect employees from potential overexposures. Emergencies also trigger clean-up requirements under paragraph (j)(1)(ii), and medical surveillance under paragraph (k)(1)(i)(C). In addition, under paragraph (m)(4)(ii)(D) of the standards for general industry and shipyards and paragraph (m)(3)(ii)(D) of the standard for construction, employers must train employees in applicable emergency procedures.

High-efficiency particulate air (HEPA) filter means a filter that is at least 99.97 percent effective in removing particles 0.3 micrometers in diameter (*see* Department of Energy Technical Standard DOE–STD–3020–2005). HEPA filtration is an effective means of removing hazardous beryllium particles from the air. The standard requires beryllium-contaminated surfaces to be cleaned by HEPA vacuuming or other methods that minimize the likelihood of exposure (see paragraphs (j)(2)(i) and (ii)). OSHA received no comments on this definition, and it is unchanged from the proposal.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

OSHA did not include a definition of ''objective data'' in the proposed rule. Use of objective data was limited in the proposed rule, and applied only to an exception from initial monitoring requirements in proposed paragraph (d)(2). Proposed paragraph (d)(2)(ii) included criteria for objective data.

The final rule allows for expanded use of objective data. Paragraph (a)(3) allows for use of objective data to support an exception from the scope of the standards. Paragraph (d)(2) allows for use of objective data as part of the performance option for exposure assessment. OSHA is therefore including a definition of ''objective data'' in paragraph (b) of the standards. The definition is generally consistent with the criteria included in proposed paragraph (d)(2)(ii), and with the use of this term in other OSHA substance-specific health standards such as the standards addressing exposure to cadmium (29 CFR 1910.1027), chromium (VI) (29 CFR 1010.1026), and respirable crystalline silica (29 CFR 1910.1053).

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice, such as license, registration, or certification, allows the person to independently provide or be delegated the responsibility to provide some or all of the health care services required in paragraph (k). The Agency recognizes that personnel qualified to provide medical surveillance may vary from State to State, depending on State licensing requirements. Whereas all licensed physicians would meet this definition of PLHCP, not all PLHCPs must be physicians.

Under paragraph (k)(5) of the standards, the written medical report for the employee must be completed by a licensed physician. Under paragraph (k)(6) of the standard, the written medical opinion for the employer must also be completed by a licensed physician. However, other requirements of paragraph (k) may be performed by a PLHCP under the supervision of a licensed physician (*see* paragraphs (k)(1)(ii), (k)(3)(i), (k)(3)(ii)(F), (k)(3)(ii)(G), and (k)(5)(iii)). The standard also identifies what information the employer must give to the PLHCP providing the services listed in this standard, and requires that employers maintain a record of this information for each employee (*see* paragraphs (k)(4) and (n)(3)(ii)(C), and the summary and explanation of paragraphs (k), Medical surveillance, in this section).

Allowing a PLHCP to provide some of the services required under this rule is consistent with other recent OSHA health standards, such as bloodborne pathogens (29 CFR 1910.1030), respiratory protection (29 CFR 1910.134), methylene chloride (29 CFR 1910.1052), and respirable crystalline silica (29 CFR 1910.1053). OSHA received no comments on this definition, and it is unchanged from the proposal.

Regulated area means an area, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the TWA PEL or STEL. For an explanation of the distinction and overlap between beryllium work areas and regulated areas, see the definition of ''beryllium work area'' earlier in this section of the preamble and the summary and explanation for paragraph (e), Beryllium work areas and regulated areas. Regulated areas appear only in the general industry and shipyard standards, and they trigger several other requirements.

Paragraphs (e)(1)(ii) and (e)(2)(ii) require employers to establish and demarcate regulated areas. Note that the demarcation requirements for regulated areas are more specific than those for other beryllium work areas (see also paragraph (m)(2) of the standards for general industry and shipyards). Paragraph (e)(3) requires employers to restrict access to regulated areas to authorized persons, and paragraph (e)(4) requires employers to provide all employees in regulated areas appropriate respiratory protection and personal protective clothing and equipment, and to ensure that these employees use the required respiratory protection and protective clothing and equipment. Paragraph (i)(5)(i) prohibits employers from allowing employees to eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas. Paragraph (m)(2) requires warning signs associated with regulated areas to meet

certain specifications. Paragraph (m)(4)(ii)(B) requires employers to train employees on the written exposure control plan required by paragraph (f)(1), including the location of regulated areas and the specific nature of operations that could result in airborne exposure.

In the proposed rule, OSHA included in the definition of the term ''regulated area'' that it was ''an area that the employer must demarcate.'' Because the requirement to demarcate regulated areas is presented elsewhere in the standards, the reference in the definition to ''an area that the employer must demarcate'' is redundant, and has been removed from the final definition of the term.

This definition of regulated areas is consistent with other substance-specific health standards that apply to general industry and shipyards, such as the standards addressing occupational exposure to cadmium (29 CFR 1910.1027 and 29 CFR 1915.1027), benzene (29 CFR 1910.1028 and 29 CFR 1915.1028), and methylene chloride (29 CFR 1910.1052 and 29 CFR 1915.1052).

This standard means the beryllium standard in which it appears. In the general industry standard, it refers to 29 CFR 1910.1024. In the shipyard standard, it refers to 29 CFR 1915.1024. In the construction standard, it refers to 29 CFR 1926.1124. This definition elicited no comments and differs from the proposal only in that it appears in the three separate standards.

(c) Permissible Exposure Limits (PELs)

Paragraph (c) of the standards establishes two permissible exposure limits (PELs) for beryllium in all forms, compounds, and mixtures: An 8-hour time-weighted average (TWA) PEL of 0.2 μg/m³ (paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0 μg/m³ (paragraph (c)(2)). The TWA PEL section of the standards requires employers to ensure that no employee's exposure to beryllium, averaged over the course of an 8-hour work shift, exceeds 0.2 μg/m³. The STEL section of the standards requires employers to ensure that no employee's exposure, sampled over any 15-minute period during the work shift, exceeds 2.0 μg/m³. While the proposed rule contained slightly different language in paragraph (c), *i.e.* requiring that ''each employee's airborne exposure does not exceed'' the TWA PEL and STEL, the final language was chosen by OSHA to remain consistent with prior OSHA health standards and to clarify that OSHA did not intend a different interpretation of the PELs in this standard. The same PELs apply to general industry, construction, and shipyards.

TWA PEL. OSHA proposed a new TWA PEL of 0.2 μg/m³ of beryllium—one-tenth the preceding TWA PEL of 2 μg/m³—because OSHA preliminarily found that occupational exposure to beryllium at and below the preceding TWA PEL of 2 μg/m³ poses a significant risk of material impairment of health to exposed workers. As with several other provisions of these standards, OSHA's proposed TWA PEL followed the draft recommended standard submitted to the Agency by Materion Corporation (Materion) and the United Steelworkers (USW) (see this preamble at section III, Events Leading to the Standards).

After evaluating the record, including published studies and more recent exposure data from industrial facilities involved in beryllium work, OSHA is adopting the proposed TWA PEL of 0.2 μg/m³. OSHA has made a final determination that occupational exposure to a variety of beryllium compounds at levels below the preceding PELs poses a significant risk to workers (see this preamble at section VII, Significance of Risk). OSHA's risk assessment, presented in section VI of this preamble, indicates that there is significant risk of beryllium sensitization,[38] CBD, and lung cancer from a 45-year (working life) exposure to beryllium at the preceding TWA PEL of 2 μg/m³. The risk assessment further indicates that, although the risk is much reduced, significant risk remains at the new TWA PEL of 0.2 μg/m³.

OSHA has determined that the new TWA PEL is feasible across all affected industry sectors (see section VIII.D of this preamble, Technological Feasibility) and that compliance with the new PEL will substantially reduce employees' risks of beryllium sensitization, Chronic Beryllium Disease (CBD), and lung cancer (see section VI of this preamble, Risk Assessment). OSHA's conclusion about feasibility is supported both by the results of the Agency's feasibility analysis and by the recommendation of the PEL of 0.2 μg/m³ by Materion and the USW.

Materion is the sole beryllium producer in the U.S., and its facilities include some of the processes where OSHA expects it will be most challenging to control beryllium exposures. Although OSHA also found that there is significant risk at the proposed alternative TWA PEL of 0.1 μg/m³, OSHA did not adopt that alternative because the Agency could not demonstrate technological feasibility at that level (see section VIII.D of this preamble, Technological Feasibility).

The TWA PEL was the subject of numerous comments in the rulemaking record. Comments from stakeholders in labor and industry, public health experts, and the general public supported OSHA's selection of 0.2 μg/m³ as the final PEL (NIOSH, Document ID 1671, Attachment 1, p. 2; National Safety Council, 1612, p. 3; The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee of the Department of Energy's National Nuclear Security Administration Lawrence Livermore National Lab (BHSC Task Group), 1655, p. 2; Newport News Shipbuilding, 1657, p. 1; National Jewish Health (NJH),1664, p. 2; The Aluminum Association, 1666, p. 1; The Boeing Company (Boeing), 1667, p. 1; American Industrial Hygiene Association (AIHA), 1686, p. 2; United Steelworkers (USW), 1681, p. 7; Andrew Brown, 1636, p. 6; Department of Defense, 1684, p. 1). Materion stated that the record does not support the feasibility of any limit lower than 0.2 μg/m³ (Document ID 1808, p. 2). OSHA also received comments supporting selection of a lower TWA PEL of 0.1 μg/m³ from Public Citizen, the AFL–CIO, the United Automobile, Aerospace & Agricultural Implement Workers of America (UAW), North America's Building Trades Unions (NABTU), and the American College of Occupational and Environmental Medicine (ACOEM) (Document ID 1689, p. 7; 1693, p. 3; 1670, p. 1; 1679, pp. 6–7; 1685, p. 1; 1756, Tr. 167). These commenters based their recommendations on the significant risk of material health impairment from exposure at the TWA PEL of 0.2 μg/m³ and below, which OSHA acknowledges.

In addition to their concerns about risk, Public Citizen and the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) argued that a TWA PEL of 0.1 μg/m³ is feasible (Document ID 1756, Tr. 168–169, 197–198). As discussed further below, however, OSHA's selection of the TWA PEL in this case was limited by the findings of its technological feasibility analysis. No commenter provided information that would permit OSHA to show the feasibility of a TWA PEL of 0.1 μg/m³ in industries where OSHA did not have sufficient information to make this determination at the proposal stage. Public Citizen instead argued that insufficient evidence that engineering and work practice controls can maintain exposures at or below a TWA PEL of 0.1

[38] As discussed in section VII of this preamble, Significance of Risk, beryllium sensitization is a necessary precursor to developing CBD.

μg/m³ should not preclude OSHA from establishing such a PEL; and that workplaces unable to achieve a TWA PEL of 0.1 μg/m³ should be required to reduce airborne exposures as much as possible using engineering and work practice controls, supplemented with a respiratory protection program (Document ID 1670, p. 5).

OSHA has determined that Public Citizen's claim that the Agency should find a PEL of 0.1 μg/m³ technologically feasible is inconsistent with the test for feasibility as described by the courts as well as the evidence in the rulemaking record. OSHA bears the evidentiary burden of establishing feasibility in a rulemaking challenge. The D.C. Circuit, in its decision on OSHA's Lead standard (*United Steelworkers of America* v. *Marshall,* 647 F.2d 1189 (D.C. Cir. 1981) (''*Lead*'')), explained that in order to establish that a standard is technologically feasible, ''OSHA must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations'' (*Lead,* 647 F.2d at 1272). ''The effect of such proof,'' the court continued, ''is to establish a presumption that industry can meet the PEL without relying on respirators'' (*Lead,* 647 F.2d at 1272). The court's definition of technological feasibility thus recognizes that, for a standard based on a hierarchy of controls prioritizing engineering and work practice controls over respirators, a particular PEL is not technologically feasible simply because it can be achieved through the widespread use of respirators (*see Lead,* 647 F.2d at 1272). OSHA's long-held policy of avoiding requirements that will result in extensive respirator use is consistent with this legal standard.

In considering an alternative TWA PEL of 0.1 μg/m³ that would reduce risks to workers further than would the TWA PEL of 0.2 μg/m³, OSHA was unable to determine that this level was technologically feasible. For some work operations, the evidence is insufficient for OSHA to demonstrate that a TWA PEL of 0.1 μg/m³ could be achieved most of the time. In other operations, a TWA PEL of 0.1 μg/m³ appears to be impossible to achieve without resort to respirators (see section VIII.D of this preamble, Technological Feasibility, for a detailed discussion of OSHA's feasibility findings). Thus, OSHA was unable to meet its legal burden to demonstrate the technological feasibility of the alternative TWA PEL of 0.1 μg/m³ (*see Lead,* 647 F.2d at 1272; *Amer. Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 990 (D.C. Cir. 1991)) and has adopted the proposed PEL of 0.2 μg/m³, for which there is substantial evidence demonstrating technological feasibility.

OSHA also invited comment on and considered an alternative TWA PEL of 0.5 μg/m³—two-and-a-half times greater than the proposed PEL that it is adopting. As noted above, OSHA determined that significant risk to worker health exists at the preceding PEL of 2.0 μg/m³ as well as at the new TWA PEL of 0.2 μg/m³. Because OSHA found that a TWA PEL of 0.2 μg/m³ is technologically and economically feasible, the Agency concludes that setting the TWA PEL at 0.5 μg/m³—a level that would leave workers exposed to even greater health risks than they will face at the new PEL of 0.2 μg/m³—would be contrary to the OSH Act, which requires OSHA to eliminate the risk of material health impairment ''to the extent feasible'' (29 U.S.C. 655(b)(5)). Thus, the Agency is not adopting the proposed alternative TWA PEL of 0.5 μg/m³.

Because significant risks of sensitization, CBD, and lung cancer remain at the new TWA PEL of 0.2 μg/m³, the final standards include a variety of ancillary provisions to further reduce risk to workers. These ancillary provisions include implementation of feasible engineering controls in beryllium work areas, respiratory protection, personal protective clothing and equipment, exposure monitoring, regulated areas, medical surveillance, medical removal, hygiene areas, housekeeping requirements, and hazard communication. The Agency has determined that these provisions will reduce the risk beyond that which the TWA PEL alone could achieve. These provisions are discussed later in this Summary and Explanation section of the preamble.

STEL. OSHA is also promulgating a STEL of 2.0 μg/m³, as determined over a sampling period of 15 minutes. The new STEL of 2 μg/m³ was suggested by the joint Materion-USW proposed rule and proposed in the NPRM. As discussed in section VII of this preamble, significant risks of sensitization, CBD, and lung cancer remain at the TWA PEL of 0.2 μg/m³. Where a significant risk of material impairment of health remains at the TWA PEL, OSHA must impose a STEL if doing so would further reduce risk and is feasible to implement (*Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1505 (D.C. Cir. 1986) (''*Ethylene Oxide*''); *see also Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1271 (D.C. Cir. 1988)). In this case, the evidence in the record demonstrates that the STEL is feasible and that it will further reduce the risk remaining at the TWA PEL. The goal of a STEL is to protect employees from the risk of harm that can occur as a result of brief exposures that exceed the TWA PEL. Without a STEL, the only protection workers would have from high short-duration exposures is that, when those exposures are factored in, they cannot exceed the cumulative 8-hour exposure at the proposed 0.2 μg/m³ TWA PEL (*i.e.,* 1.6 μg/m³). Since there are 32 15-minute periods in an 8-hour work shift, a worker's 15-minute exposure in the absence of a STEL could be as high as 6.4 μg/m³ (32 × 0.2 μg/m³) if that worker's exposures during the remainder of the 8-hour work shift are non-detectable. A STEL serves to minimize high, task-based exposures by requiring feasible controls in these situations, and has the added effect of further reducing the 8-hour TWA exposure.

OSHA believes a STEL for beryllium will help reduce the risk of sensitization and CBD in beryllium-exposed employees. As discussed in this preamble at section V, Health Effects, beryllium sensitization is the initial step in the development of CBD. Sensitization has been observed in some workers who were only exposed to beryllium for a few months (see section V.D.1 of this preamble), and tends to be more strongly associated with 'peak' and highest-job-worked exposure metrics than cumulative exposure (see section V.D.5 of this preamble). Short-term exposures to beryllium have also been shown to contribute to the development of lung disease in laboratory animals (see this preamble at section V, Health Effects). These study findings indicate that adverse effects to the lung may occur from beryllium exposures of relatively short duration. Thus OSHA expects a STEL to add further protection from the demonstrated significant risk of harm than that afforded by the new 0.2 μg/m³ TWA PEL alone.

STEL exposures are typically associated with, and need to be measured by the employer during, the highest-exposure operations that an employee performs (see paragraph (d)(3)(ii)). OSHA has determined that the STEL of 2.0 μg/m³ can be measured for this brief period of time using OSHA's available sampling and analytical methodology, and that feasible means exist to maintain 15-minute short-term exposures at or below the proposed STEL (see section VIII.D of this preamble, Technological Feasibility). Comments on the STEL were generally supportive of OSHA's

decision to include a beryllium STEL, but differed on the appropriate level. NIOSH recommended a STEL of at most 1 μg/m³, noting that available exposure assessment methods are sensitive enough to support a STEL of 1 μg/m³ and that it is likely to be more protective than the proposed STEL of 2 μg/m³ (Document ID 1960, Attachment 2, p. 4; 1725, p. 35; 1755, Tr. 22). NJH's comments also supported a STEL of 1 μg/m³ as the best option (Document ID 1664, p. 3). Public Citizen and the AFL–CIO advocated for a STEL of 1 μg/m³, stating that it would be more protective than the proposed STEL of 2 μg/m³ (Document ID 1670, p. 6; 1689, p. 7–8). The AFL–CIO and Public Citizen both stated that a STEL of 1 μg/m³ is supported in the record, including by exposure data from OSHA workplace inspections (Document ID 1670, p. 6; 1756, Tr. 171). However, no additional engineering controls capable of reducing short term exposures to or below 1.0 μg/m³ were identified by commenters. Public commenters did not provide any empirical data to suggest that those exposed to working conditions associated with a STEL of 2.0 μg/m³ would be more likely to be sensitized than those exposed to working conditions associated with a STEL of 1.0 μg/m³. However, OSHA notes that the available epidemiological literature on beryllium-related disease does not address the question of whether those exposed to working conditions associated with a STEL of 2.0 μg/m³ would be more likely to be sensitized than those exposed to working conditions associated with a STEL of 1.0 μg/m³. Detailed documentation of workers' short-term exposures is typically not available to researchers. Therefore, OSHA cannot exclusively rely on evidence relating health effects to specific short-term exposure levels to set a STEL. In setting a STEL, OSHA also examines the likelihood that a given STEL will help to reduce excursions above the TWA PEL and the feasibility of meeting a given STEL using engineering controls. The UAW emphasized that ''OSHA must include the STEL in the standard to ensure that peak exposures are characterized and controlled'' (Document ID 1693, p. 3). The UAW argued, specifically, for a STEL of five times the PEL (recommending a STEL of 0.5 μg/m³ based on a TWA PEL of 0.1 μg/m³), noting that single short-term, high-level beryllium exposures can lead to sensitization, and that UAW members in industries such as nonferrous foundries and scrap metal reclamation may experience such exposures even when not exposed above the 8 hour TWA PEL (Document ID 1693, p. 3). Ameren Services Company, a public utility that includes electric power generation companies, expressed support for the proposed PEL and STEL, but also expressed support for selecting a STEL of five times the PEL in order to maintain consistency with OSHA's typical approach to setting STELs (Document ID 1675, p. 3).

In contrast, NGK Metals Corporation (NGK) supported the proposed STEL of 2 μg/m³, and specifically argued against a STEL of 0.5 μg/m³ on the basis that a reduced STEL would not be feasible or offer significantly more protection than the proposed STEL (Document ID 1663, p. 4). Materion emphasized the need for ''proactive operational control'' of tasks that could generate high, short-term beryllium exposures, and supported the STEL of 2 μg/m³ contained in OSHA's proposed rule (Document ID 1661, pp. 3, 5). Materion indicated in its comments that the proposed STEL of 2.0 μg/m³ was based on controlling the upper range of worker short term exposures (Document ID 1661). Materion used data provided in the Johnson study of the United Kingdom Atomic Weapons Establishment (AWE) in Cardiff, Wales, as supporting evidence for the proposed STEL (Document ID 1505). However, Dr. Christine Schuler from NIOSH commented that the AWE study was not an appropriate basis for an OSHA STEL because the AWE study was based on workers showing physical signs of CBD (''If somebody became really apparently ill, then they would have identified them.'') (Document ID 1755, Tr. 35). Dr. Schuler additionally commented that the studies performed in the United States are more appropriate since they are based on identified cases of CBD at an earlier stage where there are generally very few symptoms (called asymptomatic or subclinical) (Document ID 1755, Tr. 34–35). OSHA agrees with Dr. Schuler's assessment and that the AWE study should not be used as scientific evidence to support a STEL of 2.0 μg/m³.

After careful consideration of the record, including all available data and stakeholder comments, OSHA has reaffirmed its preliminary determinations that a STEL of 2.0 μg/m³ (ten times the final PEL of 0.2 μg/m³) is technologically feasible and will help reduce the risk of beryllium-related health effects in exposed employees. As discussed in section VIII.D of this preamble, Technological Feasibility, OSHA has determined that the implementation of engineering and work practice controls required to maintain full shift exposures at or below a PEL of 0.2 μg/m³ will reduce short term exposures to 2.0 μg/m³ or below. However, adopting a STEL of 1.0 μg/m³ or lower would likely require additional respirator use in some situations. Thus, OSHA has retained the proposed value of 2.0 μg/m³ as the final STEL.

OSHA also received a comment from Paul Wambach, (an independent commenter) stating that a STEL should not be included in the final rule, arguing that the diseases associated with beryllium exposure are chronic in nature and therefore are not affected by brief excursions above the TWA PEL (Document ID 1591, p. 1). However, as discussed above, OSHA has determined that there is sufficient evidence that brief, high-level exposures to beryllium contribute to the development of beryllium sensitization and CBD to support inclusion of a STEL in the final rule (see this preamble at section V, Health Effects). This comment also discussed the statistical relationship between a 15-minute STEL and 8-hour TWA PEL and issues of sampling strategy, discussed in section VIII.D of this preamble, Technological Feasibility.

CFR Entries. OSHA's preceding PELs for ''beryllium and beryllium compounds,'' were contained in 29 CFR 1910.1000 Table Z–2 for general industry. Table Z–2 contained two PELs: (1) A 2 μg/m³ TWA PEL, and (2) a ceiling concentration of 5 μg/m³ that employers must ensure is not exceeded during the 8-hour work shift, except for a maximum peak of 25 μg/m³ over a 30-minute period in an 8-hour work shift. The preceding PELs for beryllium and beryllium compounds in shipyards (29 CFR 1915.1000 Table Z) and construction (29 CFR 1926.55 Appendix A) were also 2 μg/m³, but did not include ceiling or peak exposure limits. OSHA adopted the preceding PELs in 1972 pursuant to section 6(a) of the OSH Act (29 U.S.C. 655(a)). The 1972 PELs were based on the 1970 American National Standards Institute (ANSI) Beryllium and Beryllium Compounds standard (Document ID 1303), which in turn was based on a 1949 U.S. Atomic Energy Commission adoption of a threshold limit for beryllium of 2.0 μ/m³ and was included in the 1971 American Conference of Governmental Industrial Hygienists Documentation of the Threshold Limit Values for Substances in Workroom Air (Document ID 0543).

OSHA is revising the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z–1 to cross-reference the new general industry standard, 1910.1024. A comparable revision to 29 CFR 1915.1000 Table Z

cross-references the shipyard standard, 1915.1024, and 29 CFR 1926.55 Appendix A is revised to cross-reference the construction standard, 1926.1124. A footnote is added to 29 CFR 1910.1000 Table Z–1, which refers to 29 CFR 1910.1000 Table Z–2 for situations when the new exposure limits in 1910.1024 are stayed or otherwise not in effect. The preceding PELs for beryllium are retained in 29 CFR 1910.1000 Table Z–2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A. Footnotes are added to these tables to make clear that the preceding PELs apply to any sectors or operations where the new TWA PEL of 0.2 μg/m³ and STEL of 2.0 μg/m³ are not in effect. The preceding PELs are also applicable during the time between publication of the beryllium rule and the dates established for compliance with the rule, as well as in the event of regulatory delay, a stay, or partial or full invalidation by the Court.

(d) Exposure Assessment

Paragraph (d) of the final standards for general industry, construction, and shipyards sets forth requirements for assessing employee exposures to beryllium. The requirements are issued pursuant to section 6(b)(7) of the OSH Act, which mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.'' 29 U.S.C. 655(b)(7). Consistent with the definition of ''airborne exposure'' in paragraph (b) of these standards, exposure monitoring results must reflect the exposure to airborne beryllium that would occur if the employee were not using a respirator. Exposures must be assessed using the new performance option (*i.e.,* use of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures) or by following the scheduled monitoring option (with the frequency of monitoring determined by the results of the initial and subsequent monitoring). The performance option provides flexibility for employers who are able to accurately characterize employee exposures through alternative methods like objective data and has been successfully applied in the Chromium (VI) standard and recently included in the respirable crystalline silica standard. The scheduled monitoring option provides a framework that is familiar to many employers, having been a customary practice in past substance-specific OSHA health standards. Under either option, employers must assess the exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium.

In the proposed exposure monitoring provision, OSHA required employers to assess the exposure of employees who are, or may reasonably be expected to be, exposed to airborne beryllium. This obligation consisted of an initial exposure assessment, unless the employer relied on objective data to demonstrate that exposures would be below the action level or the short term exposure level (STEL) under any expected conditions; periodic exposure monitoring (at least annually if initial exposure monitoring indicates that exposures are at or above the action level and at or below the time-weighted average (TWA) PEL); and additional monitoring if changes in the workplace could reasonably be expected to result in new or additional exposures to beryllium. In the proposed rule, monitoring to determine employee TWA exposures had to represent the employee's average exposure to airborne beryllium over an eight-hour workday. STEL exposures had to be characterized by sampling periods of 15 minutes for each operation likely to produce exposures above the STEL. Samples taken had to reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area. Samples had to be taken within an employee's breathing zone. The proposed rule also included provisions for employee notification of monitoring results and observation of monitoring.

OSHA received comments on a variety of issues pertaining to the proposal's exposure monitoring provision. In hearing testimony, Dr. Lisa Maier from National Jewish Health (NJH) expressed general support for exposure monitoring in the workplace ''to target areas that are at or above the action level and to regulate these areas to trigger administrative controls'' (Document ID 1756, Tr. 108). All other comments regarding the exposure monitoring requirements focused on specific areas of those requirements and are discussed in the appropriate subject section below.

OSHA has retained the provisions related to exposure assessment in the final standards. These provisions are important because assessing employee exposure to toxic substances is a well-recognized and accepted risk management tool. As the Agency noted in the proposal, the purposes of requiring assessment of employee exposures to beryllium include determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure to beryllium; collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed in excess of the permissible exposure limit (PEL) or short-term exposure limit (STEL) and to ensure employees have access to accurate information about their exposure levels, as required by section 8(c)(3) of the Act, 29 U.S.C. 657(c)(3). In addition, exposure data enable physicians or other licensed health care professionals (PLHCPs) performing medical examinations to be informed of the extent of the worker's exposure to beryllium.

In the final standards, paragraph (d) is now titled ''Exposure assessment.'' This change from ''exposure monitoring'' in the proposal to ''exposure assessment'' in the final standards was made to align the provision's purpose with the broader concept of exposure assessment beyond conducting air monitoring, including the use of objective data.

General Requirements. Proposed paragraph (d)(1)(i) contained the general requirement that the exposure assessment provisions would apply when employees ''are, or may reasonably be expected to be, exposed to airborne beryllium.'' OSHA did not receive comment on this specific provision. However, in paragraph (d)(1) of the final standards for general industry, construction, and shipyards, the Agency has changed the proposed requirement that ''These exposure monitoring requirements apply when employees are, or may reasonably be expected to be, exposed to airborne beryllium'' to ''The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium.'' This change aligns the language to other OSHA standards such as respirable crystalline silica (29 CFR 1910.1053) and hexavalent chromium (δ1910.1026) as well as clarifies the employer's obligation to assess each employee's beryllium exposure. Additionally, for reasons discussed below, paragraph (d)(1) of the final standards now requires the employer to assess employee exposure in accordance with either the new performance option, added at paragraph (d)(2), or the scheduled monitoring option, moved to paragraph (d)(3) of this section. Changes from the proposed exposure monitoring provision also include an increased

frequency schedule for periodic monitoring and a requirement to perform periodic exposure monitoring when exposures are above the PEL in the scheduled monitoring option in paragraph (d)(3)(vi) and when exposures are above the STEL in the scheduled monitoring option in paragraph (d)(3)(viii).

Proposed paragraphs (d)(1)(ii)–(v) have been moved to different paragraphs in the final standards and will be discussed in the appropriate sections below.

The performance option. Proposed paragraph (d)(2) set forth initial exposure monitoring requirements and the circumstances under which employers do not need to conduct initial exposure monitoring. In the proposal, employers did not have to conduct initial exposure monitoring if they relied on historical data or objective data. The proposal also set forth requirements for the sufficiency of any historical data or objective data used to satisfy proposed paragraph (d)(2). OSHA has decided to remove this provision from the final standards as part of the change to allow employers to choose between the scheduled monitoring option and the performance option for all exposure assessment. Paragraph (d)(2) of the final standards for general industry, construction, and shipyards describes the exposure assessment performance option. OSHA has included this option because it provides employers flexibility to assess the 8-hour TWA and STEL exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to beryllium. OSHA recognizes that exposure monitoring may present challenges in certain instances, particularly when tasks are of short duration or performed under varying environmental conditions. The performance option is intended to allow employers flexibility in assessing the beryllium exposures of their employees. The performance option for exposure assessment is consistent with other OSHA standards, such as those for exposure to respirable crystalline silica (29 CFR 1910.1053) and chromium (VI) (29 CFR 1910.1026).

When the employer elects the performance option, the employer must initially conduct the exposure assessment and must demonstrate that employee exposures have been accurately characterized. As evident in final paragraph (d)(3), OSHA considers exposures to be accurately characterized when they reflect the exposures of employees on each shift, for each job classification, in each work area. However, under this option, the employer has flexibility to determine how to achieve this. For example, under this option an employer could determine that there are no differences between the exposure of an employee in a certain job classification who performs a task in a particular work area on one shift and the exposure of another employee in the same job classification who performs the same task in the same work area on another shift. In that case, the employer could characterize the exposure of the second employee based on the first employee's exposure.

Accurately characterizing employee exposures under the performance option is also an ongoing duty. In order for exposures to continue to be accurately characterized, the employer is required to reassess exposures whenever a change in production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the action level or STEL, or when the employer has any reason to believe that new or additional exposures at or above the action level have occurred (see discussion below of paragraph (d)(4) of the final standards for general industry, construction, and shipyards).

When using the performance option, the burden is on the employer to demonstrate that the data accurately characterize employee exposure. However, the employer can characterize employee exposure within a range, in order to account for variability in exposures. For example, an employer could use the performance option and determine that an employee's exposure is above the action level but below the PEL. Based on this exposure assessment, the employer would be required under paragraph (k)(1)(i)(A) to provide medical surveillance if the employee is exposed for more than 30 days per year.

OSHA has not included specific criteria for implementing the performance option in the final standards. Because the goal of the performance option is to give employers flexibility to accurately characterize employee exposures using whatever combination of air monitoring data and objective data is most appropriate for their circumstances, OSHA concludes it would be inconsistent to specify in the standards exactly how and when data should be collected. When an employer wants a more structured approach for meeting their exposure assessment obligations, it may opt for the scheduled monitoring option.

OSHA does, however, offer two clarifying points. First, the Agency clarifies that when using the term ''air monitoring data'' in this paragraph, OSHA refers to any monitoring conducted by the employer to comply with the requirements of these standards, including the prescribed accuracy and confidence requirements in paragraph (d)(5). Second, objective data can include historic air monitoring data, but that data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Additional discussion of the types of data and exposure assessment strategies that may be used by employers as ''objective data'' to accurately characterize employee exposures to beryllium can be found in the summary and explanation of ''objective data'' in paragraph (b) (''Definitions'').

Where employers rely on objective data generated by others as an alternative to developing their own air monitoring data, they will be responsible for ensuring that the data relied upon from other sources are accurate measures of their employees' exposures. Thus, the burden is on the employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to beryllium.

As with the Chromium (VI) standard, 29 CFR 1910.1026, OSHA does not limit when objective data can be used to characterize exposure. OSHA permits employers to rely on objective data for meeting their exposure assessment obligations, even where exposures may exceed the action level or PEL. OSHA's intent is to allow employers flexibility to assess employee exposures to beryllium, but to ensure that the data used are accurate in characterizing employee exposures. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that employee exposures in a given task are between the action level and PEL, the employer may choose to rely on those data to determine his or her compliance obligations (*e.g.,* medical surveillance).

OSHA has also not established time limitations for air monitoring results used to characterize employee exposures under the performance option. The burden is on the employer to show that the data accurately characterize employee exposure to beryllium. This burden applies to the age of the data as well as to the source of the data. For example, monitoring results obtained 18 months prior to the effective date of the standards could be

used to determine employee exposures, but only if the employer could show that the data were obtained during work operations conducted under conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Regardless of when they were collected, the data must accurately reflect current conditions.

Any air monitoring data relied upon by employers must be maintained and made available in accordance with the recordkeeping requirements in paragraph (n)(1) of the final standards for general industry, construction, and shipyards. Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (n)(2) of the standards.

The scheduled monitoring option. Paragraph (d)(3) of the final standards for general industry, construction, and shipyards describes the scheduled monitoring option. Parts of the scheduled monitoring option in the final standards come from proposed paragraphs (d)(1)(ii)–(iv), which set out the general exposure monitoring requirements. Proposed paragraph (d)(1)(ii) required the employer to determine the 8-hour TWA exposure for each employee, and proposed paragraph (d)(1)(iii) required the employer to determine the 15-minute short-term exposure for each employee. Both proposed paragraph (d)(1)(ii) and (d)(1)(iii) required breathing zone samples to represent the employee's exposure on each work shift, for each job classification, in each beryllium work area.

Some commenters disagreed with the requirement to perform exposure monitoring on each work shift. NGK stated that sampling on each shift is overly burdensome and unnecessary since samples are collected from those employees who are expected to have the highest exposure (Document ID 1663, p. 1). Materion and the United Steelworkers (USW) recommended representative sampling instead of sampling all employees, and sampling from the shift expected to have the highest exposures (Document ID 1680, p. 3). Materion separately commented that monitoring on all three shifts is not warranted, would be burdensome to small businesses, and does not align well with other standards (Document ID 1661, p. 14 (pdf)). In post-hearing comments, Materion submitted an analysis of exposure variation by shift at one of their facilities and argued that the data are the best available evidence that monitoring on all three shifts is not justifiable or necessary to fulfill the requirements of the OSH Act (Document ID 1807, Attachment 1, p. 5, Attachment 7, p. 82; 1958, pp. 5–6). In an individual submission, the USW also stated that three-shift monitoring would add unnecessary compliance costs. Additionally, it commented that if the operations are identical, the shift chosen will not matter, while if they are not identical, then monitoring on the highest exposed shift will overestimate exposures on the other shifts (Document ID 1681, Attachment 1, p. 8). Conversely, the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) noted in post-hearing comments that widely accepted industrial hygiene practice includes exposure monitoring during different shifts, tasks, and times of the year and that monitoring is specifically designed this way to characterize exposure under different conditions (Document ID 1809, p. 1). During the hearings, Dr. Virji from NIOSH testified that because exposure is variable and ''different things happen at different shifts,'' including maintenance activities, ''it is hard to . . . gauge . . . which shift [has] the highest exposure,'' so ''it is important that multiple shifts get representative sampling'' (Document ID 1755, Tr. 50–51).

OSHA agrees with the AFL–CIO and Dr. Virji and has retained the requirement in proposed paragraphs (d)(1)(ii) and (iii) that samples reflect exposures on each shift, for each job classification, and in each work area. This requirement is included in final paragraphs (d)(3)(i) and (ii). However, in response to the comments from Materion and the USW, OSHA restructured the exposure assessment requirements in order to provide employers with greater flexibility to meet their exposure assessment obligations by using either the performance option or the scheduled monitoring option depending on the operation and information available. OSHA believes that conducting exposure assessment on a specific schedule provides employers with a workable structure to properly assess their employees' exposure to beryllium and provides sufficient information for employers to make informed decisions regarding exposure prevention measures. Alternatively, the performance option provides employers with flexibility in accurately characterizing employee exposures to beryllium on the bases of any combination of air monitoring and objective data.

Comments submitted from Mr. Paul Wambach, a private citizen, stated that the proposed short-term exposure limit (STEL) of 2 $\mu g/m^3$ has the potential for being misinterpreted as requiring the use of impractical exposure monitoring methods that would require collecting 32 consecutive 15-minute samples while providing no real health protection benefit and should be dropped from the final rule (Document ID 1591, p. 3). OSHA's intent, however, is that compliance with the STEL can be assessed using a task specific monitoring strategy, during which representative 15-minute samples can be taken to evaluate peak exposures. OSHA maintains that consistent with the comments from Materion, the identification and control of short-term exposures is critical to the protection of worker health from exposure to beryllium.

OSHA has decided to include the scheduled monitoring option in the final standards because it provides employers with a clearly defined, structured approach to assessing employee exposures. Under paragraph (d)(3)(i) of the final standards, employers who select the scheduled monitoring option must conduct initial monitoring to determine employee exposure to beryllium. Air monitoring to determine employee exposures must represent the employee's 8-hour TWA exposure to beryllium. Final paragraph (d)(3)(ii) requires the employer to perform initial monitoring to assess the employee's 15-minute short-term exposure. Under both paragraphs (d)(3)(i) and (d)(3)(ii), samples must be taken within the employee's personal breathing zone, and must represent the employee's airborne exposure on each shift, for each job classification, in each work area. In the final standards, OSHA has changed ''in each beryllium work area'' to ''in each work area'' to avoid confusion with the beryllium work areas defined in paragraphs (b) and (e) of the final standard for general industry. In other OSHA standards, the term ''work area'' is used to describe the general worksite where employees are present and performing tasks or where work processes and operations are being carried out. Employers following the scheduled monitoring option should conduct initial monitoring as soon as work on a task or project involving beryllium exposure begins so they can identify situations where control measures are needed.

Representative sampling. Paragraph (d)(3)(iii) of the final standards, like proposed paragraph (d)(1)(iv), describes the circumstances under which employers may use representative sampling. Proposed paragraphs (d)(1)(iv)(A)–(C) permitted the use of

representative sampling to characterize exposures of non-sampled employees, provided that the employer performed such sampling where several employees performed the same job tasks, in the same job classification, on the same work shift, and in the same work area, and had similar duration and frequency of exposure; took breathing zone samples sufficient to accurately characterize exposure on each work shift, for each job classification, in each work area; and sampled the employees expected to have the highest exposure.

The USW and AFL–CIO supported the representative sampling provision in OSHA's proposed exposure monitoring requirements (Document ID 1681, p. 8; 1689, p. 11). OSHA has decided to retain the representative sampling provision in the final standards to provide employers with greater flexibility in meeting their exposure assessment obligations. Under the scheduled monitoring option, just as under the performance option, employers must accurately characterize the exposure of each employee to beryllium. In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of ''representative'' employees is sufficient. As in the proposal, representative exposure sampling is permitted under the final standards when several employees perform the same tasks on the same shift and in the same work area. However, OSHA has not included the requirement in proposed paragraph (d)(1)(iv)(A) that employees ''have similar duration and frequency of exposure'' in final paragraph (d)(3)(iii). This provision is unnecessary because final paragraph (d)(3)(iii), like proposed paragraph (d)(1)(iv)(C), requires the employer to sample the employee(s) expected to have the highest exposures to beryllium. Additionally, the requirement in proposed paragraph (d)(1)(iv)(B) that employers take ''sufficient breathing zone samples to accurately characterize exposure on each work shift, for each job classification, in each work area'' has been removed because when performing exposure monitoring under final paragraphs (d)(3)(i) or (d)(3)(ii), employers already must assess exposures based on personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area. Under these conditions, OSHA expects that exposures will be accurately characterized.

Finally, the proposed requirement in paragraph (d)(1)(iv)(C) that employers must monitor the employee(s) expected to have the highest exposures has been retained in the final standards. For example, this could involve monitoring the beryllium exposure of the employee closest to an exposure source. The exposure result may then be attributed to other employees who perform the same tasks on the same shift and in the same work area. Exposure assessment should include, at a minimum, one full-shift sample and one 15 minute sample taken for each job classification, in each work area, for each shift.

Where employees are not performing the same tasks on the same shift and in the same work area, representative sampling will not adequately characterize actual exposures of those employees, and individual monitoring is necessary.

Frequency of monitoring under scheduled monitoring option. Paragraph (d)(3) of the proposed standard required periodic monitoring at least annually if initial exposure monitoring indicated that exposures were at or above the action level and at or below the TWA PEL. The proposal did not require periodic exposure monitoring if initial monitoring indicated that exposures were below the action level.

In the NPRM, OSHA solicited comment on the reasonableness of discontinuing monitoring based on one sample below the action level. In response, many commenters discussed the importance of taking multiple samples to evaluate a worker's exposure even if initial results are below the action level. NJH emphasized that ''[i]t is NOT reasonable to discontinue monitoring after one sample result below the action level'' because ''a single sample result does not reflect the random variation in sampling and analytical methods'' (Document ID 1664, p. 6). NIOSH commented that, because occupational exposure distributions are right-skewed (*i.e.,* the mean is higher than the median so most sample results will be below the average exposure level), collecting fewer samples leads to a higher likelihood of showing compliance when it may not be warranted (Document ID 1671, Attachment 1, p. 6). Also during the hearings, Marc Kolanz of Materion stated that one sample does not provide ''a good understanding of what's out there,'' and there is ''value in trying to collect at least a few samples'' (Document ID 1755, Tr. 140). The Department of Defense (DOD) commented that it is not appropriate to discontinue monitoring based on one sample below the action level (Document ID 1684, Attachment 2, p. 3). The American College of Occupational and Environmental Medicine (ACOEM) commented that ''[t]here is significant uncertainty associated with limited sample numbers'' (Document 1685, p. 3). Ameren Corporation (Ameren), an electric utility company, stated that the number of samples needed ''depend[s] on how well the sample characterizes the work performed'' (Document ID 1675, p. 10). The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group), a non-profit organization promoting the understanding and prevention of beryllium-induced conditions and illnesses, commented that it would not consider a single sample to be a reasonable determination of exposures (Document ID 1665, p. 6). North America's Building Trades Unions (NABTU) commented that it was unreasonable to allow discontinuation of monitoring based on one sample below the action level, because that sample could be a statistical aberration, and ''the assumption that if a workplace is in compliance at one time it will stay in compliance in the future is a fallacy, particularly on an active, dynamic construction site'' (Document ID 1679, p. 8). The USW and Materion stated that exposure characterization often requires more than one sample (Document ID 1680, p. 3). Southern Company suggested that ''language regarding initial and periodic monitoring, and the discontinuation of both, [should] be consistent with existing substance specific standards'' (Document ID 1668, p. 3).

OSHA has considered these comments and has determined that if initial monitoring indicates that employee exposures are below the action level and at or below the STEL, no further monitoring is required. Paragraph (d)(3)(iv) of the final standards permits employers to discontinue monitoring of employees whose exposure is represented by such monitoring where initial monitoring indicates that exposure is below the action level and at or below the STEL. However, a single sample below the action level and at or below the STEL does not necessarily warrant discontinuation of exposure monitoring. OSHA has clarified in final paragraphs (d)(3)(i) and (d)(3)(ii) that any initial monitoring conducted under the scheduled monitoring option must reflect exposures on each shift, for each job classification, and in each work area. Therefore, where there is more than one shift or work area for a particular task, there will be more than one sample; accordingly, it is unlikely that an employer would be able to sufficiently characterize and assess employee

exposure for a given job classification under the scheduled monitoring option using a single sample.

In paragraph (d)(3) of the proposed rule, periodic exposure monitoring was required at least annually if initial exposure monitoring found exposures at or above the action level and at or below the TWA PEL. In the NPRM, OSHA asked a question about the frequency of monitoring and the reasoning behind that frequency. During the hearings, Peggy Mroz with NJH testified that periodic monitoring conducted at least every 180 days when exposures are at or above the action level is ''the most protective for workers'' (Document ID 1756, Tr. 99–100). Ms. Mroz further stated that exposure monitoring should also be conducted at least annually for all other processes and jobs where initial monitoring shows levels below the action level since changes in working conditions can affect monitoring results, and ''[i]t has already been shown that beryllium sensitization and CBD occur at measured exposures below the proposed action level'' (Document ID 1756, Tr. 100). Both NIOSH and NJH recommended more frequent monitoring for employers to fully understand levels of exposure that may vary over time and to assess whether proper controls are in place after a high exposure level is documented (Document ID 1725, p. 29; 1720, p. 5). The BHSC Task Group stated that annual monitoring is inadequate, and recommended sampling more frequently than every 180 days (Document ID 1665, pp. 15, 17). And, the AFL–CIO commented that annual exposure monitoring is inadequate and does not provide the employer with enough information to make appropriate changes to prevent and minimize exposure. The AFL–CIO cited various OSHA health standards that required more frequent periodic exposure monitoring, including cadmium, asbestos, vinyl chloride, arsenic, lead, and respirable crystalline silica (Document ID 1809, pp. 1–2). In contrast, Ameren agreed with the proposal's requirement to conduct monitoring annually if exposures are at or above the action level, because the proposal already requires additional monitoring when work conditions change (Document ID 1675, p. 4). And, the Edison Electric Institute (EEI) commented that beryllium exposure in the electric utility industry occurs during maintenance outages, ''which more closely align with the annual re-sampling requirements than the 180 [day] provisions in these alternatives'' (Document ID 1674, p. 14).

OSHA is persuaded by the commenters recommending more frequent periodic monitoring and has changed the frequency required for exposures between the action level and the TWA PEL in the scheduled monitoring option in the final standards. Paragraph (d)(3)(v) of the final standards requires monitoring every six months if initial exposure monitoring indicates that exposures are at or above the action level but at or below the TWA PEL, which is the typical frequency in other health standards for carcinogens such as respirable crystalline silica, cadmium, vinyl chloride, and asbestos for this level of exposure. Alternatively, employers in general industry, construction, and shipyards can use the performance option in paragraph (d)(2), which provides employers greater flexibility to meet their exposure assessment obligations.

In the proposal, OSHA did not require periodic exposure monitoring if initial exposure monitoring indicated that exposures were above the TWA PEL or STEL. In response to a question in the NPRM about monitoring above the PEL, Materion commented that there is no benefit to expending time and money monitoring exposures that exceed the PEL, because it is more important that activities be directed toward the exposure control plan. Based on their experience, Materion believes that employers will conduct monitoring as often as necessary to demonstrate that exposures have been reduce to below the PEL (Document ID 1661, p. 24 (pdf)). Other commenters disagreed with OSHA's proposal not to require periodic exposure monitoring above the PEL. The DOD commented that periodic monitoring should also be performed when levels are above the PEL to ensure respiratory protection is adequate and to test the effectiveness of engineering controls (Document ID 1684, Attachment 2, p. 9). In response to a question during the hearings on the benefits of monitoring above the PEL, NIOSH's Dr. Virji testified that exposure can vary within a job and that even though an employer may know exposures are high in a particular area, the information is ''useful because then it allows an understanding of what level of engineering controls that would be required to bring down the exposures to acceptable levels'' (Document ID 1755, Tr. 49–50). In her testimony, Mary Kathryn Fletcher with the AFL–CIO expressed support for monitoring above the PEL, stating that ''exposure monitoring is important to reevaluate control measures in cases of over-exposure,'' and ''[it is] important to characterize the job to know the exposures if you're going to try to reduce those exposures'' (Document ID 1756, Tr. 236). Also during the hearings, Ashlee Fitch with the Health, Safety, and Environment Department of the USW responded to a similar question on the benefits of air monitoring in cases where exposures are believed to exceed the PEL. She stated, ''You see oftentimes that employers used exposure rates to measure how well ventilation systems are working or what the exposure is, and after they implement engineering controls, what that exposure goes to'' (Document ID 1756, Tr. 282). In her testimony, Peggy Mroz with NJH expressed support for periodic exposure monitoring every 90 days where exposures exceed the TWA PEL or STEL as ''routine and regular sampling and repeated sampling should be done to assess whether proper controls are in place after a high sample is documented as we know that beryllium sensitization and chronic beryllium disease can occur within a few weeks of exposure'' (Document ID 1756, Tr. 100).

Based on these comments received in the record and testimony obtained from the public hearing, OSHA's final standards require periodic exposure monitoring every three months when exposures are above the TWA PEL or STEL under the scheduled monitoring option in paragraphs (d)(3)(vi) and (d)(3)(viii). Alternatively, employers in general industry, construction, and shipyards can use the performance option in paragraph (d)(2) which provides employers with greater flexibility to meet their exposure assessment obligations.

Proposed paragraph (d) did not include a separate provision to allow employers to discontinue monitoring if exposures were subsequently reduced to below the action level, as demonstrated by periodic monitoring. In the NPRM, OSHA solicited comment on the reasonableness of discontinuing monitoring based on one sample below the action level. As discussed more fully in the explanation of final paragraph (d)(3)(iv), many commenters discussed the importance of taking multiple samples to confirm exposures are below the action level before allowing the discontinuation of monitoring. For example, ORCHSE Strategies (ORCHSE) commented that allowing discontinuation of monitoring based on one sample is not appropriate and that two consecutive samples taken at least seven days apart, that show exposure below the action level, should be required to allow monitoring to be

discontinued (Document ID 1691, Attachment 1, p. 3).

As stated in the explanation of final paragraph (d)(3)(iv), OSHA has carefully considered these comments and agrees that a single sample is not sufficient to allow employers to discontinue monitoring. OSHA has therefore decided to add paragraph (d)(3)(vii) to the final standards. This provision requires that, where the most recent exposure monitoring indicates that employee exposure is below the action level, the employer must repeat exposure monitoring within six months of the most recent monitoring. The employer may discontinue TWA monitoring, for those employees whose exposure is represented by such monitoring, only when two consecutive measurements, taken seven or more days apart, are below the action level, except as otherwise provided in the reassessment of exposures requirements in paragraph (d)(4) of the final standards. Additionally, OSHA has added paragraph (d)(3)(viii) to the final standards. This provision requires that, where the most recent exposure monitoring indicates that employee exposure is above the STEL, the employer must repeat exposure monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken seven or more days apart, are below the STEL. At this point, the employer may discontinue monitoring for those employees whose exposure is represented by such monitoring. As discussed below, reassessment is always required whenever a change in the workplace may be reasonably expected to result in new or additional exposures at or above the action level or above the STEL or the employer has any reason to believe that new or additional exposures at or above the action level or above the STEL have occurred, regardless of whether the employer has ceased monitoring because exposures are below the action level or at or below the STEL under paragraphs (d)(3)(iv), (d)(3)(vii), or (d)(3)(viii) of the final standards.

Exposure assessment in construction and shipyard *industries.* Beryllium exposure occurs in the construction and shipyard industries primarily during abrasive blasting operations that use coal and copper slags containing trace amounts of beryllium (Document ID 1815, Attachment 85, pp. 70–72; 0767, p. 6).

During the public hearing, testimony was heard about abrasive blasting operations using slags at a shipyard facility. Mike Wright, with the USW, testified that the use of enclosure (containment) is important to prevent the escape of beryllium dust during abrasive blasting operations and that exposure monitoring could help determine the integrity of the enclosure along with establishing a perimeter where beryllium contamination is controlled (Document ID 1756, Tr. 274–275). Ashlee Fitch, also representing the USW, testified about monitoring worker exposure to beryllium in the maritime industry. Ms. Fitch stated that abrasive blasting using beryllium-containing abrasive materials should be done in full containment and that exposures outside the containment should not exceed the PEL or STEL (Document ID 1756, Tr. 244–245). Ms. Fitch recommended that in cases where full containment is used, ''the employer shall do an initial monitoring for each configuration of the containment'' and ''if the initial monitoring shows exposures above the action level, monitoring shall be performed for every blasting operation.'' She also recommended air monitoring of exposed workers outside of the containment or through monitoring of the positions where exposure is likely to be the highest, or if full containment is not used, ''around any abrasive blasting operation'' (Document ID 1756, Tr. 245). Representative Robert Scott, the ranking minority member on the Committee on Education and the Workforce of the U.S. House of Representatives (Representative Scott), commented that when workers are engaged in abrasive blasting and the abrasive blasting area is contained, exposure monitoring should be routinely performed when levels exceed the action level (Document ID 1672, p.4).

Substantially agreeing with these comments, in paragraph (d)(3) of the final standards, OSHA is requiring monitoring on each work shift, for each job classification, and in each work area when employers are following the scheduled monitoring option. OSHA also agrees that monitoring should be of the positions where exposure is likely to be the highest, so when employers engage in representative sampling under the scheduled monitoring option, final paragraph (d)(3)(iii) requires that they must sample the employee(s) expected to have the highest airborne exposure to beryllium. OSHA also agrees with Representative Scott that exposure monitoring should be routinely performed for abrasive blasting and all other operations exposing workers to beryllium when exposures exceed the action level. If exposures exceed the action level or STEL, the employer is required to monitor exposures at frequencies indicated in the scheduled monitoring option or using the performance option to accurately assess the beryllium exposure of their employees. However, OSHA does not consider monitoring to be necessary each time there is an abrasive blasting or other operation that fits within the profile of a previously taken representative sample.

Reassessment of exposures. Paragraph (d)(4) of the final standards, like paragraph (d)(4) of the proposal, describes the employer's obligation to reassess employee exposures under certain circumstances. Proposed paragraphs (d)(4)(i) and (d)(4)(ii) required the employer to conduct exposure monitoring within 30 days after a change in production processes, equipment, materials, personnel, work practices, or control methods that could reasonably be expected to result in new or additional exposure, or if the employer had any other reason to believe that new or additional exposure was occurring.

Commenters generally advocated for monitoring to assess any new exposures. For example, in her testimony, Mary Kathryn Fletcher with the AFL–CIO expressed support for exposure monitoring even if exposure is reduced as far as feasible, because exposures can change, so ''it's important to monitor as tasks change and over time, there are different procedures, different workers in the area, doing different things'' (Document ID 1756, Tr. 236). Also, NJH commented that ''periodic sampling, even of low exposure potential tasks, ensures that despite changes in processes, personnel, exhaust systems, and other control measures, the exposure remains low and workers remain safe'' (Document ID 1664, p. 6). Therefore, the Agency has decided to retain the requirement of proposed paragraph (d)(4) that employers reassess exposures, but has made minor changes to the regulatory text. OSHA has changed the title ''Additional Monitoring'' in proposed paragraph (d)(4) to ''Reassessment of exposures'' in paragraph (d)(4) of the final standards to be consistent with the change in paragraph (d) terminology from ''exposure monitoring'' to ''exposure assessment.'' OSHA has also changed the proposed requirement that employers conduct exposure monitoring within 30 days after a change in ''production processes, equipment, materials, personnel, work practices, or control methods'' that could reasonably be expected to result in new or additional exposures to the requirement in the final standards that employers must perform reassessment of exposures

when there is a change in ''production, process, control equipment, personnel, or work practices'' that may reasonably be expected to result in new or additional exposures at or above the action level or STEL. OSHA made these changes to provide clarity and consistency with other OSHA health standards.

In addition, there may be other situations that can result in new or additional exposures that are unique to an employer's work situation. In order to cover those special situations, OSHA has retained the requirement in proposed paragraph (d)(4)(ii) that the employer must reassess exposures whenever the employer has any reason to believe that a change has occurred that may result in new or additional exposures, and has added ''at or above the action level or STEL'' to final paragraph (d)(4). Under this provision, for example, an employer is required to reassess exposures when an employee has a confirmed positive result for beryllium sensitization, exhibits signs or symptoms of CBD, or is diagnosed with CBD. These conditions necessitate a reassessment of exposures to ascertain if airborne exposures contributed to the beryllium-related health effects. Additionally, reassessment of exposures would be required following a process modification that increases the amount of beryllium-containing material used, thereby possibly increasing employee exposure. Reassessment of exposures will also be required when a shipyard or construction employer introduces a new beryllium-containing slag for use in an abrasive blasting operation. Once reassessment of exposures is performed and if exposures are above the action level, TWA PEL, or STEL, the employer can take appropriate action to protect exposed employees and must perform periodic monitoring as discussed above.

Methods of sample analysis. Paragraph (d)(5) of the final standards, like proposed paragraph (d)(1)(v), addresses methods for evaluating air monitoring samples. Proposed paragraph (d)(1)(v) required employers to use a method of exposure monitoring and analysis that could measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level. This provision is largely unchanged in the final standards. OSHA has changed the title ''Accuracy of measurement'' in the proposal's paragraph (d)(1)(v) to ''Methods of sample analysis'' in paragraph (d)(5) of the final standards. OSHA made this change to more accurately describe the purpose of this requirement. Additionally, OSHA changed the requirement that employers ''use a method of exposure monitoring and analysis'' in the proposed rule to require that employers ''ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) are evaluated by a laboratory'' to clarify that employers may send samples to a laboratory for analysis, and OSHA does not intend to require employers to have a laboratory to analyze samples at the worksite.

Under final paragraph (d)(5), the employer is required to make sure that all samples taken to satisfy the monitoring requirements of paragraph (d) are evaluated by a laboratory that can measure airborne levels of beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level. The following methods meet these criteria: NIOSH 7704 (also ASTM D7202), ASTM D7439, OSHA 206, OSHA 125G, and OSHA 125G using ICP–MS. All of these methods are available to commercial laboratories analyzing beryllium samples. However, not all of these methods are appropriate for measuring beryllium oxide, so employers must verify that the analytical method used is appropriate for measuring the form(s) of beryllium present in the workplace.

In the NPRM, OSHA requested comment on whether these methods would satisfy the requirements of this paragraph, and if there were other methods that would also meet these criteria. The BHSC Task Group commented that OSHA's accuracy criteria could be met for full shift samples using available analytical methods. The BHSC Task Group agreed with the guidance in OSHA's NPRM to use ICP–MS or fluorescence to assure adequate sensitivity and analytical precision (Document ID 1655, p. 2). In response to a question on whether the current methods were sufficiently sensitive, Kevin Ashley with NIOSH testified that both the fluorescence method (NIOSH method 7704) and the inductively coupled plasma mass spectrometry (ASTM method D7439) were adequately sensitive to measure at the proposed PEL and STEL (Document ID 1755, Tr. 58). The DOD commented that the current limit of quantification (LOQ) of 0.05 μg for beryllium using the NIOSH 7300 and OSHA 125G methods would be adequate to detect exposures below the proposed action level of 0.1 μg/m^3 and the proposed STEL of 2 μg/m^3 (Document ID 1684, Attachment 2, p. 9). OSHA has identified several sampling and analysis methods for beryllium that are capable of detecting beryllium at air concentrations below the final action level of 0.1 μg/m^3 and the final STEL of 2.0 μg/m^3 for a 15-minute sampling period (see Chapter IV of the Final Economic Analysis, Technological Feasibility). Therefore, OSHA has determined that the sampling and analytical methods currently available to employers are sufficient to measure beryllium as required in paragraph (d) of the final standards.

Rather than specifying a particular method that must be used, the final standards allow for a performance-oriented approach that allows the employer to use the method and analytical laboratory of its choosing as long as that method meets the accuracy specifications in paragraph (d)(5) and the reported results represent the total airborne concentration of beryllium for the worker being characterized. Other methods, such as a respirable fraction sample or size selective sample, would not provide results directly comparable to either PEL, and therefore would not be considered valid.

Employee Notification of Assessment Results. Paragraph (d)(6) of the final standards, like proposed paragraph (d)(5), addresses employee notification requirements. OSHA did not receive comment specifically on this provision, but several commenters supported the exposure monitoring provisions as a whole, and after reviewing the record, OSHA has decided to retain the employee notification requirements in the final standards. OSHA has changed the title ''Employee Notification of Monitoring Results'' in proposed paragraph (d)(5) to ''Employee Notification of Assessment Results'' in final paragraph (d)(6) to reflect the change in the title of paragraph (d). This requirement is consistent with other OSHA standards, such as those for respirable crystalline silica (29 CFR 1910.1053), methylenedianiline (29 CFR 1910.1050), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

Proposed paragraph (d)(5)(i) required employers to notify each employee of his or her monitoring results within 15 working days after receiving the results of any exposure monitoring. Both the employees whose exposures were measured directly and those whose exposures were represented by the monitoring had to be notified. The employer had to notify each employee individually in writing or post the monitoring results in an appropriate location accessible to all employees required to be notified. Proposed paragraph (d)(5)(i) is now paragraph (d)(6)(i) in the final standards, and has

been edited to reflect the change in language from ''exposure monitoring'' to ''exposure assessment,'' discussed earlier. This can be in print or electronically as long as the affected employees have access to the information and have been informed of the posting location. Final paragraph (d)(6)(i) for general industry, construction, and shipyards is substantively unchanged from the proposal. However, due to the transient nature of construction work and the need to receive exposure assessment results while the work is still occurring, OSHA recommends that employers in the construction industry make every effort to notify employees of their monitoring results as soon as possible.

Proposed paragraph (d)(5)(ii) required that, whenever exposures exceeded the TWA PEL or STEL, the written notification required by proposed paragraph (d)(5)(i) include (1) suspected or known sources of exposure and (2) a description of the corrective action(s) that have been taken or will be taken by the employer to reduce the employee's exposure to or below the TWA PEL or STEL where feasible corrective action exists but was not implemented at the time of the monitoring. OSHA did not receive comment on this specific provision, and after reviewing the record, including comments supporting paragraph (d) generally, OSHA has decided to retain a notification requirement focused on individual exposure assessments and the corrective actions being taken for exposures above the PEL or STEL. It is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and to provide employees with information about their exposures. Furthermore, notification to employees of exposures above a prescribed PEL and the corrective actions being taken is required under section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). In order to provide consistency with other OSHA health standards, OSHA has removed the requirement in proposed paragraph (d)(5)(ii) that employers include suspected or known sources of exposure in the written notification. Proposed paragraph (d)(5)(ii), as revised, is now paragraph (d)(6)(ii) in the final standards.

Observation of monitoring. Paragraph (d)(7) of the final standards, like proposed paragraph (d)(6), requires employers to provide for observation of exposure monitoring. OSHA did not receive comment on this specific provision, and after reviewing the record, including comments supporting paragraph (d) generally, OSHA has decided to retain it in the final standards because it promotes occupational safety and health and is required by the OSH Act. Section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)) mandates that regulations requiring employers to keep records of employee exposures to toxic materials or harmful physical agents provide employees or their representatives with the opportunity to observe monitoring or measurements.

Proposed paragraph (d)(6)(i) required the employer to provide an opportunity to observe any exposure monitoring required by the standards to each employee whose airborne exposure was measured or represented by the monitoring and to each employee's representative(s). Proposed paragraph (d)(6)(i) is now paragraph (d)(7)(i) in the final standards, and is substantively unchanged from the proposal. When observation of monitoring required entry into an area where the use of protective clothing or equipment was required, proposed paragraph (d)(6)(ii) required the employer to provide the observer with that personal protective clothing or equipment, at no cost. The employer was also required to ensure that the observer used such clothing or equipment appropriately. Proposed paragraph (d)(6)(ii) is now paragraph (d)(7)(ii) in the final standards, and is substantively unchanged from the proposal. Paragraph (d)(6)(iii) of the proposal required employers to ensure that each observer complied with all applicable OSHA requirements and the employer's workplace safety and health procedures. Proposed paragraph (d)(6)(iii) is now paragraph (d)(7)(iii) in the final standards. OSHA has changed the proposed language to require that employers ensure that each observer follows all other applicable safety and health procedures to clarify that the burden to comply with OSHA requirements remains on the employer, not the observer.

(e) Beryllium Work Areas and Regulated Areas (General Industry); Regulated Areas (Shipyards); and Competent Person (Construction)

Paragraph (e) of the standards for general industry and shipyards sets forth the requirements for establishing, maintaining, demarcating, and limiting access to certain areas of the workplace to aid in minimizing employee exposure to beryllium. As discussed below, the general industry standard includes requirements for both ''work areas'' and ''regulated areas,'' which are subsets of work areas. The shipyard standard includes requirements for regulated areas, but not work areas. Paragraph (e) of the construction standard does not require either work areas or regulated areas, but instead includes requirements for a ''competent person,'' who has responsibility for demarcating certain areas of beryllium exposure for similar purposes.

Specifically, paragraph (e)(1)(i) and (e)(2)(i) of the standard for general industry requires employers to establish, maintain, and demarcate one or more ''beryllium work area,'' which is defined as a work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. OSHA intends these beryllium work area provisions to apply to the area surrounding the process, operation, or task where airborne beryllium is released or the potential for dermal contact is created. Beryllium work areas are also referenced in the general industry standard in paragraphs (f)(1) (the written exposure control plan), (f)(2) (engineering and work practice controls), and (j) (housekeeping). Under paragraphs (e)(1)(ii) and (e)(1) of the standards for general industry and shipyards, respectively, employers are also required to establish and maintain regulated areas wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. As indicated and discussed in more detail below, the final standards for shipyards and construction do not contain provisions for beryllium work areas and the standard for construction does not require employers to establish regulated areas. In lieu of regulated areas, paragraph (e) of the final standard for construction, Competent Person, consists of a set of requirements designed to provide most of the same protections as regulated areas in general industry and shipyards, using a competent person instead of demarcated areas to achieve these ends.

The requirements to establish beryllium work areas and regulated areas or designate competent persons serve several important purposes. First, requiring employers to establish and demarcate beryllium work areas in general industry ensures that workers and other persons are aware of the potential for work processes to release airborne beryllium or cause dermal contact with beryllium. Second, the required demarcation of regulated areas in general industry and shipyards in accordance with the paragraph (m) requirements for warning signs ensures that all persons entering regulated areas

will be aware of the serious health effects associated with exposure to beryllium. Similarly, assignment of a competent person to carry out the provisions of paragraph (e) in the construction standard where exposures may exceed the TWA PEL or STEL provides employees in construction with a knowledgeable on-site authority to convey information about the hazards of beryllium exposure. Third, limiting access to regulated areas (general industry and shipyards) or areas where exposures may exceed the TWA PEL or STEL (construction) restricts the number of workers potentially exposed to beryllium at levels above the TWA PEL or STEL. Finally, provisions for respiratory protection and PPE ensure that those who must enter regulated areas (general industry and shipyards) or areas where exposures may exceed the TWA PEL or STEL (construction) are properly protected, thereby reducing the risk of serious health effects associated with airborne beryllium exposure and dermal contact with beryllium.

The remainder of this section provides detailed discussion of each provision in paragraph (e) of the final standards for general industry, shipyards, and construction, as well as comments OSHA received on paragraph (e) of the proposed standard, OSHA's response to these comments, and the reasons for OSHA's decisions regarding the provisions of paragraph (e) in each final standard.

Beryllium Work Areas (General Industry). Provisions for the establishment of beryllium work areas were included in the proposed standard for general industry in paragraph (e)(1)(i). This proposed provision required employers to establish and maintain beryllium work areas where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA explained that it intended the provision to apply to all areas and situations where employees are actually exposed to airborne beryllium and to areas and situations where the employer has reason to anticipate or believe that airborne exposures may occur. The Agency further explained that—unlike the requirements for regulated areas—the proposed requirements were not tied to a particular level of exposure, but rather were triggered by the presence of airborne beryllium at any exposure level. The provision was based on a provision recommended by Materion Corporation (Materion) and the United Steelworkers (USW) in their joint submission, (see previous discussion in the Introduction to this Summary and Explanation section).

A number of stakeholders commented on the proposed definition of a beryllium work area. Some commenters, such as NGK Metals Corporation (NGK) and ORCHSE Strategies (ORCHSE), argued that the definition of a beryllium work area is vague and requested that OSHA trigger the requirement to establish and maintain beryllium work areas at a measureable threshold, such as the action level (*e.g.,* Document ID 1663, p. 1; 1691, Attachment 1, p. 15). Edison Electric Institute (EEI), an industry association representing electric utility companies, also did not agree with the beryllium work area definition (Document ID 1674, p. 13). Like NGK and ORCHSE, EEI recommended that OSHA tie the beryllium work area requirements to a quantifiable exposure level, like the action level or the PEL (Document ID 1674, p. 13). The Boeing Company (Boeing) also recommended the use of a quantifiable trigger, but suggested a much lower trigger of 0.02 μg/m^3 (Document ID 1667, p. 3). Boeing explained that not including a specific threshold can lead to inconsistent results because it depends on the sensitivity of the measurement method (Document ID 1667, p. 3).

Other commenters supported the proposed standard's establishment of beryllium work areas at any level of airborne beryllium exposure. For example, AWE commented that its ''supervised beryllium workspaces'' align with the proposal's beryllium work areas (Document ID 1615, p. 1). NIOSH observed that the proposed approach is feasible and appropriate for beryllium work settings where work such as production, processing, handling, and manufacturing of beryllium products is performed and areas where needed preventive controls can be relatively easily demarcated (Document ID 1725, pp. 29–30). Materion and USW reiterated their support for provisions related to beryllium work areas ''where operations generate airborne beryllium particulate'', which were included in the recommended model standard they submitted to OSHA (Document ID 1680, p. 3).

The purpose of a beryllium work area is to establish a demarcated area in which workers and other persons authorized to be in the area are made aware of the potential for beryllium exposure and must take certain precautions accordingly. OSHA finds that establishing beryllium work areas where exposures are at the action level or above the PEL would not adequately protect exposed workers operating outside demarcated regulated areas, for which the applicable trigger is the TWA PEL or STEL. Because, as discussed in Section V, Health Effects, there is still a potential health risk to workers exposed to beryllium below the action level, the establishment and demarcation of beryllium work areas at any level of airborne exposure will provide additional protection for these workers by ensuring that they are aware of the presence of processes that release beryllium. OSHA similarly finds that Boeing's suggested trigger of 0.02 μg/m^3 is not suitable because OSHA has not established a level of exposure at which beryllium does not pose a risk to workers (see this preamble at Section VI, Risk Assessment). Therefore, OSHA finds that establishing and demarcating beryllium work areas wherever processes or operations release beryllium is more protective. OSHA also does not agree with those commenters who find the trigger for establishing beryllium work areas vague. As explained previously, OSHA has modified the beryllium work areas provision in the final standard for general industry to specify that the source of the airborne beryllium exposure and potential for dermal contact triggering the requirement for a beryllium work area must be generated from a process or operation within that area, not just the fact that an employee may be handling an article containing beryllium. An employer can (but is not required to) use air monitoring to determine the presence of airborne beryllium in the area surrounding the process, operation, or task that may be releasing beryllium or wipe sampling to determine the presence of beryllium on surfaces that workers may come into contact with. Affording the employer such flexibility to comply with this performance-based provision does not make it impermissibly vague. Accordingly, OSHA has decided to retain, as modified, the requirement that beryllium work areas must be established and maintained where there is a process or operation that can release beryllium and employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level. However, as discussed below, OSHA has somewhat modified the definition of beryllium work areas in response to comments from other stakeholders and NIOSH.

Two electric utility companies, Southern Company and Ameren Corporation (Ameren), argued that a work area requirement defined by any level of airborne beryllium exposure was subjective and would result in their entire facility falling under this

requirement (Document ID 1668, pp. 3–4; 1675 p. 5). The Aluminum Association stated that there may be areas where airborne beryllium exposures are present but have been found through exposure assessments and monitoring to be insignificant; therefore, beryllium work areas are overly broad as defined in the proposal and should be dropped from the final standard (Document ID 1666, p. 2). The American College of Occupational and Environmental Medicine (ACOEM) also did not agree with the proposed definition of beryllium work areas because it is not specific to workplaces where beryllium is used or processed (Document ID 1685, p. 2). ACOEM argued that airborne beryllium is essentially ubiquitous at very low levels, and that the proposed definition of beryllium work areas could be interpreted to apply to most worksites regardless of work activity. Therefore, ACOEM suggested clarifying the requirement using language that specifies ''worksites in which any beryllium or beryllium-containing materials are or have been processed using methods capable of generating dust or fume'' (Document ID 1685, p. 2).

OSHA did not intend a scenario where an entire facility becomes a beryllium work area from environmental or other non-occupational sources of beryllium. Nor did the Agency intend to cause the entirety of any worksite covered by the rule to become a beryllium work area, even where the amount of airborne beryllium is insignificant in the sense that it is residually present at very low levels in areas of a facility where work processes that release airborne beryllium do not occur. (Note that the best available scientific evidence has not identified a medically insignificant level of beryllium exposure; as discussed in Section VI, Risk Assessment, beryllium sensitization has been found among individuals whose exposures are below the action level.) Such a situation might occur in a coal-fired electric generating plant or a foundry where a very small amount of beryllium may be detectable far away from the processes that released it. To avoid these unintended consequences, OSHA has modified the beryllium work areas provision in the final standard for general industry to specify that the source of the airborne beryllium exposure and potential for dermal contact triggering the requirement for a beryllium work area must be generated from a process or operation within that area. This modification is similar to ACOEM's suggestion to define beryllium work areas as areas where beryllium or beryllium-containing materials are or have been processed (Document ID 1685, p. 2). While the trigger for beryllium work area is based on whether the beryllium is processed by controlling the release of airborne beryllium from the particular process, operation, or task, the employer can limit the size of the beryllium work area and eliminate the likelihood of an entire facility becoming a beryllium work area. OSHA believes this modified definition of beryllium work areas addresses the concerns raised by employers and ACOEM, while also maintaining the protective benefits associated with beryllium work areas for beryllium-exposed employees.

In addition to commenting on the level of exposure that should trigger the establishment and maintenance of a beryllium work area, NIOSH offered an opinion on the type of exposure that should trigger beryllium work areas. Specifically, NIOSH argued that limiting the definition of beryllium work area to employee exposure to airborne beryllium omits the potential contribution of dermal exposure to total exposure (Document ID 1725, p. 30). To support its point, NIOSH cited to Armstrong *et al.* (2014), which reported that work processes associated with elevated risk for beryllium sensitization had high air/high dermal exposure, high air/low dermal exposure, or low air/high dermal exposure indicating that dermal exposures should be considered as relevant pathways (Document ID 1725, p. 30). OSHA agrees with NIOSH and has modified the beryllium work areas section of the final standard for general industry to include potential dermal exposure.

OSHA also made two other minor, nonsubstantive changes to the proposed provision to help streamline the final general industry standard. First, instead of restating the definition of beryllium work area in paragraph (e)(1)(i) (as in the proposal), OSHA has modified final paragraph (e)(1)(i) in the proposal to merely refer to the term as defined in paragraph (b) of the standard for general industry. Second, the definition of beryllium work area in the final general industry standard includes the qualifier ''where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level.'' This is a modification from the proposed beryllium work area definition wording ''where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.'' Both of these changes were intended only to simplify the language of the regulatory text and should not be read to suggest a change in substantive requirements or the Agency's intent.

The construction and shipyard sectors were not included in the proposed standard. However, OSHA requested comments on Regulatory Alternative #2a in the NPRM, which would apply all provisions of the proposed standard to facilities in construction and shipyards, including provisions pertaining to the establishment of beryllium work areas. Following careful consideration of the comments OSHA received from a variety of stakeholders and from NIOSH on this topic, OSHA has concluded that the requirement to establish and maintain beryllium work areas are not appropriate for construction or shipyards. The work processes (primarily abrasive blasting), worksites, and conditions in construction and shipyards differ substantially from those typically found in general industry; as discussed further below, establishment of beryllium work areas in these sectors is likely to be impractical. However, OSHA has modified the standards so that most of the protective measures related to beryllium work areas in the general industry standard apply to operations in construction and shipyards, using triggers more suitable for these sectors. Thus, OSHA believes the final standards for construction and shipyards provide employees protection similar to employees in general industry, but avoid the difficulties associated with establishment of beryllium work areas in the context of abrasive blasting operations in these sectors.

NIOSH commented that while it supported triggering the requirement to establish beryllium work areas at any level of airborne exposures, it is not clear how such a requirement would work in an outdoor environment (Document ID 1725, p. 30). It explained that it is possible that even ambient conditions could cause an outdoor work environment to qualify as a ''beryllium work area'' (Document ID 1725, p. 30). NIOSH also noted that it was unclear how to delineate beryllium work areas in an outdoor setting when abrasive blasting the outer hull of a large ship and questioned how the beryllium work area trigger of any level of airborne exposure to beryllium could be applied only to that specified area (Document 1755, Tr. 21). NIOSH further explained that establishing a beryllium work area for abrasive blasting in an outdoor environment is difficult because outdoor blasting operations often involve large structures and constant moving of the operation (Document ID 1755, Tr. 55).

Newport News Shipbuilding (NNS) similarly commented that since beryllium is primarily encountered in shipyards as a trace element in coal slag blasting media, the requirement to establish and maintain beryllium work areas is not appropriate for shipyards. NNS stated, ''[i]t is relatively easy to control a work area to a stated number such as a permissible exposure limit or an action level, but controlling 'regardless of level of exposure' for a trace contaminant in dust is impractical'' (Document ID 1657, pp. 1–2).

Recognizing the difficulties described by NIOSH and NNS, the Agency decided not to require employers in construction and shipyards to establish and maintain beryllium work areas. However, OSHA has modified provisions associated with beryllium work areas in paragraph (f)(1) and paragraph (h) of the proposed standard so as to provide employees in all sectors with largely equivalent protective measures. For example, employers in all sectors are required to create, implement, and maintain a written exposure control plan that lists jobs and operations where beryllium exposure may occur, and that documents procedures for limiting cross-contamination and migration of beryllium (see Summary and Explanation of paragraph (f)(1)). Similarly, whereas employers in general industry are required under paragraph (f)(2) to take certain steps to reduce airborne beryllium in beryllium work areas where exposures meet or exceed the action level, employers in construction and shipyards have a nearly identical requirement to take steps to reduce exposures where exposures meet or exceed the action level. Thus, the only provisions related to beryllium work areas that apply in general industry but not in construction and shipyards are those OSHA is persuaded add protective value in general industry but would be unworkable or ineffective in the construction and shipyard contexts of abrasive blasting and outdoor operations, *e.g.,* certain housekeeping provisions related to surface contamination (see Summary and Explanation, paragraph (j), Housekeeping, for further discussion).

Regulated Areas. Paragraph (e)(1)(ii) of the proposed standard required employers to establish and maintain regulated areas wherever employees are, or can reasonably be expected to be, exposed to airborne concentrations of beryllium in excess of the TWA PEL or STEL. OSHA explained that the requirement to establish and maintain regulated areas would apply if any exposure monitoring or objective data indicate that airborne exposures are in excess of either the TWA PEL or STEL, or if the employer has reason to anticipate or believe that airborne exposures may be above the TWA PEL or STEL, even if the employer has not yet characterized or monitored those exposures. For example, if newly introduced processes involving beryllium appear to be creating dust and have not yet been monitored, the employer should reasonably anticipate that airborne exposures could exceed the TWA PEL or STEL. In this situation, the employer would be required to designate the area as a regulated area to protect workers and other persons until monitoring results establish that exposures are at or below the TWA PEL and STEL. In the proposed standard, work in regulated areas triggered additional requirements for medical surveillance (see Summary and Explanation for paragraph (k)), PPE (see Summary and Explanation for paragraph (h)), and hazard communication (see Summary and Explanation for paragraph (m)). The construction and shipyard sectors were not included in the proposed standard, but were included in Regulatory Alternative #2a in the NPRM, which would extend all provisions of the proposed standard for general industry to construction and shipyards, including provisions pertaining to regulated areas. OSHA requested comments on this proposed regulatory alternative.

OSHA received relatively few comments on the proposed provisions for regulated areas, which were largely similar to the regulated areas provisions included in previous substance-specific standards. In general, commenters did not oppose the concept of regulated areas. Clive LeGresly with AWE noted that their organization establishes ''Controlled'' beryllium workspaces that align with the final standards' regulated areas (Document ID 1615, p. 4). However, some commenters suggested modifications to OSHA's proposed definition of regulated areas. In their comments, the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) and National Jewish Health (NJH) both supported the concept of regulated areas but recommended they be established when exposures are at or above the action level (Document ID 1655, p. 7; 1664, p. 3). Finally, the Department of Defense (DoD) argued that having both beryllium work areas and regulated areas was confusing and burdensome, and suggested that the final standard should include only areas with airborne beryllium above the TWA PEL or STEL, which they described as better defined and more enforceable than the provisions for beryllium work areas in the proposed standard (Document ID 1684, Attachment 2, p. 2). After carefully considering the record on regulated areas, OSHA has decided to modify some of the provisions associated with regulated areas to address commenters' concerns where appropriate, but to retain paragraph (e)(1)(ii) as proposed in the final standard for general industry. Thus, final paragraph (e)(1)(ii) in general industry requires employers to establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. A detailed discussion of OSHA's decisions and reasoning follows.

As applied to general industry, OSHA has not accepted the DoD's suggestion that only work areas where exposures exceed the TWA PEL or STEL need to be demarcated as limited-access or regulated areas. Because employees who are exposed to airborne beryllium below the TWA PEL and STEL and who have dermal contact with beryllium are at risk of adverse health effects, OSHA finds that it is appropriate to establish and demarcate beryllium work areas wherever work processes create such exposures and are primarily located in indoor settings, as OSHA finds is typical of operations in general industry. As discussed above, the requirement for the establishment and maintenance of beryllium work areas is necessary to alert workers to the presence of beryllium and to trigger basic exposure prevention methods, such as hygiene facilities and housekeeping. However, it is also appropriate to establish regulated areas with more stringent requirements, such as respiratory protection, limited access, and warning signs, where exposures may exceed the TWA PEL or STEL. OSHA concludes that beryllium work areas and regulated areas serve distinct purposes, and each provides important protections to employees. Therefore, OSHA has decided to retain both beryllium work areas and regulated areas in the final standard for the general industry standard. As explained elsewhere in this section, OSHA finds that requirements to establish and demarcate beryllium work areas are not appropriate to operations in construction and shipyards, and that the objectives of regulated areas are better

achieved through the use of a competent person in construction.

OSHA has also carefully considered the recommendation by the BHSC Task Group and NJH to use the action level rather than the TWA PEL or STEL to trigger the provisions of the proposed standard associated with regulated areas, and finds that it has some merit. For example, in the proposed standard, employees who work in regulated areas for more than 30 days in a 12-month period would be eligible for medical surveillance. Because employees exposed to beryllium at levels below the TWA PEL are at significant risk of material impairment of health as a result of their exposure (Section VII, Significance of Risk), OSHA is persuaded that the action level is a more appropriate trigger for the provision of medical surveillance. Eligibility for medical surveillance at the action level is also consistent with previous OSHA standards where significant risk remains at the TWA PEL, such as the recently published respirable crystalline silica standard. In addition, because beryllium sensitization can occur from dermal contact with beryllium regardless of whether airborne exposures are above or below the TWA PEL or STEL, OSHA believes it is appropriate to apply PPE requirements much more broadly than the proposed standard, which relied heavily on work in regulated areas as a trigger for PPE.

However, OSHA does not believe that all provisions associated with regulated areas should apply at exposure levels below the TWA PEL and STEL. Employers are required to restrict access to regulated areas, thereby limiting the number of employees potentially exposed to beryllium at levels above the TWA PEL or STEL and limiting others' risk of serious health effects associated with such exposure. OSHA finds that lowering the exposure trigger for regulated areas could lead to the creation of large restricted areas, and therefore large numbers of employees with access to restricted areas where exposures may range anywhere between the action level and high above the final PEL. And, as discussed previously, establishing and demarcating regulated areas ensures that workers and other persons are aware of the potential presence of airborne beryllium at levels above the TWA PEL or STEL and ensures that all persons entering regulated areas are made aware of the dangers of exposure to beryllium at these levels. Moreover, in general industry, the requirement to demarcate beryllium work areas triggered by any level of beryllium exposure resulting from a process or operation, provides awareness for the potential hazard of beryllium contact or exposure at levels below the action level. For these reasons, OSHA believes that it is appropriate to retain the proposed standard's definition of regulated areas and related provisions for restricted access and demarcation.

In addition, OSHA finds that it is inappropriate to extend mandatory provision and use of respirators (triggered by work in regulated areas in the proposed standard) to all workers whose exposures meet or exceed the action level. As discussed elsewhere in this Summary and Explanation, OSHA's longstanding policy is to avoid issuing standards that result in widespread use of respiratory protection due to issues of health, safety, and effectiveness that can occur with employees' regular use of respirators (see Summary and Explanation for paragraph (f), Methods of Compliance, and paragraph (g), Respiratory Protection).

For the reasons described above, OSHA has decided to adopt more protective triggers for some of the provisions associated with regulated areas in the proposed standard. OSHA has expanded eligibility for medical surveillance to employees who work for at least 30 days in a 12-month period in operations where airborne beryllium exposures meet or exceed the action level (previously, employees who work for at least 30 days in a 12-month period in a regulated area; see Summary and Explanation for paragraph (k), Medical Surveillance). OSHA has also expanded PPE requirements to all employees whose work involves dermal contact with beryllium (see Summary and Explanation for paragraph (h), PPE). These expanded PPE requirements in recognition of the dermal risk posed by beryllium also are responsive to a request from Public Citizen that beryllium work areas and regulated areas be broadly defined in order to ensure ''appropriate protections against dermal exposure to beryllium, and dermal sensitization'' (Document ID 1756, Tr. 176–77).

As discussed in the Summary and Explanation of paragraph (a), Scope and application, OSHA received comments from a variety of stakeholders on Regulatory Alternative #2a presented in the NPRM, which extends all provisions of the proposed standard to the construction and shipyard sectors. Following careful consideration of these comments, OSHA determined that it is appropriate to extend all provisions of the proposed standard to cover facilities in construction and shipyards, except where some provisions of the general industry standard may be inappropriate due to the nature of workplaces or work processes in construction or shipyards. OSHA has additionally reviewed comments received on the topic of regulated areas in construction and shipyards, to determine whether it is appropriate to modify the requirements for regulated areas in these sectors. Based on its review, as well as OSHA's previous experience regulating chemical exposures in these sectors, the Agency has concluded that provisions for regulated areas (as opposed to the larger beryllium work areas) are appropriate to include in the final standard for shipyards. In construction, OSHA does not find regulated area requirements to be appropriate but has decided instead to require employers to meet the goals of the regulated areas provisions using a competent person approach, which the Agency believes will be more effective in construction work settings. OSHA's review of the record and reasons for these decisions follow.

In the NPRM, OSHA requested comment on whether the provisions of the abrasive blasting substandard in the Ventilation standard for construction (29 CFR 1926.57, paragraph (f)) and the standard for Mechanical paint removers in shipyards (29 CFR 1915.34(c)) provide adequate protection to employees exposed to beryllium from abrasive blasting operations in these sectors. As discussed previously in the Summary and Explanation for paragraph (a), Scope and application, commenters argued persuasively that these abrasive blasting standards do not adequately protect beryllium-exposed construction and shipyard employees, and that OSHA should extend all provisions of the general industry standard to these sectors (*e.g.,* Document ID 1679; 1963). However, the Abrasive Blasting Manufacturers Alliance (ABMA) stated that the proposed provisions for regulated areas in general industry would be inconsistent with regulations for abrasive blasting in shipyards, which do not always require such designated areas (Document ID 1673, p. 22). A similar concern could apply to requirements for regulated areas in construction.

In OSHA's view, the provisions of the abrasive blasting standards in shipyards and in construction provide important baseline requirements appropriate to any situation where abrasive blasting is conducted in these sectors. However, the abrasive blasting standards are not intended to provide comprehensive requirements for all abrasive blasting operations, because some operations may involve hazards unique to the particular process or blast media in use.

Operations that use beryllium-containing blast media present unique risks of beryllium sensitization and CBD to exposed employees (see Section V, Health Effects), and thus require protective measures beyond those of the abrasive blasting standards. As discussed above, regulated areas and related provisions include requirements that are key to protecting employees from the effects of beryllium exposure, such as restricted access, respiratory protection, and warning signs. OSHA concludes that provisions similar to the requirements for regulated areas in the final standard for general industry will provide shipyard employees necessary protection complementing that found in the shipyard mechanical paint remover standard, and is not in conflict with the provisions or intent of that standard.

OSHA has similarly concluded that the beryllium standard should apply to construction because it will better protect employees exposed to beryllium while abrasive blasting than application of the Ventilation standard alone. However, comments in the record and OSHA's experience regulating chemical exposures in construction indicate that the establishment of regulated areas is not the most effective way to ensure that construction employees receive the protections associated with regulated areas in the general industry standard. This decision is chiefly based on the Agency's recognition that conditions at construction worksites present challenges to establishing regulated areas due to the varied and changing nature of construction work. Some of these challenges were noted in the preamble to the recent respirable crystalline silica standard (81 FR 16285) and also apply here. For example, construction tasks, and specifically abrasive blasting, are commonly performed outdoors. Exposure-generating tasks could be short or long in duration and are typically performed at non-fixed workstations or worksites. Moreover, construction tasks may move to different locations during the workday. Such conditions could make it difficult to establish and maintain regulated areas as required by the general industry and shipyard standards.

At the same time, OSHA finds that construction workers, like their counterparts in general industry and shipyards, need to be made aware of those locations in their workplace where airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. Therefore, OSHA has decided to adopt the method that was recently included in the recent respirable crystalline silica standard for construction, as well as in some prior construction standards. There, in lieu of establishing regulated areas, the Agency included a requirement for a designated competent person to implement procedures in the written exposure control plan to restrict access to work areas, where necessary, to limit exposures to respirable crystalline silica to achieve the primary objectives of a regulated area. OSHA has concluded that a similar approach is appropriate in this rulemaking. The Agency finds that this flexible approach balances the unique conditions of the construction industry with the need to protect construction employees.

In summary, OSHA has decided to include regulated area requirements in the final standards for general industry and shipyards. The requirements to establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL, can be found in paragraph (e)(1)(ii) of the standard for general industry and (e)(1) of the standard for shipyards. Other requirements related to regulated areas, *e.g.,* the requirements to identify and limit access to regulated areas, are discussed in more detail below. In addition, OSHA has decided not to include requirements for regulated areas in the final construction standard, but has provided analogous protections for construction employees through the competent person provisions in paragraph (e) of the final construction standard. The competent person requirements are also discussed in detail below.

In addition, NIOSH suggested that since demarcated areas may be difficult to establish and maintain in some construction or maritime settings, OSHA could consider alternative ways to provide the protections associated with such areas to employees in these sectors. For example, respiratory protection could be triggered by exposure to a threshold airborne level, or dermal protections could be triggered based on performance of tasks involving dermal contact with beryllium (Document ID 1755, Tr. 21–22). OSHA has adopted NIOSH's suggestion to tie certain protective measures to employee inhalation exposures or dermal contact rather than using the intermediary step of establishing demarcated areas where such areas are not required in the construction or maritime sectors. For example, as explained below in the discussion of competent person requirements, respiratory protection requirements apply to employees in construction who have or may reasonably be expected to have airborne exposure above the TWA PEL or STEL. In addition, requirements for provision and use of PPE are triggered based on the potential for dermal contact with beryllium in all three standards (see the Summary and Explanation for paragraph (h), Personal protective clothing and equipment). Thus, PPE is available to all employees whose work may involve dermal contact with beryllium, irrespective of whether they work in an industry where demarcated areas are required.

Demarcation of regulated areas. Proposed paragraph (e)(2) included the requirements for the demarcation of beryllium work areas and regulated areas. Under proposed paragraph (e)(2)(i), employers were required to identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area. OSHA explained that the demarcation must effectively alert workers and other persons that airborne beryllium may be present. Proposed paragraph (e)(2)(ii) required employers to demarcate each regulated area in accordance with the paragraph (m)(2) hazard communication provisions of this standard. OSHA did not further specify requirements for demarcation, proposing instead to offer employers flexibility in determining the best means to demarcate beryllium work areas and regulated areas. The Agency requested comment on each of these proposed provisions, including whether the standard should specify what types of demarcation employers must use or take a more performance-oriented approach. See 80 FR 47786.

OSHA received several comments on demarcation in general industry and maritime settings. First, NIOSH advocated the need for more specification on how to demarcate regulated areas (Document ID 1671, Attachment 1, p. 6). OSHA believes, however, that allowing employers to choose how to best demarcate regulated areas (as well as beryllium work areas) is consistent with its preference for performance-based approaches where, as here, the Agency has determined that employers, based on their knowledge of the specific conditions of their workplace, are in the best position to make such determinations. For example, if an employer knows that exposures in a particular work area might exceed the PEL on one particular day only, that employer might choose a temporary method of demarcation. Conversely, an employer might choose to use a more permanent method of demarcation for a beryllium work area that contains a

potentially beryllium-releasing operation that occurs daily. In some workplaces employers might choose to use barricades, in others textured flooring, roped-off areas, ''No entry''/ ''No access'' signs, or painted boundary lines. OSHA generally approves of each of these methods, provided that the particular method or methods the employer selects are clear and understandable enough to alert workers to the boundaries of the beryllium work area or regulated area. This may mean, for example, including more than one language on a sign, if the inclusion of a second language would make the sign understandable to a particular workforce with limited English reading skills.

OSHA has identified several factors that it considers to be appropriate considerations for employers when they are determining how to demarcate beryllium work areas and regulated areas. These factors include the configuration of the beryllium work area or regulated area; whether the beryllium work area or regulated area is permanent; the airborne concentrations of beryllium in the beryllium work area or regulated area; the number of employees working in areas adjacent to any beryllium work area or regulated area; and the period of time the beryllium work area or regulated area is expected to have hazardous exposures. OSHA also notes that the use of a performance-oriented approached to the demarcation of regulated areas is consistent with previous health standards, such as respirable crystalline silica (29 CFR 1910.1053) and chromium (VI) (29 CFR 1910.1026).

Moreover, although proposed paragraph (e)(2)(ii) allowed employers to demarcate regulated areas in a variety of ways, it also contained specific requirements for the posting and wording of a warning sign in accordance with proposed paragraph (m)(2). OSHA included this requirement in the proposal because it preliminarily found that employees must recognize when they are entering a regulated area, and understand the hazards associated with the area, as well as the need for respiratory protection. Signs are an effective means of accomplishing these objectives. Therefore, OSHA included a proposed requirement for employers to post all entrances to regulated areas with signs that bear the following legend:

DANGER
BERYLLIUM
BERYLLIUM MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

Ameren, an electric power utility, objected to the proposal's demarcation requirement. Specifically, Ameren stated that ''[c]onfined space areas such as a boiler penthouse during abrasive blasting activities would be hard to demarcate since the entrance to the regulated area is small and would block access to the area for personnel and equipment. It would also be difficult to establish areas for activities such as cleaning fly ash off of plant piping or structural steel.'' Ameren suggested alternate, training-based means of informing employees of beryllium exposures, such as job planning and job safety briefings (Document ID 1675, p. 11). OSHA disagrees that its performance-oriented approach does not accommodate these circumstances. As discussed above, demarcation requirements for beryllium work areas and regulated areas allow employers maximum flexibility in designing forms of demarcation that best fit the nature of their facilities and processes. Forms of demarcation, such as tape, that do not block access to areas and can be applied in areas where fly ash is cleaned are not difficult to design or implement. Furthermore, training to inform employees of the location of beryllium exposures is a valuable complement to, but should not replace, demarcation in the final standards. The reinforcement of training with demarcation is an important protection to ensure that employees, who may work frequently in beryllium work areas and regulated areas, are continually aware of the location of beryllium exposures in their workplace. See summary and Explanation for paragraph (m), discussing employee training requirements. Also, requirements for demarcation ensure that persons other than employees, who may enter the worksite but may not receive training, are adequately informed of the presence of beryllium.

Commenters also opined on the signage requirement in proposed paragraph (e)(2)(ii). Specifically, the ABMA argued that the beryllium specific signs required in the proposed standard for general industry are not appropriate for use in shipyard abrasive blasting, since this operation involves potential exposure to a number of hazardous chemicals (Document ID 1673, p. 22). OSHA disagrees and is maintaining the sign requirement in the final standards (with slightly altered language, noted below). Beryllium specific signs are appropriate and necessary to inform employees and others of the specific health hazards associated with beryllium exposure. Although employees should also be made aware of other hazardous chemicals they may be occupationally exposed to, training and signage regarding these other chemicals must necessarily be addressed elsewhere, and these concerns should not preclude OSHA from requiring appropriate warning signs for beryllium exposure. OSHA notes that in comments from the U.S. House of Representatives Committee on Education and the Workforce, the committee urged OSHA to implement ''demarcation (through postings of warnings) if there is abrasive blasting with beryllium containing materials'' by shipyard workers (Document ID 1672, p. 4).

After carefully reviewing the record, OSHA finds that the proposed approach for the demarcation of beryllium work areas and regulated areas strikes a reasonable balance between the difficulties of establishing and maintaining these areas with the need to alert those exposed of the risks involved, to reduce the number of employees exposed to beryllium, and to protect those employees exposed to high levels of airborne beryllium. In particular, OSHA finds that the general performance-oriented approach in the proposed requirements, when coupled with the specificity of the signage requirements for regulated areas, provides employers with a good balance of direction and flexibility. The final standards do not require employers to establish and demarcate beryllium work areas or regulated areas by permanently segregating and isolating processes generating airborne beryllium. Instead, the standards allow employers to use temporary or flexible methods to demarcate beryllium work areas and regulated areas. In sum, OSHA finds that these flexible, performance-based requirements will accommodate open work spaces, changeable plant layouts, and sporadic or occasional beryllium use without imposing undue costs or burdens. Therefore, OSHA has decided to include paragraphs (e)(2)(i) and (e)(2)(ii), as proposed, in the final standard for general industry and to include regulated areas demarcation requirements in paragraph (e)(2) of the shipyard standard identical to those of paragraph (e)(2)(ii) of the general industry standard. However, OSHA notes that the required legend for the signage has been amended slightly to include the words ''REGULATED AREA,'' as discussed in the Summary and Explanation for paragraph (m),

Communication of hazards, in this preamble. (OSHA is not including the proposed demarcation provisions in the final standard for construction because, as discussed above, the construction standard does not require the establishment or maintenance of either beryllium work areas or regulated areas.)

Paragraph (e)(3) of the proposed standard required employers to limit access to regulated areas. Because of the serious health effects of exposure to beryllium and the need for persons entering the regulated area to be properly protected, OSHA proposed that the number of persons allowed to access regulated areas should be limited to: (i) Persons the employer authorizes or requires to be in a regulated area to perform work duties; (ii) persons entering a regulated area as designated representatives of employees for the purposes of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this standard; and (iii) persons authorized by law to be in a regulated area.

The first group, persons the employer authorizes or requires to be in a regulated area to perform work duties, may include workers and other persons whose jobs involve operating machinery, equipment, and processes located in regulated areas; performing maintenance and repair operations on machinery, equipment, and processes in those areas; conducting inspections or quality control tasks; and supervising those who work in regulated areas.

The second group encompasses persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring under paragraph (d)(7). As explained in the summary and explanation section on paragraph (d) for exposure assessment, providing employees and their representatives with the opportunity to observe monitoring is consistent with the OSH Act and OSHA's other substance-specific health standards, such as those for respirable crystalline silica (29 CFR 1910.1053), cadmium (29 CFR 1910.1027), and methylene chloride (29 CFR 1910.1052).

The third group consists of persons authorized by law to be in a regulated area. This category includes persons authorized to enter regulated areas by the OSH Act, OSHA regulations, or any other applicable law. OSHA compliance officers would fall into this group.

As discussed in the NPRM, limiting access to regulated areas restricts the number of persons potentially exposed to beryllium at levels above the TWA PEL or STEL, and thus reduces the risk of beryllium-related health effects for employees and others who do not need access to regulated areas. As explained previously in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to extend all provisions of the general industry standard to construction and shipyards except where the Agency finds that they are not appropriate to construction and shipyard settings. OSHA did not receive comments on this provision in the proposed standard, and did not receive comments or evidence indicating that restricted access areas are not appropriate in construction and shipyards. However, as discussed previously, OSHA has determined that protections associated with regulated areas in general industry will be more effectively accomplished with a competent person provision in construction.

OSHA has therefore decided to retain paragraph (e)(3) as proposed in the final standard for general industry, and to add an identical provision to the shipyard standard and an analogous provision to the construction standard. Thus, final paragraph (e)(3) requires employers in general industry and shipyards to limit access to regulated areas to: (i) Persons the employer authorizes or requires to be in a regulated area to perform work duties; (ii) persons entering a regulated area as designated representatives of employees for the purposes of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this standard; and (iii) persons authorized by law to be in a regulated area. And paragraph (e) of the construction standard requires the designation of a competent person, who, among other things, will implement the written exposure control plan under paragraph (f) of this standard. As discussed in more detail below, paragraph (f)(1)(i)(H) of the construction standard requires employers to establish and implement procedures to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors.

Proposed paragraph (e)(4) required employers to provide and ensure that each employee entering a regulated area uses personal protective clothing and equipment, including respirators, in accordance with paragraphs (g) and (h) of the proposed standard. As discussed in the NPRM, provisions for respiratory protection and PPE ensure that those who must enter regulated areas are properly protected, thereby reducing the risk of serious health effects associated with airborne beryllium exposure and dermal contact with beryllium. As explained previously in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to extend all provisions of the general industry standard to construction and shipyards except where the Agency finds that they are not appropriate to construction and shipyard settings. OSHA did not receive comments on this provision in the proposed standard for general industry, and did not receive comments or evidence indicating that restricted access areas are not appropriate in construction and shipyards. However, as discussed previously in this section, OSHA has determined that protections associated with regulated areas in general industry will be more effectively accomplished with a competent person provision in construction.

OSHA has therefore decided to retain paragraph (e)(4) as proposed in the final standard for general industry, and to add an identical provision to the shipyard standard and an analogous provision to the construction standard. Thus, final paragraph (e)(4) of the general industry and shipyard standards requires employers to provide and ensure that each employee entering a regulated area uses respiratory protection in accordance with paragraph (g) and personal protective clothing and equipment in accordance with paragraphs (h) of the final standard for general industry. Wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL in construction settings, paragraph (e) of the construction standard requires the employer to designate a competent person to ensure that all employees use respiratory protection and PPE in accordance with paragraphs (g) and (h) of the standard.

Competent Person (Construction). To balance the unique conditions present in the construction industry with the need to protect construction industry employees from high airborne exposures, OSHA has chosen to adopt an approach in the construction standard for restricting access to high-exposure areas similar to that used in the recent respirable crystalline silica standard for construction. This approach requires the employer to designate a competent person or persons, who will, among other things, implement the written exposure control plan, including procedures used to

restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL; ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard. OSHA finds this approach offers construction employers a flexible means of providing protection to their employees.

The competent person requirement is a well-known and accepted concept in OSHA standards; competent person provisions are included in at least 20 of OSHA's construction standards, including OSHA substance-specific standards for construction, such as lead (29 CFR 1926.62), asbestos (29 CFR 1926.1101), cadmium (29 CFR 1926.1127), and respirable crystalline silica (29 CFR 1926.1153). In addition, OSHA's general safety and health provisions for construction require the employer to initiate and maintain programs for accident prevention, as may be necessary, and such programs require frequent and regular inspections of job sites, materials, and equipment by a designated competent person (29 CFR 1926.20(b)(1) and (2)).

Competent person provisions are also commonly included in American National Standard Institute (ANSI) standards for construction. NIOSH and its state partners also routinely recommend the need for, and role of, designated competent persons in investigation reports conducted under NIOSH's Fatality Assessment and Control Evaluation program. Thus, OSHA finds that the use of a competent person is consistent with current industry practices in that many construction employers are already using a designated competent person.

Moreover, although OSHA did not include a competent person requirement in the proposed rule, stakeholders indicated that such a requirement would be appropriate if the Agency chose to include the construction industry within the scope of this rulemaking. For example, North America's Building Trades Unions (NABTU) testified that beryllium construction work should be done under the supervision of a competent person (Document ID 1756, Tr. 231–232). NABTU added that the most important point of having a competent person designated in the standard is to ensure there is an agent of the employer on site who has the appropriate authority to correct hazards (Document ID 1805, Attachment 1, p. 4).

Based on these comments and the reasons described above, OSHA has decided to include competent person requirements in the final rule for construction, instead of requiring regulated areas. In paragraph (b) of the construction standard, OSHA defines competent person as an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The definition also specifies that the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard.

In order to craft an appropriate definition for this term, OSHA considered stakeholder comments, including NABTU's above comments on the need for a competent person in the construction standard, and the definition of competent person in the safety and health regulations for construction (29 CFR 1926.32(f)). Under 29 CFR 1926.32(f), competent person is defined as a person capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees and who is authorized to take prompt corrective measures to eliminate them. OSHA's definition for competent person in the construction standard is consistent with the 1926.32(f) definition with several minor changes. For example, the Agency tailored this definition to beryllium by specifying ''beryllium hazards'' instead of ''unsanitary, hazardous, or dangerous'' conditions. In addition, OSHA replaced the word ''one'' with ''individual,'' which is merely an editorial change. The Agency also removed the phrase ''in the surroundings or working conditions'' and changed it to ''in the workplace'' to make it specific to the workplace. And the Agency removed the phrase ''to eliminate them'' and changed it to ''to eliminate or minimize them'' to denote there may be cases where complete elimination would not be feasible. Finally, OSHA changed ''predictable'' to ''foreseeable'' to make the wording consistent with the scope of this construction standard (paragraph (a)).

OSHA also decided that it was important to detail the necessary characteristics and authority of a competent person in the standard to ensure that he or she is truly competent to carry out the tasks designated under paragraph (e). Thus, under paragraph (b) of the construction standard, the competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of the construction standard. However, OSHA has chosen not to specify particular training requirements for competent persons. The Agency finds that it is not practical to specify in the rule the elements and level of training required for a competent person. And the Agency does not find it appropriate to mandate a ''one size fits all'' set of training requirements to establish the competency of competent persons in every conceivable construction setting. Therefore, the training requirement for a competent person is performance-oriented. This approach is consistent with most OSHA construction standards, such as cadmium (29 CFR 1926.1127), lead (29 CFR 1926.62) and respirable crystalline silica (1926.1153), which include a performance-based approach by not specifying training or qualifications required for a competent person.

Like the regulated area provisions in general industry and shipyards, paragraph (e)(1) of the construction standard applies wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. As discussed in more detail above with regard to the establishment and maintenance of regulated areas in general industry and shipyards, OSHA finds that this exposure level trigger is appropriate for provisions such as this one.

Paragraph (e) of the standard for construction further specifies that wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL, the employer shall designate a competent person to: (1) Make frequent and regular inspections of job sites, materials, and equipment; (2) implement the written exposure control plan under paragraph (f) of this standard; (3) ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and (4) ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard. OSHA finds that these responsibilities, together, offer construction employees similar protection to those afforded to general industry and shipyard employees while offering construction employers more flexibility to suit their workplaces.

Under paragraph (e)(1) of the construction standard, the competent person must make frequent and regular

inspections of job sites, materials, and equipment. OSHA included this requirement in order to ensure that the competent person has the necessary information to carry out the rest of his or her duties. For example, the competent person's second responsibility (as discussed below) is to implement the written exposure control plan under paragraph (f) of this standard. Among other things, the written exposure control plan includes procedures for minimizing cross-contamination (paragraph (f)(1)(i)(D)). In order to implement these procedures on a construction worksite, the competent person may need to know about the unique characteristics of the jobsite and the materials and equipment used therein. Similarly, in order to carry out his or her duty to implement the procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, and to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors, as required by paragraph (f)(1)(i)(I), the competent person will equally need to be familiar with the jobsite, materials, and equipment in order to know where high exposures might occur.

Under paragraph (e)(2) of the construction standard, OSHA is requiring that the competent person implement the written exposure control plan because the plan specifies what must be done to consistently identify and control beryllium hazards on a job site. See Summary and Explanation for paragraph (f), Written exposure control plan. In construction, a competent person is needed to ensure that the requirements of the written exposure control plan are being met under variable conditions. The subjects that must be included in the written exposure control plan for construction are consistent with the duties of a competent person in past OSHA standards. Therefore, this requirement should be familiar to construction employers covered by this standard.

In addition, under paragraph (f)(1)(i)(I) the written exposure control plan must contain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors. By requiring the competent person to implement these procedures, OSHA is offering similar protection to construction employees as given to general industry and shipyard employees through the regulated area provisions in the general industry and shipyard standards.

OSHA is cognizant that the written exposure control plan requirement regarding the exposures generated by other employers or sole proprietors is important in construction because at multi-employer worksites, the actions of one employer may expose employees of other employers to hazards. A competent person can help communicate hazards to other employers. OSHA expects that the employers or their competent persons will work with general contractors at construction sites to avoid high exposures of employees working alongside others by implementing administrative procedures such as scheduling high-exposure tasks when others will not be in the area. However, if this does not occur, the competent person has authority to implement other administrative procedures that would be effective for protecting employees in situations where an employer was not made aware that another employer or sole proprietor would be conducting abrasive blasting operations on the worksite. Upon encountering such situations on a worksite, the competent person is expected to remind employees to stay away from the abrasive blasting site and make sure that employees he or she oversees are positioned at a safe distance from the abrasive blasting activity

In addition to limiting access to high exposure areas, the standard for construction requires the competent person to ensure that employees use respiratory protection and personal protective clothing and equipment while in high exposure areas (paragraph (e)(3)–(4)). This is an important requirement because without demarcated regulated areas, employees would not have signs to remind them of the need to use such protective equipment. It is therefore the competent person's responsibility to provide the necessary warnings.

OSHA is not requiring a competent person for the general industry and shipyard standards. OSHA has determined that in most cases, general industry scenarios are not as variable as those in construction. For example, most work is performed indoors and therefore, not subject to variables such as wind shifts and moving exposure sources that could significantly affect exposures or complicate establishment of regulated areas. Employers covered under the general industry and shipyard standards are more likely to have health and safety professionals on staff who could assist with implementation of the standard. Finally, competent persons have not been included in other OSHA substance-specific standards for general industry. For example, a competent person requirement was included in the construction standard for cadmium because of environmental variability and the presence of multiple employers on the job site, but a competent person requirement was not included in the general industry standard for cadmium (29 CFR 1910.1027; 29 CFR 1926.1127; 57 FR 42101, 42382 (9/14/1992)). A competent person requirement was included in the construction standard for respirable crystalline silica for similar reasons (81 FR 16811). These factors explain and support OSHA's conclusion that there is no regulatory need for including a competent person requirement in the beryllium standards for general industry and shipyards.

(f) Methods of Compliance

Paragraph (f) of the standards establishes methods for reducing employee exposure to beryllium through the use of a written exposure control plan and engineering and work practice controls. Paragraph (f)(1)(i) of each of the standards requires employers to establish, implement, and maintain a written exposure control plan and specifies the information that must be included in the plan. Paragraph (f)(1)(ii) establishes requirements for employers to review their plan(s) at least annually and update it under specified circumstances. Finally, paragraph (f)(1)(iii) requires employers to make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium.

Paragraph (f)(2) of the final standards requires employers to implement engineering and work practice controls to reduce beryllium exposures to employees. Where airborne exposure exceeds the TWA PEL or STEL, the employer must implement engineering and work practice controls to reduce airborne exposure to or below the exceeded exposure limit(s). Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by engineering and work practice controls, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard. In addition,

paragraph (f)(2) includes limited requirements for implementation of exposure controls where operations release airborne beryllium exceeding the action level. Finally, paragraph (f)(3) prohibits the employer from rotating employees to different jobs to achieve compliance with the TWA PEL and STEL.

Paragraph (f)(1)(i) of the proposed rule would have required employers to establish, implement, and maintain a written exposure control plan for beryllium work areas, containing an inventory of operations and job titles reasonably expected to have exposure at or above the action level; an inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL; procedures for minimizing cross-contamination, keeping surfaces in the beryllium work area as free as practicable of beryllium; minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace, and removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators; and an inventory of engineering and work practice controls required by paragraph (f)(2) of the proposed standard.

Several commenters offered broad support for the inclusion of paragraph (f)(1)'s provisions in the final rule (*e.g.,* Document ID 1681, Attachment 1, p. 9; 1689, p. 11; 1690, p. 1). For example, United Steelworkers (USW) stated: ''[a] written plan will help to ensure that exposure controls and safety practices are continually followed. This will also provide workers and other stakeholders with information necessary in evaluating the health and safety protections and provisions provided by the employer'' (Document ID 1681, p. 9). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) also supported the inclusion of written exposure control plan requirements (Document ID 1689, p. 11). It argued that ''[r]equiring employers to properly make use of a written plan is an essential tool for continuously controlling exposures and using proper safety practices'' (Document ID 1689, p. 11). The National Council for Occupational Safety and Health (National COSH) agreed, stating that ''[a] comprehensive program to protect workers from these exposures, that includes a requirement for a written beryllium control plan, regular exposure monitoring, medical surveillance, medical removal protection benefits, and training would provide much needed protection for beryllium exposed workers'' (Document ID 1690, p. 1). Written exposure control plan requirements were also included in the draft proposed rule submitted to the Agency by Materion Corporation (Materion) and United Steelworkers (USW) (Document ID 0754, p. 6).

OSHA agrees with the opinions expressed by these commenters. Requiring employers to articulate where exposures occur and how those exposures will be controlled will help to ensure that they have a complete understanding of the controls needed to comply with the rule. Thus, OSHA expects a written exposure control plan will be instrumental in ensuring that employers comprehensively and consistently protect their employees. Consequently, the Agency has decided to include written exposure control plan requirements in paragraph (f)(1) of the final standards.

In the preamble to the proposal, OSHA explained that adherence to the written exposure control plan will help reduce skin contact with beryllium, which can lead to beryllium sensitization, and airborne exposure, which can lead to beryllium sensitization, CBD, and lung cancer (80 FR 47787). Because skin contact and airborne exposure can occur in any workplace within the scope of the standard, OSHA preliminarily decided to require a written exposure control plan for all employers within the scope of the standard.

OSHA received comments regarding the proposed trigger for written exposure control plan requirements. For example, NGK Metals Corporation (NGK) argued that requiring employers to develop and maintain a written exposure control plan for facilities where exposures are below the action level is burdensome, and recommended that the written plan be required only where exposures exceed the action level (Document ID 1663, p. 2). EEI asserted that a requirement for a written exposure control plan should apply to areas where exposures meet or exceed the action level or PEL, so as to be consistent with other health standards (Document ID 1674, p. 13).

OSHA has re-examined the provisions of (f)(1) in light of these comments and reaffirms its preliminary decision to require all employers within the scope of the standard to establish, implement, and maintain a written exposure control plan. The Agency finds that the requirements that apply where exposures are below the action level (*e.g.,* a list of operations and job titles reasonably expected to involve airborne exposure or dermal contact with beryllium; descriptions of procedures for handling beryllium-contaminated PPE and respirators; and descriptions of procedures for minimizing cross-contamination and migration of beryllium) are important to preventing beryllium sensitization and CBD, and are not overly burdensome. Moreover, many of the requirements in the plan are intended to complement the housekeeping and hygiene requirements that all facilities in the scope of the standard must already meet, and do not create significant burdens for employers beyond documentation of their procedures for meeting the requirements of other paragraphs in the standards, such as (h) Personal protective clothing and equipment, (i) Hygiene areas and practices, and (j) Housekeeping.

Proposed paragraph (f)(1)(i)(A)–(H) set forth the required contents of the written exposure control plan. Under the proposal, the employer's written exposure control plan was required to include: (1) An inventory of operations and job titles reasonably expected to have exposure; (2) an inventory of operations and job titles reasonably expected to have exposure at or above the action level; (3) an inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL; (4) procedures for limiting beryllium contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within the beryllium work area; (5) procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium; (6) procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace; (7) an inventory of engineering and work practice controls used by the employer to comply with paragraph (f)(2) of this standard; and (8) procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

Stakeholders offered comments on the proposed written control plan contents. For example, the Boeing Company suggested that OSHA should revise the proposed provision requiring ''procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium'' to define specific surface contaminant levels (Document ID 1667, p. 4). The apparent advantage of providing a target surface contaminant level is that employers could use surface sampling to determine whether they are in compliance with the standard's requirements for surface cleaning. However, as OSHA explained

in the Summary and Explanation for paragraph (j), Housekeeping, the relationship between a precise amount of surface contamination and health risk is unknown. Therefore, OSHA cannot find that a particular level of contamination is safe. Rather, OSHA has determined that keeping surfaces as clean as practicable is appropriate because promptly removing beryllium deposits prevents them from becoming airborne, thus reducing employees' inhalation exposure, and helps to minimize the likelihood of skin contact with beryllium. Moreover, the term ''free as practicable'' is accepted language and has been used in previous standards, such as standards addressing exposure to lead and chromium (VI). Consequently, OSHA has decided to retain the ''free as practicable'' language in the final rule for general industry. (As discussed in more detail below, the final standards for construction and shipyards do not include this requirement.)

After careful consideration of the record, OSHA reaffirms the need for the written exposure control plan to contain each of the provisions included in the proposal. This written record of which operations and job titles are likely to have exposures at certain levels and which housekeeping provisions and engineering and work practice controls the company has selected to control exposures required in paragraph (f) will make it easier for employers to implement monitoring, hygiene practices, housekeeping, engineering and work practice controls, and other measures. The provisions contained in (f)(1)(i)(D), (E), (F), and (H) of the proposed rule will work to minimize the spread of beryllium throughout and outside the workplace and to reduce the likelihood of skin contact and re-entrainment of beryllium particulate.

Therefore, OSHA has decided to retain the proposed contents of the written exposure control plan in the standard for general industry, with the following revisions. First, OSHA has modified the proposed requirement to include an inventory of operations and job titles reasonably expected to have exposure, including by dermal contact. As discussed in detail in the Summary and Explanation for paragraph (h), Personal protective clothing and equipment (PPE), OSHA finds that it is important to protect employees from dermal contact with beryllium. OSHA therefore finds that the written exposure control plan should inform employees and others of jobs and operations where dermal contact with beryllium is reasonably expected, and has added dermal contact with beryllium to paragraph (f)(1)(i)(A) of the final standards. Thus, the final standard for general industry requires the employer to include a list of operations and job titles reasonably expected to involve airborne exposure to beryllium or dermal contact with beryllium in their written exposure control plan(s).

Second, OSHA modified the language of proposed paragraphs (f)(1)(i)(A), (B), (C), and (G) by replacing the term ''inventory'' with the term ''list''. This change in wording does not imply a change in the intent of the provision. Rather, OSHA made this change to clarify the Agency's intent to require employers to simply identify jobs, operations and controls that match the criteria of these provisions, and that employers are not required to provide more extensive description of such jobs and operations. Third, OSHA modified (f)(1)(i)(D) by deleting ''but not limited to'' from the phrase ''including but not limited to preventing the transfer of beryllium'', because the term ''including'' implies that the examples to follow are not intended to be exhaustive. This change in wording does not imply a change in the intent of the provision.

Fourth, OSHA has edited the proposed text, which required an ''inventory'' of operations and job titles reasonably expected to ''have'' exposure; exposure at or above the action level; and exposure above the TWA PEL or STEL. The final text requires a ''list'' of operations and job titles reasonably expected to ''involve'' airborne exposure to or dermal contact with beryllium; airborne exposure at or above the action level; and airborne exposure above the TWA PEL or STEL. This is an editorial change to provide greater clarity to better describe the actual requirement, and does not change the intent of the provision. Fifth, OSHA modified the proposed requirement to inventory engineering and work practice controls required by paragraph (f)(2) of this standard to include respiratory protection. This change ensures that the respiratory protection requirement, which is included in (f)(2)(iv) of the final standards, is treated in the same manner as the engineering and work practices control requirements in (f)(2)(i) and (f)(2)(iii).

Finally, OSHA has included one additional provision in the final rule for general industry that was not contained in the proposal. Specifically, paragraph (f)(1)(i)(H) of the final rule requires employers to include within their written exposure control plan a list of personal protective clothing and equipment required by paragraph (h) of this standard. This provision is added in recognition of the importance of personal protective clothing and equipment in protecting exposed employees, particularly those employees who may have dermal contact with beryllium. With the addition of this new provision, proposed paragraph (f)(1)(i)(H) (regarding procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators) has been redesignated as paragraph (f)(1)(i)(I) of the final rule for general industry.

OSHA has incorporated most provisions of the proposed paragraph (f)(1)(i) into the final standards for construction and shipyards, with certain modifications due to the work processes and worksites particular to these sectors. As explained in the Summary and Explanation for paragraph (j), Housekeeping, OSHA has determined that abrasive blasting operations are the primary source of beryllium exposure in the construction and shipyard sectors and has chosen not to include provisions related to surface cleaning in the final standards for these sectors due to the extreme difficulty of maintaining clean surfaces during blasting operations. OSHA has therefore decided to exclude the provision regarding procedures for keeping surfaces as free as practicable of beryllium (proposed paragraph (f)(1)(i)(E)) from the construction and shipyard standards. And due to the difficulty of controlling contamination during blasting operations, OSHA has decided to include a more performance-oriented provision on cross-contamination in the standards for construction and shipyards than in paragraph (f)(1)(i)(D) of the general industry standard. Employers are still required to establish and implement procedures for minimizing cross-contamination of beryllium in construction and shipyard industries. However, the written exposure control plan provision on cross-contamination simply requires ''procedures for minimizing cross-contamination''; it does not specify ''procedures for minimizing cross-contamination, including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas'' as in general industry. OSHA has included the proposed provision for minimizing the migration of beryllium in the standards for construction and shipyards, but has removed the reference to beryllium work areas since these are not established in construction

and shipyards. The written exposure control plan provision on migration in these sectors requires the plan to include ''procedures for minimizing the migration of beryllium within or to locations outside the workplace.''

Because the requirements pertaining to surfaces contained in final paragraph (f)(1)(i)(E) of the general industry standard do not appear in the construction and shipyard standards, the numbering of the provisions differs from that of the general industry standard. For the construction and shipyard standards, requirements pertaining to the migration of beryllium appear in paragraphs (f)(1)(i)(E); requirements for a list of engineering controls, work practices, and respiratory protection are in paragraphs (f)(1)(i)(F); requirements for a list of personal protective clothing and equipment are in paragraphs (f)(1)(i)(G); and requirements pertaining to removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators, appear in paragraph (f)(1)(i)(H). Additional discussion of some of these requirements may be found in this section of the preamble, Summary and Explanation, at paragraph (h), Personal Protective Clothing and Equipment; paragraph (i), Hygiene Areas and Practices; and paragraph (j), Housekeeping.

OSHA has also included paragraph (f)(1)(i)(I) in the construction standard only, requiring employers in the construction sector to establish, implement and maintain procedures to restrict access where airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. This addition is related to OSHA's decision, explained in the Summary and Explanation of paragraph (e), not to include a requirement to establish regulated areas in the construction standard, and to achieve the protective benefits associated with regulated areas by other means. In the general industry and shipyard standards, the employer must limit access to regulated areas to persons who are authorized or required to be in a regulated area to perform work duties, observation, or other limited circumstances. OSHA has determined that restricting access to areas where airborne exposures exceed or may reasonably be expected to exceed the TWA PEL or STEL is appropriate to reduce employees' and others' risk of adverse health effects associated with airborne beryllium exposure. OSHA has therefore established alternative methods to ensure that construction employees do not enter such areas unnecessarily. To this end, the final standard for construction includes paragraph (f)(1)(i)(I), which requires employers to establish, implement and maintain procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, in order to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors. Significantly, the construction standard additionally includes paragraph (e), Competent Person, which requires employers to designate a competent person to implement the written exposure control plan. The competent person is therefore responsible for ensuring that the procedures to restrict access are followed in the workplace.

National Jewish Health (NJH) submitted a comment to OSHA regarding the importance of training, labeling, housekeeping measures, restricted entry to beryllium-contaminated areas, and technologies such as sticky mats and boot scrubbers in controlling employees' exposure to beryllium. NJH requested that OSHA emphasize the importance of such measures in paragraph (f) of these standards (Document ID 1664, p. 6). OSHA agrees with NJH that all of these approaches are helpful, and in some cases essential, to reducing employees' exposure. Training and some forms of labeling and access restriction are specifically required in other paragraphs of the standards. Specific tools such as sticky mats and boot scrubbers are not required in the standards, but are approaches employers should consider as part of their control procedures. All of the methods mentioned by NJH are ways to limit migration of beryllium and cross-contamination, and are therefore appropriate for inclusion in an employer's written exposure control plan(s).

The final standards' paragraph (f)(1)(i) differs from the proposal in that it requires a written exposure control plan for each facility, whereas the proposal would have required a written exposure control plan for beryllium work areas within each facility. In addition, OSHA has removed the phrase ''in the beryllium work area'' from provision (f)(1)(i)(E) of the final standard for general industry, so that it now reads: ''Procedures for keeping surfaces as free as practicable of beryllium''. OSHA made these changes because it changed the definition of a ''beryllium work area'' in the proposed standard for general industry. The proposed standard defined a beryllium work area to include any area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure. As discussed previously in the Summary and Explanation for paragraph (e), the final standard for general industry defines a beryllium work area to include only those areas containing a process or operation that releases beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. Accordingly, OSHA made these changes to the wording of (f)(1)(i) and (f)(1)(i)(E) to maintain the intent of proposed paragraph (f)(1)(i)(A), to require employers to list all jobs and operations throughout their facilities involving beryllium exposure, and paragraph (f)(1)(i)(E) to control dermal contact with beryllium wherever airborne beryllium may settle on surfaces in their facilities. If employers' procedures to prevent migration of beryllium from work areas to other areas of the facility are fully effective (paragraph (f)(1)(i)(F)), further steps to keep surfaces as free as practicable of beryllium will not be necessary. However, if the employer is unable to consistently prevent transfer of beryllium from work areas to other areas of the facility, the employer must develop and implement additional procedures to keep surfaces outside of the beryllium work areas as free as practicable of beryllium.

Paragraph (f)(1)(ii) of the proposed rule would have required the employer to update the exposure control plan when: (A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium; (B) an employee is confirmed positive, is diagnosed with CBD, or shows signs or symptoms associated with exposure; or (C) the employer has any reason to believe that new or additional exposures are occurring or will occur. OSHA did not receive any comments on this provision. However, as noted in the proposal, employers such as Materion and Axsys Technologies, who have worked to identify and document the exposure sources associated with cases of sensitization and CBD in their facilities, have used this information to develop and update beryllium exposure control plans (Document ID 0634; 0473; 0599). OSHA found that this process, whereby an employer uses employee health outcome data to check and improve the effectiveness of the employer's exposure

control plan, is consistent with other performance-oriented aspects of these standards. Thus, after considering the record on this issue, OSHA has decided to retain proposed paragraph (f)(1)(ii) in the final rule, with the modifications discussed below, to ensure that the employer's plan reflects the current conditions in the workplace.

The first modification is that OSHA added a requirement to review and evaluate the effectiveness of each written exposure control plan at least annually. OSHA finds that an annual review is appropriate because workplace conditions can change. In addition, by requiring employers to check the effectiveness of their plans annually, the standards offer employers the opportunity to better protect their employees by reflecting on any lessons learned throughout the previous year. The final annual review requirement is consistent with previous OSHA standards, such as the standards addressing bloodborne pathogens (29 CFR 1910.1030) and respirable crystalline silica (29 CFR 1910.1053).

Second, OSHA changed the proposed language of (f)(1)(ii)(B), which would have required employers to update their written exposure control plans when an employee is confirmed positive for beryllium sensitization, is diagnosed with CBD, or shows signs or symptoms associated with exposure. This change is related to another change from the proposed standard, which would have required notification of employers whenever an employee is confirmed positive for beryllium sensitization. As explained in the Summary and Explanation for paragraph (k), Medical Surveillance, OSHA has modified this provision so that employers are not automatically notified of cases of sensitization or CBD among their employees. However, employers will receive a written medical opinion from the licensed physician that may include a referral for an evaluation at a CBD Diagnostic Center (*see* (k)(6)(iii)) or a recommendation for medical removal from exposure to beryllium (*see* (k)(6)(v)). An employee may also provide the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis. Final paragraph (f)(1)(ii)(B) has been revised from the proposal to reflect the circumstances under the final standards where an employer will be notified that an employee has, or may have, a beryllium-related health effect. This includes when the employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of the standard (*i.e.,* when the employee provides the employer with a written medical report indicating a confirmed positive finding or CBD diagnosis, or the employer receives a written medical opinion recommending removal from exposure to beryllium); when the employer is notified that an employee is referred for evaluation at a CBD Diagnostic Center, or when an employee shows signs and symptoms associated with exposure. Third, OSHA further modified (f)(1)(ii)(B) to clarify the Agency's understanding that signs and symptoms may be related to inhalation or dermal exposure, as discussed in Section V, Health Effects. Final paragraph (f)(1)(ii)(B) therefore refers to signs and symptoms of ''airborne exposure to or dermal contact with beryllium''. Fourth, OSHA modified the wording of (f)(1)(ii) to require the employer to update ''each'' written exposure control plan rather than ''the'' written exposure control plan, since an employer who operates multiple facilities is required to establish, implement and maintain a written exposure control plan for each facility.

Paragraph (f)(1)(ii) of the final standards thus requires the employer to review and evaluate the effectiveness of each written exposure control plan at least annually and update it when: (A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional airborne exposure to beryllium; (B) the employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD Diagnostic Center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or (C) the employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

Paragraph (f)(1)(iii) of the proposed rule would have required the employer to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)). As discussed above and in the NPRM, access to the exposure control plan will enable employees to partner with their employers in keeping the workplace safe. OSHA did not receive comments specific to this provision, and has decided to retain it in the final standard for general industry and include it in the final standards for construction and shipyards.

Proposed paragraph (f)(2) established a hierarchy of controls that employers must use to reduce beryllium exposures. This paragraph required employers to rely on engineering and work practice controls as the primary means to reduce exposures. As a general matter, where airborne exposure exceeded the TWA PEL or STEL, proposed paragraph (f)(2) required employers to implement engineering and work practice controls to reduce airborne exposure to or below the PELs. Wherever the employer demonstrated that it is not feasible to reduce airborne exposure to or below the PELs through the use of engineering and work practice controls, the employer would have been required to implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard. In addition, proposed paragraph (f)(2) included limited requirements for implementation of exposure controls for each operation in a beryllium work area.

OSHA's long-standing hierarchy of controls policy was supported by a number of commenters, including USW; the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group); AWE; AFL–CIO; 3M; and National Jewish Health (*e.g.,* Document ID 1963, p. 12; 1655, pp. 8, 16; 1618, p. 8 (pdf); 1689, p. 11; 1625, p. 6 (pdf); 1664, p. 6). For example, the BHSC Task Group stated that OSHA's mandate ''to assure safe and healthy workplaces requires it to reinforce fundamental industrial hygiene tenets. Prime among these is application of a hierarchy of controls'' (Document ID 1655, p. 16). Similarly, 3M indicated that it ''agree[d] with OSHA that the hierarchy of controls—effective engineering and work practice controls—should be the primary means to help reduce employee exposures to beryllium and its compounds'' (Document ID 1625, p. 6 (pdf)). 3M added that ''when engineering controls and work practices cannot reduce employee exposure to beryllium to below the PEL, then the employer must protect employees' respiratory health through the use of respirators'' (Document ID 1625, p. 6 (pdf)). NJH added that

> . . . engineering and/or work practice controls are critical in reducing beryllium exposure and we have consulted with clients on this issue. In identifying controls, using the hierarchy of industrial controls to start with elimination or substitution . . . followed by engineering controls and process

controls such as enclosures, local exhaust ventilation, and wet methods . . . is crucial (Document ID 1664, p. 6).

After a careful review of the record, OSHA concludes that requiring primary reliance on engineering and work practice controls is necessary and appropriate because reliance on these methods is consistent with good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with OSHA's traditional adherence to a hierarchy of controls. The Agency finds that engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored continually and inexpensively, allow for predictable performance levels, and can efficiently remove toxic substances from the workplace. Once removed, the toxic substances no longer pose a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of control equipment is not as vulnerable to human error as is personal protective equipment.

OSHA has identified several key methods of reducing exposures: (1) Substitution; (2) isolation (*e.g.,* enclosures); (3) ventilation; and (4) process controls (*e.g.* wet methods, automation). Substitution refers to the replacement of a toxic material with another material that reduces or eliminates the harmful exposure. When available, substitution can replace a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects.

Isolation, *i.e.,* separating workers from the source of the hazard, is another effective engineering control employed to reduce exposures to beryllium. Isolation can be accomplished by either containing the hazard or isolating workers from the source of the hazard. For example, to contain the hazard, an employer might install a physical barrier around the source of exposure to contain a toxic substance within the barrier. Isolating the source of a hazard within an enclosure restricts respirable dust from spreading throughout a workplace and exposing employees who are not directly involved in exposure-generating operations. Or, alternatively, an employer might isolate employees from the hazard source by placing them in a properly ventilated space or at some distance from the source of the beryllium exposure.

Ventilation is another engineering control method used to minimize airborne concentrations of a contaminant by supplying or exhausting air. The primary type of ventilation system used to control beryllium exposure is local exhaust ventilation (LEV). LEV is used to remove an air contaminant by capturing it at or near the source of emission, before the contaminant spreads throughout the workplace. If designed properly, LEV systems efficiently remove contaminants and provide for cleaner and safer work environments.

Work practice controls involve adjustments in the way a task is performed. In many cases, work practice controls complement engineering controls in providing worker protection. For example, periodic inspection and maintenance of process equipment and control equipment such as ventilation systems is an important work practice control. Frequently, equipment which is in disrepair or near failure will not perform normally. Regular inspections can detect abnormal conditions so that timely maintenance can then be performed. If equipment is routinely inspected, maintained, and repaired or replaced before failure is likely, there is less chance that hazardous exposures will occur.

Workers must know the proper way to perform their job tasks in order to minimize their exposure to beryllium and to maximize the effectiveness of control measures. For example, if an exhaust hood is designed to provide local ventilation and a worker performs a task that generates a contaminant away from the exhaust hood, the control measure will be of no use. Workers can be informed of proper operating procedures through information and training. Good supervision further ensures that proper work practices are carried out by workers. By persuading a worker to follow proper procedures, such as positioning the exhaust hood in the correct location to capture the contaminant, a supervisor can do much to minimize unnecessary exposure. Employees' exposures can also be controlled by scheduling operations with the highest exposures at a time when the fewest employees are present.

Under the hierarchy of controls, respirators can be another means of providing employees effective protection from exposure to air contaminants. However, to be effective, respirators must be individually selected, fitted and periodically refitted, conscientiously and properly worn, regularly maintained, and replaced as necessary. In many workplaces, these conditions for effective respirator use are difficult to achieve. The absence of any one of these conditions can reduce or eliminate the protection the respirator provides to some or all of the employees. For example, certain types of respirators require the user to be clean shaven to achieve an effective seal where the respirator contacts the employee's skin. Failure to ensure a tight seal due to the presence of facial hair compromises the effectiveness of the respirator.

Respirator effectiveness ultimately relies on employers educating employees on the necessary good work practices and ensuring that employees adopt those practices. In contrast, the effectiveness of engineering controls does not rely so heavily on actions of individual employees. Engineering and work practice controls are capable of reducing or eliminating a hazard from a worksite, while respirators protect only the employees who are wearing them correctly. Furthermore, engineering and work practice controls permit the employer to evaluate their effectiveness directly through air monitoring and other means. It is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. OSHA therefore continues to consider the use of respirators to be the least satisfactory approach to exposure control.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators can impose substantial physiological burdens on employees, including the burden imposed by the weight of the respirator; increased breathing resistance during operation; limitations on auditory, visual, and olfactory sensations; and isolation from the workplace environment. Job and workplace factors such as the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity can also impose physiological burdens on employees wearing respirators. These stressors may interact with respirator use to increase the physiological strain experienced by employees.

Certain medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee wearing the respirator at an increased risk of illness, injury, and even death. These medical conditions include cardiovascular and respiratory diseases (*e.g.,* a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), and reduced pulmonary function caused by other factors (*e.g.,* smoking or prior exposure to respiratory hazards), neurological or

musculoskeletal disorders (*e.g.,* epilepsy, lower back pain), and impaired sensory function (*e.g.,* a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease (*see* 63 FR 1152, 1208–1209 (1/8/98)).

In addition, safety problems created by respirators that limit vision and communication must always be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult, annoying, and fatiguing. In addition, movement of the jaw in speaking can cause leakage, thereby reducing the efficiency of the respirator and decreasing the protection afforded the employee. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to employees and can cause employees to refrain from wearing the respirator, thereby rendering it ineffective.

These potential burdens placed on employees by the use of respirators were acknowledged in OSHA's revision of its respiratory protection standard, and are the basis for the requirement (29 CFR 1910.134(e)) that employers provide a medical evaluation to determine the employee's ability to wear a respirator before the employee is fit tested or required to use a respirator in the workplace (*see* 63 FR at 1152). Although experience in industry shows that most healthy employees do not have physiological problems wearing properly chosen and fitted respirators, nonetheless common health problems can cause difficulty in breathing while an employee is wearing a respirator.

For these reasons, all OSHA substance-specific health standards have recognized and required employers to observe the hierarchy of controls, favoring engineering and work practice controls over respirators. And the Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see* Section II, Pertinent Legal Authority for further discussion of these cases).

Therefore, OSHA has decided to require the use of the long-established hierarchy of controls in this standard. Because engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace, while respirators protect only the employees who are wearing them and depend on the selection and maintenance of the respirator and the actions of employees, OSHA holds to the view that engineering and work practice controls offer more reliable and consistent protection to a greater number of employees, and are therefore preferable to respiratory protection. Thus, the Agency continues to conclude that engineering and work practice controls provide a more protective first line of defense than respirators and must be used first when feasible.

The provisions related to engineering and work practice controls begin in paragraph (f)(2)(i). Paragraph (f)(2)(i)(A) of the proposed rule stated that, for each operation in a beryllium work area (*i.e.,* any work area involving airborne beryllium exposure), the employer shall ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure: (1) Material and/or process substitution; (2) ventilated partial or full enclosures; (3) local exhaust ventilation at the points of operation, material handling, and transfer; or (4) process control, such as wet methods and automation. Under proposed paragraph (f)(2)(i)(B), an employer would be exempt from using the above controls to the extent that: (1) The employer can establish that such controls are not feasible; or (2) the employer can demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation.

Because OSHA recognized that these proposed provisions are not typical for OSHA standards, which usually require engineering controls only where exposures exceed the PEL(s), the Agency asked for comments on the potential benefits of including such provisions in the beryllium standard, the potential costs and burdens associated with them, and whether OSHA should include these provisions in the final standard (80 FR 47789). In addition, the Agency examined and asked for comment on Regulatory Alternative #6, which would exclude the provisions of proposed paragraph (f)(2)(i) from the final standard.

Comments on these provisions focused mainly on the trigger for proposed paragraph (f)(2)(i) or the action level exemption in proposed paragraph (f)(2)(i)(B)(*2*) and fell into one of two categories. The first group of stakeholders argued that the engineering and work practice controls requirement in proposed paragraph (f)(2)(i) was too broad. Specifically, they objected to the inclusion of a requirement for controls where exposures do not exceed the TWA PEL or STEL. For example, NGK argued that ''this provision essentially halves the PEL by requiring engineering controls above the action level'' (Document ID 1663, p. 2). NGK asserted that engineering controls should only be required where exposures exceed the TWA PEL or STEL, concluding that the ''mandatory use of certain engineering controls'' should be removed (Document ID 1663, p. 4). Similarly, Ameren disagreed with the proposed requirement to use at least one engineering control in areas where, it stated, there may be only minimal exposures and thus no benefit to be gained from installing additional controls (Document ID 1675, p. 5).

The second set of commenters argued that the engineering and work practice controls requirement in proposed paragraph (f)(2)(i) was too narrow. These commenters objected to the exemption in proposed paragraph (f)(2)(i)(B)(2), which exempted employers from using one of the controls listed in (f)(2)(i) to the extent that the employer could demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation. USW commented that the only legitimate reasons not to require engineering controls below the action level are if such a requirement is technologically or economically infeasible (Document ID 1681, p. 10). The AFL–CIO and National COSH similarly recommended that the final standard require engineering and work practice controls wherever airborne beryllium is present (Document ID 1689, p. 11; 1690, p. 3). The AFL–CIO based their recommendation on the capacity of beryllium at very low concentrations to cause beryllium sensitization and its carcinogenicity (Document ID 1689, p. 12).

OSHA has carefully reviewed the opinions and arguments of these commenters, and has concluded that the requirement to implement at least one form of exposure control on beryllium-releasing processes will serve to reduce the significant risk of both CBD and lung cancer remaining at the TWA PEL (*see* Section VII, Significance of Risk), and will also reduce the likelihood of exposures exceeding the PEL in the absence of any engineering or work practice control. OSHA therefore disagrees with Ameren's argument that the requirements of (f)(2)(i) will not benefit workers, and with NGK's position that engineering controls should not be required below the TWA

PEL and STEL. OSHA also disagrees with NGK's characterization of the list of controls provided in (f)(2)(i) as a ''mandatory use of certain engineering controls'' (Document ID 1663, p. 4). Rather, the list includes a broad range of possible approaches to eliminate, capture or control beryllium emissions at the source so as to reduce employees' exposure to airborne beryllium, and provides employers great flexibility in selection of at least one such approach where required by the standards.

However, while the Agency upholds the importance of requiring at least one engineering or work practice control where operations release beryllium, it disagrees with comments that such controls should be required wherever there is airborne beryllium at any level. OSHA recognizes that a significant risk of developing beryllium-related adverse health effects remains at the action level. But the Agency finds that an exemption from the requirement to implement at least one of the controls listed in proposed paragraph (f)(2)(i)(A) when exposures are demonstrably below the action level strikes a reasonable balance between providing additional protection for employees who are at risk and the burdens associated with implementing controls that may provide little or no benefit (*i.e.,* where airborne exposures are minimal). The action level serves as a reasonable and administratively convenient benchmark for a number of provisions in the standards (*e.g.,* periodic exposure monitoring, medical surveillance); OSHA finds that the action level serves a comparable purpose with regard to the requirement to implement at least one of the controls listed in proposed paragraph (f)(2)(i)(A) as well.

Moreover, as discussed in the NPRM, the inclusion of the engineering and work practice control provision in proposed paragraph (f)(2)(i)(A) addresses a concern regarding the proposed PEL. OSHA expects that day-to-day changes in workplace conditions might cause frequent excursions above the PEL in workplaces where periodic sampling indicates exposures are between the action level and the PEL. Normal variability in the workplace and work processes, such as workers' positioning or patterns of airflow, can lead to excursions above the PEL. Substitution or controls such as those outlined in proposed paragraph (f)(2)(i)(A) provide the most reliable means to control variability in exposure levels. And, as noted above, they have the added benefit of further reducing beryllium exposures to employees where such means are feasible, and so reducing the significant risk of beryllium-related adverse health effects associated with airborne exposures at the TWA PEL and the action level (*see* Section VII, Significance of Risk). In addition, OSHA finds that the exemption in proposed paragraph (f)(2)(i)(B)(*2*) will reduce the cost burden on employers with operations where measured exposures are below the action level, and therefore less likely to exceed the PEL in the course of typical exposure fluctuations. OSHA notes that this exemption is similar to a provision in 1,3-Butadiene (29 CFR 1910.1051), which requires an exposure goal program where exposures exceed the action level. Therefore, OSHA has retained the proposed provisions of paragraph (f)(2)(i) and the proposed exemptions. The Agency also revised the enumeration of the paragraphs for clarity in the final standards.

OSHA has made a number of clarifying changes to the language of proposed paragraph (f)(2)(i), none of which is meant to change the meaning of the proposed language. First, OSHA revised the proposed language of (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) by specifying that this provision applies to each operation in a beryllium work area ''that releases airborne beryllium.'' The proposed language could have been interpreted to require controls on operations that do not release airborne beryllium, if such operations happened to be performed in a beryllium work area; it was not OSHA's intent to require employers to apply controls to any operations that do not release beryllium. Second, OSHA added the term ''airborne'' preceding ''exposure'' in proposed (f)(2)(i)(A) and (f)(2)(i)(B)(*2*) (paragraphs (f)(2)(i) and (f)(2)(ii)(B) in the final standards) to clarify the type of exposure addressed by these provisions. Third, OSHA removed the phrase ''engineering and work practice controls'' preceding the list of controls provided in proposed paragraph (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) for brevity. Fourth, OSHA modified the language of proposed paragraph (f)(2)(i)(A) (paragraph (f)(2)(i) in the final standards) to require employers to ''reduce'', rather than ''minimize'' airborne exposure because ''reduce'' is more consistent with the requirement; employers are not required to implement more than one such control unless exposures exceed the TWA PEL or STEL. OSHA has included a non-mandatory appendix presenting a non-exhaustive list of engineering controls employers may use to comply with paragraph (f)(2)(i) (*see* Appendix A).

The fifth and sixth clarifying changes to proposed paragraph (f)(2)(i) address the types of control measures that are acceptable for complying with the provision. The Southern Company suggested that isolation/containment should be considered for inclusion in the listed controls in proposed paragraph (f)(2)(i)(A) (Document ID 1668, p. 5). OSHA agrees that isolation is an appropriate method of exposure control, and proposed paragraph (f)(2)(i)(A)(*2*) listed ''ventilated partial or full enclosures'', which are forms of isolation. Paragraph (f)(2)(i)(B) of the final standards indicates ''isolation, such as ventilated partial or full enclosures'' to make clear that alternative forms of isolation are also acceptable. In addition, USW and Materion recommended that proposed paragraph (f)(2)(i)(A)(3), which read ''local exhaust ventilation at the points of operation, material handling, or transfer'' be revised to read ''local exhaust ventilation such as at the points of operation, material handling, or transfer'' to broaden the applicability of the provision (Document ID 1680, p. 4). OSHA agrees that the suggested revision more accurately describes acceptable control measures, and has adopted the recommended change in the final standards (now designated as paragraph (f)(2)(i)(C)).

The seventh and final clarifying change to proposed paragraph (f)(2)(i) pertains to the proposed requirement for employers to demonstrate that airborne exposures are below the action level using personal breathing zone samples taken 7 days apart. In response to a comment from Ameren Corporation, which stated that some operations are short in duration and taking samples precisely 7 days apart may not be possible (Document ID 1675, p. 5), OSHA changed the text of the standards to ''at least 7 days apart'', which was the Agency's intention.

With these changes, final paragraph (f)(2)(i) of the general industry standard requires that, for each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure: (A) Material and/or process substitution; (B) isolation, such as ventilated partial or full enclosures; (C) local exhaust ventilation, such as at the points of operation, material handling, and transfer; or (D) process control, such as wet methods and automation. Final paragraph (f)(2)(ii) allows that an employer is exempt from using the above controls to the extent that: (A) The employer can establish that such controls are not feasible; or (B) the employer can demonstrate that airborne exposure is below the action level, using

no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

Final paragraph (f)(2)(i) of the construction and shipyard standards also requires employers to ensure that one of the four enumerated types of control is in place to reduce airborne exposure and exempts employers who can establish that such controls are not feasible or demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least seven days apart, for each affected operation. However, the triggers in construction and shipyards differ from that in general industry: whereas the general industry standard requires employers to put one of the controls in place for each operation in a beryllium work area that releases airborne beryllium, the construction and shipyard standards do not require the establishment of beryllium work areas. In lieu of that trigger, the construction and shipyard provision requires the placement of a control where exposures are or can reasonably be expected to be at or above the action level. OSHA selected the action level as a trigger for this requirement because, as indicated above, the Agency finds that an exemption from the requirement to implement at least one of the controls is appropriate when exposures are below the action level.

Congressman Robert C. Scott, Ranking Member of the House Committee on Education and the Workforce, recommended that the final standards should require abrasive blasting (the primary source of beryllium exposure in construction and maritime) to be conducted within containments whenever feasible (Document ID 1672, p. 4). OSHA agrees that containment is an effective approach to limit exposures outside of the blasting operation, and is protective of workers in nearby areas or performing ancillary activities. However, because abrasive blasting is performed in a wide variety of occupational settings and alternative methods of exposure control (for example, use of wet methods) may be effective in some settings, OSHA does not require the use of containment whenever feasible in blasting operations. Rather, paragraph (f)(2) is intended to provide employers flexibility to determine an appropriate approach to maintain airborne exposures below the TWA PEL and STEL and, in accordance with (f)(2)(i), reduce airborne exposures that exceed the action level.

If exposures exceed the TWA PEL or STEL after the employer has implemented the control(s) required by paragraph (f)(2)(i), paragraph (f)(2)(iii) requires the employer to implement additional or enhanced engineering and work practice controls to reduce exposures to or below the PELs. For example, an enhanced engineering control may entail a redesigned hood on a local exhaust ventilation system to more effectively capture airborne beryllium at the source. The employer must use engineering and work practice controls, to the extent that such controls are feasible, to achieve the PELs.

Whenever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs using the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), however, paragraph (f)(2)(iv) requires the employer to implement and maintain engineering and work practice controls to reduce exposures to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard. As indicated previously, OSHA's long-standing hierarchy of controls policy was supported by a number of commenters (*e.g.,* Document ID 1963, p. 12; 1655, pp. 8, 16; 1618, p. 8; 1689, p. 11; 1625, p. 6; 1664, p. 6). Paragraphs (f)(2)(iii) and (f)(2)(iv) in the final standards are substantively consistent with the proposal, with minor changes to clarify that the provisions address only airborne exposures, and that paragraph (f)(2)(iii) applies to both the TWA PEL and STEL.

Finally, paragraph (f)(3) of the proposed rule would have prohibited the employer from rotating workers to different jobs to achieve compliance with the PELs. As explained in the NPRM, worker rotation can potentially reduce exposures to individual employees, but increases the number of employees exposed. Because OSHA has determined that exposure to beryllium can result in sensitization, CBD, and cancer, the Agency considers it inappropriate to place more workers at risk. Since no absolute threshold has been established for sensitization or resulting CBD or the carcinogenic effects of beryllium, it was considered prudent to limit the number of workers exposed at any concentration by prohibiting employee rotation.

This provision is not a general prohibition of worker rotation wherever workers are exposed to beryllium. It is only intended to restrict its use as a compliance method for the PEL (*e.g.,* by exposing twice as many workers to beryllium for half the amount of time). It is not intended to bar the use of worker rotation as deemed appropriate by the employer in activities such as to provide cross-training or to allow workers to alternate physically demanding tasks with less strenuous activities. This same provision is included in the standards for asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101), chromium (VI) (29 CFR 1910.1026), 1,3-butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1910.1050 and 29 CFR 1926.60). OSHA did not receive any objections to or comments on this provision and includes it in all three of the final standards to limit the number of employees at risk.

(g) Respiratory Protection

Paragraph (g) of the standard establishes the requirements for the use of respiratory protection. Specifically, this paragraph requires that employers provide respiratory protection at no cost to the employee and ensure that employees utilize such protection during the situations listed in paragraph (g)(1). As detailed in paragraph (g)(2), the selection and use of required respiratory protection must comply with OSHA's Respiratory Protection standard (29 CFR 1910.134). In addition, paragraph (g)(3) requires employers to provide employees entitled to respiratory protection with a powered air-purifying respirator (PAPR) instead of a negative pressure respirator, if a PAPR is requested by the employee.

Paragraph (g)(1) requires employers to ensure that each employee required to use a respirator does so. Accordingly, simply providing respirators to employees will not satisfy an employer's obligations under paragraph (g)(1) unless the employer also ensures that each employee properly wears the respirator when required. Paragraph (g)(1) also requires employers to provide required respirators at no cost to employees. This requirement is consistent with the OSH Act's holding employers principally responsible for complying with OSHA standards, with similar provisions under other OSHA standards, and specifically with OSHA's Respiratory Protection standard, which also requires employers to provide required respiratory protection to employees at no cost (29 CFR 1910.134(c)(4)).

Paragraph (g)(1) requires appropriate respiratory protection during certain enumerated situations. Paragraph (g)(1)(i) requires respiratory protection during the installation and implementation of feasible engineering

and/or work practice controls where airborne exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. The Agency understands that changing workplace conditions may require employers to install new engineering controls, modify existing controls, or make other workplace changes to reduce employee exposure to or below the TWA PEL and STEL. In these cases, the Agency recognizes that installing appropriate engineering controls and implementing proper work practices may take time, and that exposures may be above the PELs until such work is completed. See paragraph (g)(1)(ii), discussed below. During this time, employers must demonstrate that they are making prompt, good faith efforts to obtain and install appropriate engineering controls and implement effective work practices, and to evaluate their effectiveness for reducing airborne exposure to beryllium to or below the TWA PEL and STEL.

Paragraph (g)(1)(ii) requires the provision and use of respiratory protection during any operations, including maintenance and repair operations and other non-routine tasks, when engineering and work practice controls are not feasible and airborne exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. OSHA included this provision because the Agency realizes that certain operations may take place when engineering and work practice controls are not operational or capable of reducing exposures to or below the TWA PEL and STEL. The installation of necessary engineering controls, covered by paragraph (g)(1)(i), is a particular example of this more general circumstance. For another example, during maintenance and repair operations, engineering controls may lose their full effectiveness or require partial or total breach, bypass, or shutdown. Under these circumstances, if exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL, the employer must provide and ensure the use of respiratory protection.

Paragraph (g)(1)(iii) requires the provision and use of respiratory protection where beryllium exposures exceed the TWA PEL or STEL, even after the employer has installed and implemented all feasible engineering and work practice controls. OSHA anticipates that there will be some situations where feasible engineering and work practice controls are insufficient to reduce airborne exposure to beryllium to levels at or below the TWA PEL or STEL (see this preamble at section VIII.D, Technological Feasibility). In such cases, the standard requires that employers implement and maintain engineering and work practice controls to reduce exposure to the lowest levels feasible and supplement those controls by providing respiratory protection (paragraph (f)(2)(iv)). OSHA emphasizes that even where employers are able to demonstrate that engineering and work practice controls are not feasible or sufficient to reduce exposure to levels at or below the TWA PEL and STEL the use of respirators to achieve the PELs is only a supplement, and not a substitute for, such ''lowest level feasible'' controls.

Paragraph (g)(1)(iv) requires the provision and use of respiratory protection in emergencies. Under the final standards, an emergency is defined as ''any uncontrolled release of airborne beryllium'' (see paragraph (b) of the standards). During emergencies, engineering controls may not be functioning fully or may be overwhelmed or rendered inoperable. Also, emergencies may occur in areas where there are no engineering controls. The standard recognizes that the provision of respiratory protection is critical in emergencies, as beryllium exposures may be very high and engineering controls may not be adequate to control an unexpected release of airborne beryllium.

Boeing suggested limiting requirement of respirator use triggered by this definition of emergency, as it would not be practical to provide respirators to and train the large number of employees in the event of a fire or explosion (Document ID 1667, pp. 4–5). OSHA wishes to clarify that paragraph (g)(1)(iv) is not intended to require employers to provide respirators to all employees who may pass through areas where beryllium-releasing processes are housed, in the event of a general evacuation due to an event such as a fire or explosion. Rather, in the event that an uncontrolled release of beryllium occurs (f)(1)(iv) requires employers to provide respirators to employees who work in the vicinity of beryllium-releasing processes and employees who respond to such an emergency, because these employees will be in the immediate vicinity of an uncontrolled release.

Paragraph (g)(1)(v) requires the provision and use of respiratory protection when an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level. As explained in the summary and explanation of paragraph (l), Medical Removal Protection, an employee who is diagnosed with CBD or confirmed positive for beryllium sensitization and who works in a job with airborne exposure at or above the action level is eligible for medical removal protection (MRP). An employee who is eligible for MRP may choose medical removal from jobs with exposure at or above the action level, or may choose to remain in a job with exposure at or above the action level provided that the employee uses respiratory protection in accordance with the provisions of this paragraph (g), Respiratory Protection. This provision was not included in the proposed standard. However, OSHA received comments emphasizing the importance of reducing or eliminating the exposure of sensitized employees. For example, National Jewish Health (NJH) stated that ''removal from exposure is the best form of prevention'' (Document ID 1664, p. 4). The United Steelworkers (USW) commented that workers who are sensitized to beryllium or are in the early stages of chronic beryllium disease can significantly benefit from a reduction in their exposure to beryllium, based on evidence reviewed in Section VIII (Significant Risk) of the NPRM (Document ID 1963, p. 13). OSHA is cognizant that employees who are MRP-eligible (*i.e.,* confirmed positive for beryllium sensitization or diagnosed with CBD) may decide not to take medical removal protection (MRP) or otherwise alert the employer to their condition. Therefore, OSHA included paragraph (g)(1)(v) in the final standards to provide these employees access to respiratory protection if their airborne exposures are expected to be at or above the action level. While not as protective as removal from any beryllium exposure, NJH's comments indicate that such protection has the potential to delay or avoid the onset of CBD in sensitized individuals and to mitigate or retard the effects of CBD in employees who are in the early stages of CBD. Because OSHA has not made a finding of significant risk at exposure levels below the action level, OSHA has chosen not to require provision and use of respirators for employees exposed below the action level, including sensitized employees. However, OSHA does not assume the absence of risk below the action level, especially to this particularly vulnerable population Indeed, it is the Agency's recommendation that employers voluntarily provide such protection to employees who self-identify that they have tested positive for sensitization if they ask for it and will be exposed to beryllium below the action level, or for whom a licensed physician has

recommended such protection. OSHA intends to issue additional guidance regarding non-mandatory respiratory protection for this group of at-risk employees along with other compliance guidance in connection with these standards.

OSHA received no comments objecting to paragraph (g)(1). Therefore, except for minor edits for clarity explained in the introduction to this section, it is unchanged from the proposal.

Whenever respirators are used to comply with the requirements of this standard, paragraph (g)(2) requires that the employer implement a comprehensive written respiratory protection program in accordance with OSHA's Respiratory Protection standard (29 CFR 1910.134). The Respiratory Protection standard is designed to ensure that employers properly select and use respiratory protection in a manner that effectively protects exposed employees. Under 29 CFR 1910.134(c)(1), the employer's respiratory protection program must include:

- Procedures for selecting appropriate respirators for use in the workplace;
- Medical evaluations of employees required to use respirators;
- Respirator fit testing procedures for tight-fitting respirators;
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
- Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;
- Procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
- Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators; and
- Procedures for evaluating the effectiveness of the program.

In accordance with OSHA's policy to avoid duplication and to establish regulatory consistency, paragraph (g)(2) incorporates by reference the requirements of 29 CFR 1910.134 rather than reprinting those requirements in this standard. OSHA notes that the respirator selection provisions in 29 CFR 1910.134 include requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs) that OSHA adopted in 2006 (71 FR 50122 (Aug. 24, 2006)). The APFs and MUCs provide employers with critical information for the selection of respirators to protect workers from exposure to atmospheric workplace contaminants. In incorporating the Respiratory Protection standard by reference, OSHA intends that any future change to that standard will automatically apply to this standard as well. As appropriate, OSHA will note the intended effect on this standard (and other standards) in either the text or preamble of the amended Respiratory Protection standard, but does not anticipate the need for a conforming amendment to this standard.

Moreover, the situations in which respiratory protection is required under these standards are generally consistent with the requirements in other OSHA health standards, such as those for chromium (VI) (29 CFR 1910.1026), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). Those standards and this standard also reflect the Agency's traditional adherence to a hierarchy of controls in which engineering and work practice controls are preferred to respiratory protection (see the discussion of paragraph (f) earlier in this section of the preamble).

OSHA received no comments objecting to paragraph (g)(2). OSHA added language to clarify that both the selection and use of respiratory protection must be in accordance with the Respiratory Protection standard. Other than that change and some minor edits for clarity, paragraph (g)(2) is unchanged from the proposal.

Paragraph (g)(3) requires the employer to provide a powered air-purifying respirator (PAPR) instead of a negative pressure respirator at no cost to the employee when an employee entitled to respiratory protection under (g)(1) of these standards requests a PAPR. The employee may select any form of PAPR (half mask, full facepiece, helmet/hood, or loose fitting facepiece), so long as the PAPR is selected and used in compliance with the Respiratory Protection standard (29 CFR 1910.134) and provides adequate protection to the employee in accordance with paragraph (g)(2) of these standards. For example if an employee is using a half mask respirator with an APF of 10 then a loose fitting PAPR with an APF of 25 would be an appropriate alternative. However, if the employee is required to use a full face respirator with an APF of 50 then the appropriate PAPR alternative would be a tight fitting PAPR.

The requirement to provide a PAPR upon request of the employee (paragraph (g)(3)) is similar to provisions in several previous OSHA standards, including inorganic arsenic (CFR 1910.1018), lead (CFR 1910.1025), cotton dust (1910.1043), asbestos (CFR 1910.1001), and cadmium (1910.1027). In promulgating these standards, OSHA cited several reasons why PAPRs can provide employees with better protection than negative pressure respirators, including superior reliability and comfort, reduced interference with work processes, and superior protection, especially for employees who cannot obtain a good face fit with a negative pressure respirator (*e.g.,* 43 FR 19584, 19619; 43 FR 52952, 52993; 51 FR 22612, 22698). Based on these considerations, OSHA required employers to provide PAPRs upon request to facilitate consistent and effective use of respiratory protection by employees when needed, and particularly in situations where respirator use is required for long periods of time (see 43 FR 52952, 52993; 51 FR 22612, 22698).

The PAPR provision was not included in the proposed standard. However, OSHA solicited public comment on the issue of whether employers should be required to provide employees with PAPRs upon request. During the public comment period and public hearing for the beryllium NPRM, several commenters supported a requirement for employers to provide a PAPR upon an employee's request, including the Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) (Document ID 1655, p. 8), a representative of the Department of Defense (Document ID 1684, Attachment 2, p. 4), ORCHSE Strategies (ORCHSE) (Document ID 1691, p. 4), NJH (Document ID 1664, p. 5), Kimberly-Clark Professional (KCP) (Document ID 1676, p. 3), and North America's Building Trades Unions (NABTU) (Document ID 1679, p. 9). Dr. Lisa Maier of the NJH stated, ''The beryllium standard should require employers to provide PAPRs when requested by the employee. We have consulted with clients on respiratory protection for beryllium exposure and found that employees are more likely to comply with respiratory protection requirements when they have an option regarding the type of respirator they wear'' (Document ID 1664, p. 7). Joann Kline of KCP similarly commented that ''[f]it, style, comfort and worker preference are significant factors in the effectiveness of protection . . . Allowing a worker to choose PPE, including PAPRs, makes it much more likely that it will be comfortable and accepted. PAPRs in particular add to worker comfort, especially in hot environments, because of the flow of

fresh air on and around the wearer's face'' (Document ID 1676, p. 3).

Likewise, ORCHSE commented that ''[c]omfort is a significant factor in the ability of employees to wear respiratory protection consistently, especially during an entire work shift, and/or under hot or stressful conditions. Employees experiencing discomfort, which is likely with negative-pressure respirators, are more apt to remove or otherwise compromise the effectiveness of their respirators while in the workplace. It is thus prudent for employers to provide the type of respiratory protection employees are more likely to use consistently and correctly'' (Document 1691, p. 4). Chris Trahan of NABTU cited the susceptibility of some employees to beryllium sensitization as a reason to require employers to provide PAPRs to employees upon their request (Document ID 1679, p. 9). As discussed in Section V, some individuals are genetically susceptible to beryllium-induced sensitization and CBD, and may develop these conditions from exposure to beryllium at levels well below the PEL and STEL included in this standard. Genetically susceptible individuals may therefore benefit from the enhanced protection provided by a PAPR, which have APFs ranging from 50 to 1000 depending on type.

OSHA also received comments opposing a requirement for employers to provide PAPRs upon employee request. For example, Julie A. Tremblay of 3M commented that the incorporation of the Respiratory Protection Standard (29 CFR 1910.134) by reference, particularly paragraph (d)(1)(i) and paragraph (e)(6)(ii), adequately addresses issues of appropriate respirator selection (Document ID 1625, Attachment 1, p. 2). *1910.134(d)(1)(i)* directs the employer to select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability. 1910.134(e)(6)(ii) states that if the PLHCP finds a medical condition that may place the employee's health at increased risk if a negative pressure respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; however, if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR. OSHA received a similar comment from Charlie Shaw of Southern Company (Document ID 1668, p. 5). Two other commenters, William Orr of Ameren Corporation (Ameren) and Daniel Shipp of the International Safety Equipment Association (ISEA), stated that respiratory protection selection should be based primarily on the required APF given the exposure concentration of beryllium (Document ID 1675, p. 12; 1682, p. 1). However, Mr. Orr also commented that workers handling beryllium-containing materials should have access to loose fitting respirators for added dermal protection so long as the respirator's APF is appropriate to the work performed (Document ID 1675, p. 12). Mr. Orr also argued that a PAPR option is not necessary in the beryllium context: ''A PAPR should only be required if the exposure level dictates that the protection of a PAPR is necessary. The level of protection in the asbestos standard (CFR 1910.1001) is applicable to protection from airborne fibers with the unique characteristics of asbestos. The level of protection for beryllium should closer resemble particulate metal protection such as seen in the standards for metals such as lead or hexavalent chromium'' (Document ID 1675, p. 12). (As discussed above, the Agency notes that the OSHA lead standard (CFR 1910.1025) does include a PAPR requirement, as does the standard for cadmium (1910.1027), also a metal).

Finally, OSHA received a comment from USW (Document ID 1681) recommending that OSHA limit the type of PAPR provided under (g)(3) to types with close-fitting facepieces. USW stated that ''[t]he types with close-fitting face pieces can be quite effective, but it is easy to over breathe other types, especially the loose-fitting helmets'' (Document ID 1681, p. 22).

OSHA has carefully considered all comments received on the issue of requiring employers to provide employees with PAPRs upon request, and agrees with Dr. Maier of NJH, Ms. Trahan of NABTU, and other commenters who have argued that providing employees a choice in selection of respiratory protection will improve the effectiveness of respiratory protection in reducing risk of sensitization and disease from occupational beryllium exposure. While the provisions of the Respiratory Protection standard provide important baseline requirements appropriate to all situations where respiratory protection is required, as discussed above, OSHA recognizes that provisions beyond those of the Respiratory Protection standard are appropriate in some circumstances to ensure that required respiratory protection is used on a consistent basis and as effectively as possible. As discussed in section V, Health Effects and section VI, Risk Assessment of this preamble, beryllium sensitization and CBD can result from small, short-term beryllium exposure in some individuals. Accordingly, consistent and effective respirator usage has played an important role in minimizing risk among workers in occupational settings such as beryllium processing, where it has proven difficult to reduce airborne exposures below 0.2 $\mu g/m^3$ using engineering controls. Based on this evidence, OSHA concludes that provision of PAPRs at the employee's request will provide employees necessary protection beyond that found in provisions of the Respiratory Protection standard, where provision of a PAPR for reasons of fit, comfort and reliability is at the employer's discretion. Contrary to the comments of Mr. Orr and Mr. Shipp cited above, the evidence that beryllium sensitization can result from short-term, low-level airborne beryllium exposure supports the provision of PAPRs upon request rather than relying on APF alone. Finally, while OSHA agrees with the USW that PAPRs with close-fitting facepieces can be more effective than loose-fitting helmets, the Agency recognizes that loose-fitting helmets may be required in certain work conditions or due to difficulty achieving proper fit for some workers. Therefore, the standards allow for selection of any type of PAPR, but require that the PAPR selected provide adequate protection to the employee in accordance with the Respiratory Protection standard.

(h) Personal Protective Clothing and Equipment

Paragraph (h) of the standards requires employers to provide employees with personal protective clothing and equipment (PPE) where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL and where there is reasonable expectation of dermal contact with beryllium. Paragraph (h) also contains provisions for the safe removal, storage, cleaning, and replacement of the PPE required by the standards. To protect employees from adverse health effects, these PPE requirements are intended to prevent dermal exposure to beryllium, and prevent the accumulation of airborne beryllium on clothing, shoes, and equipment, which can result in additional inhalation exposure. The requirements also protect employees in other work areas, as well as employees and other individuals outside the workplace, from exposures that could occur if contaminated clothing were to transfer beryllium to those areas. The standards require the employer to

provide PPE at no cost to employees, and to ensure that employees use the provided PPE in accordance with the written exposure control plan as described in paragraph (f)(1) of these standards and OSHA'S Personal Protective Equipment standards (29 CFR part 1910 Subpart I, 29 CFR part 1926 Subpart E, and 29 CFR part 1915 Subpart I). PPE, as used in the description of paragraph (h), refers to both clothing and equipment used to protect an employee from either airborne exposure to or dermal contact with beryllium. The requirements in paragraph (h) are the same in general industry, construction, and shipyards, except for the references to OSHA's Personal Protective and Life Saving Equipment standard for construction (29 CFR part 1926 Subpart E) in the construction standard and OSHA's Personal Protective Equipment standard for shipyards (29 CFR part 1915 Subpart I) in the shipyard standard. Requiring PPE is consistent with section 6(b)(7) of the OSH Act, which states that, where appropriate, standards shall prescribe suitable protective equipment to be used in connection with hazards (29 U.S.C. 655(b)(7)). The requirements for PPE are based upon widely accepted principles and conventional practices of industrial hygiene, and are similar to the PPE requirements in other OSHA health standards, such as chromium (VI) (29 CFR 1910.1026), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), and methylenedianiline (MDA; 29 CFR 1910.1050).

The final provisions in paragraph (h) are the same as the proposed provisions, with several exceptions. First, in the final standards OSHA has used the term ''contact'' instead of ''exposure'' where the standards refer to the skin, so as to distinguish clearly between exposure via the skin (dermal route) and the inhalation route of exposure in the regulatory text. Second, OSHA has deleted the proposed provision in paragraph (h)(1)(ii) requiring PPE where employees' skin may become ''visibly contaminated'' with beryllium and instead will require use of PPE whenever there is a reasonable expectation of dermal contact with beryllium. Third, the final standards' requirements for provision and use of PPE apply where employees may reasonably be expected to have dermal contact with beryllium regardless of whether the beryllium is in a soluble or poorly soluble (sometimes called 'insoluble') form, instead of just soluble beryllium compounds as in proposed paragraph (h)(1)(iii). Fourth, paragraph (h)(2)(iii) now requires that storage facilities for PPE prevent cross contamination. Finally, OSHA has made a few minor changes to clarify or streamline the regulatory text. The comments and OSHA's reasoning leading to these changes are discussed below.

Paragraph (h)(1)(i) requires the provision and use of PPE for employees exposed to any form of airborne beryllium above the TWA PEL or STEL, or where exposure can reasonably be expected to exceed the TWA PEL or STEL, because such exposure would likely result in skin contact by means of deposits on employees' skin or clothes or on surfaces touched by employees. The term ''reasonably be expected'' is intended to convey OSHA's intent that the requirement for provision and use of PPE is defined by an employee's potential exposure, not by any particular individual's actual exposure. For example, if one employee's exposure assessment results indicate that the employee's exposure is above the PEL, it would be reasonable to expect that another employee doing a similar task would have exposures above the PEL and thus would require PPE.

Paragraph (h)(1)(ii) requires the provision and use of PPE where employees are reasonably expected to have dermal contact with beryllium. This requirement applies to beryllium-containing dust, liquid, abrasive blasting media, and other beryllium-containing materials that can penetrate the skin, regardless of the level of airborne exposure. It is not intended to apply to dermal contact with solid objects (for example, tools made of beryllium alloy) unless the surface of such objects is contaminated with beryllium in a form that can penetrate the skin. Dermal contact with beryllium can result in absorption of beryllium through the skin and induce sensitization, a necessary precursor to CBD, as discussed further in Health Effects, section V.A.2.

As mentioned above, the requirements of paragraph (h)(1) of the final standards differ from those of the proposed standard. Paragraph (h)(1) of the proposed standard required employers to provide employees with PPE where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; where work clothing or skin may become visibly contaminated with beryllium, including during maintenance and repair activities or during non-routine tasks; and where employees' skin is reasonably expected to be exposed to soluble beryllium compounds. In the NPRM, OSHA discussed concerns with the proposed requirements, requested public comment on proposed paragraph (h)(1), and presented Regulatory Alternative 13. Alternative 13, as described by OSHA, would replace the requirement for PPE where there is visible contamination with a requirement for appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. OSHA requested comments on this alternative, including the benefits and drawbacks of a broader PPE requirement and any relevant data or studies the Agency should consider. As discussed below, OSHA adopted Regulatory Alternative 13 in the final standard based on comments received in the public comment period and public hearing and on the scientific evidence in the record.

The proposed requirement to use PPE where clothing or skin may become ''visibly contaminated'' with beryllium was a departure from most OSHA standards, which do not specify that contamination must be visible in order for PPE to be required. For example, the standard for chromium (VI) (29 CFR 1910.1026) requires the employer to provide appropriate PPE where a hazard is present or is likely to be present from skin or eye contact with chromium (VI). The lead (29 CFR 1910.1025) and cadmium (29 CFR 1910.127) standards require PPE where employees are exposed above the PEL or where there is potential for skin or eye irritation regardless of airborne exposure level. In the case of MDA (29 CFR 1910.1050), PPE must be provided where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL. While OSHA's language regarding PPE requirements varies somewhat from standard to standard, previous standards emphasize the potential for contact with a substance that can cause health effects via dermal exposure, and do not condition the provision and use of PPE on visible contamination with the substance.

Nearly all comments OSHA received on the proposed requirement for employers to provide PPE where work clothing or skin may become ''visibly contaminated'' with beryllium stated that this provision would not be sufficiently protective of beryllium-exposed workers (Document ID 1615, p. 8; 1625, p. 2; 1655, pp. 9–10; 1658, p. 6; 1664, pp. 3–4; 1671, Attachment 1, p. 7; 1676, pp. 2–3; 1677, p. 2; 1679, p. 9; 1685, p. 3; 1688, p. 3; 1689, p. 12; 1691, pp. 4–5). Dr. Paul Schulte of NIOSH stated that ''visibly contaminated'' is not

an appropriate trigger for PPE requirements, citing evidence from Day *et al.* (2007, Document ID 1548) that biologically relevant amounts of beryllium can accumulate on the skin without becoming visible, and evidence from Armstrong *et al.* (2014, Document ID 0502) that work surfaces in beryllium manufacturing facilities are typically contaminated with beryllium even where airborne exposures are low (Document ID 1671, Attachment 1, p. 7). Dr. Lisa Maier of NJH commented, ''[v]isibly contaminated' is not an appropriate trigger for PPE requirements; as noted by OSHA, 'small particles may not be visible to the naked eye' and as such PPE to protect from skin exposure should be worn for all tasks where there is potential for skin contact with beryllium particles'' (Document ID 1664, pp. 3–4). Dr. Atul Malhotra of the American Thoracic Society (ATS) stated that ''the use of 'visibly contaminated' as a trigger for PPE is problematic for multiple reasons . . . visual inspection cannot accurately estimate the amount of beryllium or its chemical state. Use of 'visibly contaminated' is also not supported by the literature cited, which demonstrates skin exposure and sensitization in work settings considered clean, with no visible contamination'' (Document ID 1688, p. 3).

In addition, some comments and testimony indicated that the term ''visibly contaminated'' is ambiguous and likely to be confusing to employers and others responsible for implementing the PPE requirements of the beryllium standards. According to Mr. Daniel Shipp of the International Safety Equipment Association (ISEA), ''[v]isible contamination' is not an appropriate trigger for PPE. This term is too subjective to be useful'' (Document ID 1682, p. 2).

Based on its evaluation of the evidence in the record, OSHA agrees with the commenters on these points. The Agency has determined that contact with and absorption of even minute amounts of beryllium through the skin may cause beryllium sensitization (see section V, Health Effects, subsection 2, Dermal Exposure) and that a ''visibly contaminated'' standard could allow for too much dermal exposure and be insufficiently protective of workers. In addition, as discussed in Section VI, Risk Assessment, studies conducted jointly by NIOSH and Materion Corporation (Materion) showed that a comprehensive approach to PPE is key to reducing risk of sensitization even in facilities that implement stringent exposure control and housekeeping programs (*See* Section VI. Risk Assessment).

Materion, whose joint submission with the United Steelworkers union of a proposed standard was the basis for the ''visibly contaminated'' language, discussed the use of the term in its post hearing comments (Document ID 1808, pp. 4–5). Materion indicated that the typical workplace cannot reasonably be expected to measure skin or surface contamination for the purpose of determining whether PPE use is necessary. Even if this was done, ''such measures are lagging metrics which, by definition, are post potential exposure'' (Document ID 1808, p. 5). Materion believed that a standard relying on visual cues to check for contamination is easily understood by workers and management and is a useful part of a beryllium worker protection model.

OSHA has considered Materion's comments supporting use of the terms ''visibly contaminated'' and ''visibly clean.'' The Agency finds that the provision in the final standard requiring PPE wherever there is a reasonable expectation of any dermal contact with beryllium more clearly conveys to employers the idea that the provision and use of PPE should be used as a precaution against potential dermal contact. OSHA believes the proposed requirements for PPE where clothing or skin may become ''visibly contaminated'' may be reasonably interpreted by employers to mean that PPE is only required where work processes release quantities of beryllium sufficient to create deposits visible to the naked eye. If this were the case, employers' provision of PPE to employees would certainly lag behind potential exposure, if such provision occurs at all. Additionally, National Jewish Health agreed with OSHA that small particles may not be visible to the naked eye (Document ID 1664 p. 4). Therefore, OSHA has determined that the language of the final standards is more easily understood and applied so as to preempt dermal contact with beryllium and therefore prevent adverse health effects caused by dermal contact, such as beryllium sensitization. OSHA also notes that employers are not required to measure skin or surface contamination under the provisions governing the use and handling of PPE. Thus the Agency concludes that the changes made to the proposed rule adequately address Materion's concerns and more closely express OSHA's intent.

OSHA also requested comment on proposed paragraph (h)(1)'s requirement for PPE to limit dermal contact with soluble beryllium compounds, and whether employers should also be required to provide PPE to limit dermal contact with poorly soluble (referred to as insoluble in the proposal) forms of beryllium. The solubility of beryllium was a consideration in the PPE requirements of the proposed standard because dermal absorption may occur at a greater rate for soluble beryllium than for poorly soluble beryllium.

Comments submitted on the topic of beryllium solubility and dermal absorption indicate that beryllium in poorly soluble forms, as well as soluble forms, can be absorbed through the skin and cause sensitization (Document ID 1664, p. 3; 1671, p. 7; 1688, p. 3). Dr. Schulte of NIOSH stated that PPE should be required to protect against exposure to poorly soluble compounds as these forms can produce soluble beryllium ions in sweat, and because beryllium in any form can enter the body through minor abrasions, which are commonly found on the skin of industrial employees (Document ID 1671, p. 7). (See further discussion in Section V, Health Effects, subsection 2, Dermal Exposure.)

General comments on whether OSHA should adopt more comprehensive PPE requirements similar to those specified in Regulatory Alternative 13 were, by and large, supportive. The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) (Document ID 1655, pp. 16–17), NJH (Document ID 1664, pp. 3–4, 7), NIOSH (Document ID 1671, p. 7), Kimberly-Clark Professional (KCP) (Document ID 1676, p. 2), the DOE's National Supplemental Screening Program (NSSP) (Document ID 1677, p. 2), ISEA (Document ID 1682, p. 2), the American College of Occupational and Environmental Medicine (ACOEM) (Document ID 1685, p. 3), ATS (Document ID 1688, p. 3), the AFL–CIO (Document ID 1689, p. 12), and ORCHSE Strategies (ORCHSE) (Document ID 1691, p. 4) all urged OSHA to adopt Regulatory Alternative 13 or similar requirements. The BHSC Task Group commented that its experience at Department of Energy Sites ''strongly suggests that this alternative should be adopted, since the concept of 'visibly contaminated' is not sufficient to ensure an absence of such contamination on the skin'' (Document ID 1655, p. 17). In addition, the BHSC Task Group noted that elimination of dermal contact with beryllium helps reduce the risk of sensitization (Document ID 1655, p. 17).

Similarly, several commenters indicated that a more appropriate trigger for the provision and use of PPE under

paragraph (h)(1) would be whenever an employee has the potential for skin contact with beryllium (Document ID 1664, p. 3; 1671, Attachment 1, p. 7; 1676, pp. 2–3). Dr. Lisa Maier from NJH indicated, in her testimony, that ''personal protective equipment (PPE) such as gloves, respirators, protective clothing should be used wherever there is a potential for respiratory or skin exposure'' (Document ID 1720 p. 6). Another commenter ''strongly recommend[ed] a PPE requirement wherever exposure to beryllium, soluble or insoluble, is reasonably expected'' (Kimberly-Clark Professional, Document ID 1676, p. 3).

In contrast, Ameren Corporation (Ameren) and NGK Metals (NGK) recommended against adoption of Regulatory Alternative 13. According to Ameren, ''[t]race beryllium in fly ash is unlikely to cause sensitization issues but PPE would be required under this alternative'' (Document ID 1675, p. 6). Ameren, however, did not provide further information or evidence to support this claim. NGK suggested the language ''visibly contaminated with beryllium particulate or solutions'' as a trigger for the standards' PPE requirements, to clarify that PPE is not required when handling clean, solid materials that contain beryllium (Document ID 1663, pp. 2, 5). OSHA does not find these comments persuasive. OSHA included operations and industries where beryllium is present as a trace contaminant in the scope of the beryllium standard only when these operations and industries have the potential to release airborne exposures exceeding the action level of 0.1 μg/m^3, at which sensitization is known to occur (see Section VI, Risk Assessment). With regard to NGK's suggested language, the Agency believes the commenter's intention to clarify OSHA's position on clean, solid materials is already captured in the regulatory text of the standards. Paragraph (h)(1)(ii) is not intended to require the provision of PPE to employees whose only contact with beryllium is handling articles that do not have surface contamination with beryllium.

In summary, OSHA has concluded that beryllium surface contamination may not be visible yet may still cause sensitization. Because small beryllium particles can pass through intact or broken skin and cause sensitization, limiting the requirements for PPE based on surfaces that are ''visibly contaminated'' may not adequately protect workers from beryllium exposure. Submicron particles (less than 1 μg in diameter) are not visible to the naked eye and yet may pass through the skin and cause beryllium sensitization. And although solubility may play a role in the level of sensitization risk, the available evidence indicates that contact with poorly soluble as well as soluble beryllium can cause sensitization via dermal contact (see this preamble at section V, Health Effects). Based on these considerations, OSHA has adopted Regulatory Alternative 13 in paragraph (h)(1)(ii) of the final standards, which requires the employer to provide PPE and ensure its use wherever there is a reasonable expectation of dermal contact with beryllium to any extent and of any type.

The USW recommended further specification of the PPE provisions, requesting clarification of the terms ''skin'' and ''exposure'' in the proposed standard's PPE requirements (Document ID 1680, p. 4; 1681, p. 12). As discussed previously, the term ''contact'' has replaced ''exposure'' where the final standard refers to the skin. This change was made in order to clearly distinguish between airborne and contact exposure in the text of the standards. OSHA's intention in using the term ''contact'' is straightforward, meaning any instance in which beryllium touches an employee's body. ''Skin'' refers to the exterior surface of all parts of an employee's body including face, arms, scalp, ears, and nostrils. OSHA notes that processes that have the potential to expose workers' eyes to beryllium will generally also expose the face, and forms of PPE such as face shields used to protect the face generally also protect the eyes (*e.g.,* face shields for use in situations where there is a danger of being splashed in the face with beryllium-containing liquid, or a hooded respirator where the employee is exposed to beryllium-containing fumes).

The USW also requested that OSHA include a specific requirement for provision of PPE to workers performing maintenance and repair activities and during non-routine tasks, to ensure that PPE is worn during tasks for which airborne exposure levels are not assessed (Document ID 1680, pp. 4–5; 1681, p. 12). This comment was submitted in response to the proposed standard, which would have required PPE where airborne exposures exceed the TWA PEL or STEL, but not in all cases where dermal contact occurs and airborne exposure levels are lower. OSHA believes the USW's concern has been addressed by the PPE requirements of the final standards, which apply wherever there is reasonable expectation of dermal contact with beryllium, including during maintenance and repair activities and non-routine tasks that involve beryllium-releasing processes or that are conducted in beryllium-contaminated areas.

OSHA also received a suggestion from the Boeing Company (Boeing) to amend proposed paragraph (h)(1)'s requirement to ensure use of appropriate PPE in accordance with the written exposure control plan, by adding ''or equally as effective documentation'' (Document ID 1667, p. 5). Boeing argued that the suggested language would allow employers to provide the required information through use of existing processes instead of through the creation of a second document (Document ID 1667, pp. 3–5). OSHA considered Boeing's comment, but decided against adding the suggested language. OSHA determined that it would create unnecessary ambiguity in the requirements for documentation in the context of both compliance and enforcement, as employers and CSHOs would need to determine what constitutes ''equally effective documentation.'' If an employer such as Boeing already has documents describing appropriate use of PPE that comply with the requirements of these standards, OSHA believes those documents can easily be incorporated into the employer's written exposure control plan. Taking this approach would eliminate the potential for confusion or redundancy caused by implementing multiple documents on PPE.

The employer must exercise reasonable judgment in selecting appropriate PPE. This requirement is consistent with OSHA's current standards for provision of personal protective equipment for general industry (29 CFR part 1910 Subpart I), construction (29 CFR part 1926 Subpart E), and shipyards (29 CFR part 1915 Subpart I). As described in the non-mandatory appendix providing guidance on conducting a hazard assessment for OSHA general industry standards (29 CFR 1910 Subpart I Appendix B), the employer should ''exercise common sense and appropriate expertise'' in assessing hazards. By ''appropriate expertise,'' OSHA means that individuals conducting hazard assessments must be familiar with the employer's work processes, materials, and work environment. A thorough hazard assessment should include a walk-through to identify sources of hazards to employees, wipe sampling to detect beryllium contamination on surfaces, review of injury and illness data, and employee input on the hazards to which

they are exposed. Information obtained in this manner provides a basis for the identification and evaluation of potential hazards. OSHA believes that the implementation of a comprehensive and thorough program to determine areas of potential exposure, consistent with the employer's written exposure control plan, is a sound safety and health practice and a necessary element of ensuring overall worker protection.

Based on the hazard assessment results, the employer must determine what PPE is necessary to protect employees from beryllium exposure. The requirements for choosing PPE under OSHA's personal protective equipment standards (*e.g.,* 29 CFR 1910 Subpart I for general industry) are performance-oriented, and are designed to allow the employer flexibility in selecting the PPE most suitable for each particular workplace. The type of PPE needed will depend on the potential for exposure, the physical properties of the beryllium-containing material used, and the conditions of use in the workplace. For example, shipping and receiving activities may necessitate only work uniforms and gloves. In other situations, such as when a worker is performing facility maintenance, gloves, work uniforms, coveralls, and respiratory protection may be appropriate. Beryllium compounds can exist in acidic or alkaline form, and these characteristics may influence the choice of PPE. Face shields may be appropriate in situations where there is a danger of being splashed in the face with beryllium or a liquid containing beryllium. Coveralls with a head covering may be appropriate when a sudden release of airborne beryllium could result in beryllium contamination of clothing, hair, or skin. Respirators are addressed separately in the explanation of paragraph (g) earlier in this section of the preamble.

Although some personal protective clothing may be worn over street clothing, it is not appropriate for workers to wear protective clothing over street clothing if doing so could reasonably result in contamination of the workers' street clothes. In situations in which it is not appropriate for workers to wear protective clothing over their street clothes employers must select and ensure the use of protective clothing that is worn in lieu of (rather than over) street clothing, and must provide change rooms under paragraph (i)(2).

The Abrasive Blasting Manufacturers Alliance (ABMA) asserted that the PPE requirements under this standard are not consistent with the abrasive blasting requirements for construction and maritime (*e.g.,* 29 CFR 1926.57(f), 29 CFR 1915.34) (Document ID 1673, pp. 22–23). OSHA disagrees, based on the performance-oriented nature of the PPE requirements in the final beryllium standards. If an employer provides PPE that is appropriate and suitable for abrasive blasting and that protects the employee's skin, this would be compliant with the requirements under this final beryllium standard.

Paragraph (h)(2) contains requirements for removal and storage of PPE. This provision is intended to reduce beryllium contamination in the workplace and limit beryllium exposure outside the workplace. Wearing contaminated clothing outside the beryllium work area could lengthen the duration of exposure and carry beryllium from beryllium work areas to other areas of the workplace. In addition, contamination of personal clothing could result in beryllium being carried to employees' cars and homes, increasing employees' exposure as well as exposing others to beryllium hazards. An NJH collaborative study with NIOSH documented inadvertent transfer of beryllium from the workplace to workers' automobiles, and stressed the need for separating clean and contaminated (''dirty'') PPE (Document ID 0474, Sanderson, 1999). Toxic metals brought by workers into the home via contaminated clothing and vehicles continue to result in exposure to children and other household members. A recent study of battery recycling workers found that lead surface contamination above the Environmental Protection Agency level of concern (≥40 $\mu g/ft^2$) was common in the workers' homes and vehicles (Document ID 1875, Centers for Disease Control and Prevention, 2012, pp. 967–970).

Under paragraph (h)(2)(i), beryllium-contaminated PPE must be taken off at the end of the work shift, at the completion of tasks involving beryllium exposure, or when PPE becomes visibly contaminated with beryllium, whichever comes first. This provision is identical to the corresponding paragraph in the proposed standard, except for a slight reorganization to improve clarity and readability. Paragraph (h)(2)(i) is intended to convey that PPE contaminated with beryllium should not be worn when tasks involving beryllium exposure have been completed for the day. For example, if employees perform work tasks involving beryllium exposure for the first two hours of a work shift, and then perform tasks that do not involve exposure, they should remove their PPE after the exposure period to avoid the possibility of increasing the duration of exposure and contamination of the work area from beryllium residues on the PPE (*i.e.,* re-entrainment of beryllium particulate). If, however, employees are performing tasks involving exposure intermittently throughout the day, or if employees are exposed to other contaminants where PPE is needed, this provision requires the employer to ensure that the employee wears is not intended to prevent them from wearing the PPE until the completion of their shift, unless it has become visibly contaminated with beryllium.

PPE that is visibly contaminated with beryllium should be changed at the earliest reasonable opportunity. This provision is intended to protect employees working with beryllium and their co-workers from exposure due to accumulation of beryllium on PPE, and reduces the likelihood of cross-contamination from beryllium-contaminated PPE. Unlike the ''visibly contaminated'' language used in paragraph (h)(1)(ii) of the proposal, which has been removed, OSHA has determined that it is appropriate to use the same language here. Because the purpose of PPE is to serve as a barrier between an employee's body and ambient or surface beryllium, PPE becomes contaminated with beryllium immediately as part of its protective function. Requiring PPE to be changed upon contamination with any amount of beryllium is unreasonable and unnecessary to protect employees. This is because contamination of PPE with beryllium during work processes does not reduce the effectiveness of PPE or create hazards to employees unless sufficient beryllium accumulates on the PPE to impair its function or create additional exposures, such as by dispersing accumulated beryllium into the air. Furthermore, the process of changing contaminated PPE can create opportunities for both inhalation exposure and dermal contact with beryllium. The use of ''visibly contaminated'' protects employees from potential exposures while changing PPE by limiting requirements to change PPE during work tasks involving beryllium exposure to those circumstances when changing it is necessary to maintain its protective function and prevent deposits of beryllium from accumulating and dispersing.

Using the ''visible contamination'' trigger in (h)(1)(ii) to determine when employees must wear PPE in the first instance would have reduced the protectiveness of the standard. Thus, OSHA determined that it would be inappropriate to use such a trigger in that context. However, as explained above, using ''visibly contaminated'' in

paragraph (h)(2)(i) actually increases the protectiveness of the standard. It provides a cue for when it is unacceptable for a worker to continue to work in his or her contaminated PPE, regardless of whether a shift or a task involving beryllium exposure has been completed. This common sense approach is supported by Materion in its post-hearing comments: ''If a job is such that company supplied work clothing may become dirty, wear a personal protective over-garment to keep your work clothing and your person clean. If your work clothing becomes dirty, change it.'' (Document ID 1752).

Paragraph (h)(2)(ii) requires employees to remove PPE consistent with the written exposure control plan required by paragraph (f)(1). Paragraph (f)(1) specifies that the employer's written exposure control plan must contain procedures for minimizing cross-contamination, and procedures for the storage of beryllium-contaminated PPE, among other provisions. While proposed paragraph (h)(2)(ii) only required personal protective clothing to be removed pursuant to the written exposure control plan, the final language includes personal protective equipment as well as clothing. This change was made to ensure consistency with the rest of paragraph (h) and to confirm OSHA's intent that beryllium-contaminated personal protective equipment should be treated with the same care as contaminated clothing in order to prevent additional airborne exposure and dermal contact.

Paragraph (h)(2)(iii) requires employers to ensure that protective clothing is kept separate from employees' street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan. The language of this provision has been modified slightly from the proposed standard to emphasize prevention of cross-contamination as well as implementation of the written exposure control plan, consistent with other requirements intended to limit beryllium migration and cross-contamination. OSHA believes these provisions are necessary to prevent the spread of beryllium throughout and outside the workplace.

The remainder of paragraph (h)(2) is unchanged from the proposal and did not elicit comments from stakeholders. To further limit exposures outside the workplace, paragraph (h)(2)(iv) requires employers to ensure that beryllium-contaminated PPE is only removed from the workplace by employees who are authorized to do so for the purpose of laundering, cleaning, maintaining, or disposing of such PPE. These items must be brought to an appropriate location away from the workplace. To be an appropriate location for purposes of paragraph (h)(2)(iv), the facility must be equipped to handle beryllium-contaminated items in accordance with these standards. The standards further require in paragraph (h)(2)(v) that PPE removed from the workplace for laundering, cleaning, maintenance, or disposal be placed in closed, impermeable bags or containers. These requirements are intended to minimize cross-contamination and migration of beryllium, and to protect employees or other individuals who later handle beryllium-contaminated items. Required warning labels should alert those handling the contaminated PPE of the potential hazards of exposure to beryllium. Such labels must conform with the hazard communication standard (29 CFR 1910.1200) and paragraph (m)(3) of these standards. These warning requirements are meant to reduce confusion and ambiguity regarding critical hazard information communicated in the workplace by requiring that this information be presented in a clear and uniform manner.

Paragraph (h)(3) of the standards addresses the cleaning and replacement of PPE. Proper cleaning is necessary to ensure that neither the workers who use the PPE nor those who clean and maintain it are exposed to beryllium via inhalation or dermal contact. Proper replacement is necessary to ensure that the PPE continues to function effectively in protecting workers from exposure. Paragraph (h)(3) is unchanged from the proposal.

Paragraph (h)(3)(i) requires the employer to ensure that reusable PPE is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness. In keeping with the performance orientation of the standards, OSHA does not specify how often PPE should be cleaned, repaired, or replaced. Appropriate time intervals for these actions may vary widely based on the types of PPE used, the nature of the beryllium exposures, and other circumstances in the workplace. However, even in the absence of a mandated schedule, these requirements must be completed at a frequency, and in a manner, sufficient to ensure that PPE continues to serve its intended purpose of protecting workers from beryllium exposure.

Several commenters discussed the merits of the use of disposable PPE versus reusable PPE. These commenters indicated that OSHA should allow the use of disposable PPE, which could be both more protective and, in some cases, less costly, than reusable PPE (Document ID 1676, p. 3; 1682, p. 3). In response, OSHA notes that it is not prohibiting the use of disposable PPE. As discussed above, OSHA is leaving the decision regarding appropriate PPE to employers after they do their hazard assessments. While these commenters indicated that the regulatory text seems to focus on reusable PPE, the requirements specifically regarding reusable PPE are necessary to ensure that workers who handle this PPE downstream (for example, workers who launder or repair PPE) are protected and that reusable PPE is appropriately handled and cleaned before being reused. These provisions are not meant to indicate that OSHA prefers reusable PPE over disposable PPE.

Under paragraph (h)(3)(ii), removal of beryllium from PPE by blowing, shaking, or any other means which disperses beryllium in the air is prohibited as this practice could result in unnecessary and harmful exposure to airborne beryllium. Paragraph (h)(3)(iii) requires the employer to inform, in writing, any person or business entity who launders, cleans, or repairs PPE required by this standard of the potentially harmful effects of exposure to airborne beryllium and dermal contact with beryllium, and of the need to handle the PPE in accordance with this standard. This provision is intended to limit dermal and inhalation exposure to beryllium, and to emphasize the need for hazard awareness and protective measures consistent with these standards among persons who clean, launder, or repair beryllium-contaminated items.

(i) Hygiene Areas and Practices

Paragraph (i) of the final standards for general industry, construction, and shipyards requires that, when certain conditions are met, the employer must provide employees with readily accessible washing facilities and change rooms. Additionally, paragraph (i) of the final standard for general industry requires that, when certain conditions are met, the employer must provide showers for employee use. Paragraph (i) of all three standards also requires the employer to take certain steps to minimize exposure in eating and drinking areas, and prohibits certain practices that may contribute to beryllium exposure. The final standards' hygiene provisions are consistent with other OSHA standards providing similar protection. For example, OSHA health standards for hexavalent chromium (29 CFR 1910.1026) and lead (29 CFR

1910.1025) include hygiene provisions along with engineering control requirements to protect workers from exposure to toxic substances. OSHA's standards addressing sanitation in general industry (29 CFR 1910.141), construction (29 CFR 1926.51) and shipyard employment (29 CFR 1915.88) also include hygiene provisions, requiring the employer to provide change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing whenever employees are required by an OSHA standard to wear protective clothing because of the possibility of contamination with toxic materials. The sanitation standards also include provisions for washing facilities and prohibit storage or consumption of food or beverages in any area exposed to a toxic material.

OSHA requested comment on the hygiene provisions of the proposed standard for general industry, which was similar in most respects to the hygiene provisions of the final general industry standard. It required employers to provide readily accessible washing facilities, change rooms and showers and to ensure the use of these facilities for each employee exposed to beryllium when necessary. The proposed standard also required employers to take certain steps to minimize exposure in eating and drinking areas and prohibited certain practices that may contribute to beryllium exposure. The remainder of this section discusses general comments on the hygiene section; explains the hygiene provisions of the final standards and OSHA's response to comments on each provision; and discusses differences between the proposed and final standards and differences between the final standards for each sector.

Most commenters agreed with the need for hygiene areas and practices to protect workers from airborne exposure to and dermal contact with beryllium (Document ID 1664, p. 7; 1665, pp. 10–11; 1667, pp. 5–6; 1675, p. 13; 1679, p. 9; 1680, p, 5; 1689, p. 12). However, one commenter stated that its engineering control systems eliminated the need for hygiene facilities (Document ID 1615, p. 8). OSHA disagrees that engineering controls alone are sufficient to eliminate the need for hygiene areas and practices. Because significant risk of beryllium sensitization and CBD remain below the TWA PEL in the final beryllium standards, ancillary provisions such as requirements for hygiene areas and practices are appropriate to further reduce that risk. *See Building and Constr. Trades Dept.* v. *Brock (Asbestos II),* 838 F.2d 1258, 1274 (D.C. Cir. 1988). As discussed in this preamble at Section V, Health Effects and Section VI, Risk Assessment, dermal contact with beryllium can cause beryllium sensitization, the first step in the development of CBD. Compliance with the hygiene provisions of the final standards will reduce the amount and duration of employees' dermal contact with beryllium, and will therefore more effectively reduce employees' risk of developing CBD than would compliance with the TWA PEL alone.

Another commenter noted that hygiene areas and practices specified in the proposal exceed requirements for abrasive blasting operations discussed in OSHA's Ventilation standard for construction (29 CFR 1926.57) and Mechanical paint removers standard in maritime employment (29 CFR 1915.34) (Document ID 1673, p. 23). Ancillary provisions in standards for specific substances such as beryllium complement these general OSHA standards. As OSHA noted in Section XVIII of the NPRM, the standards for abrasive blasting provide protection primarily to blasting operators, and do not apply to other employees who are likely to experience beryllium exposures, such as blasting helpers and cleanup workers. In addition, OSHA expects the hygiene provisions in the final beryllium standards to decrease the airborne exposure and dermal contact even of employees who wear respiratory protection and PPE required by other standards, and will therefore reduce significant risk of beryllium-related health effects among abrasive blasters in construction and shipyards.

Paragraph (i)(1) of the proposed standard required that employers provide, for each employee working in a beryllium work area, readily accessible washing facilities to remove beryllium from the hands, face, and neck. It also required employers to ensure that each employee exposed to beryllium use these facilities when necessary.

The requirements for washing facilities will reduce employees' skin contact with beryllium, the possibility of accidental ingestion and inhalation of beryllium, and the spread of beryllium within and outside the workplace. As discussed in Section V of this preamble, Health Effects, respiratory tract, skin, eye, or mucosal contact with beryllium can result in beryllium sensitization, which is a necessary first step toward the development of CBD. Also, beryllium can contaminate employees' clothing, shoes, skin, and hair, prolonging workers' beryllium exposure and exposing others such as family members if proper hygiene practices are not observed. A study by Sanderson *et al.* measured the levels of beryllium on workers' skin and vehicle surfaces at a machining plant. The study showed beryllium was present on workers' skin and in their vehicles, demonstrating that workers carried residual beryllium on their hands when leaving work (Sanderson *et al.,* 1999, Document ID 0474). In addition, dermal contact with beryllium has been shown to occur even at low airborne exposure levels. For example, skin wipe sample analysis of dental laboratory technicians performing grinding operations demonstrated that beryllium was present on the hands of workers even when airborne exposures were well below the TWA PEL (Document ID 1878, pp. 8–9).

The requirements in the standards to use washing facilities are performance-oriented, simply requiring employees to use the washing facilities to remove beryllium from their skin when the criteria in paragraph (i)(1) of the standards are met. Typically, washing facilities will consist of one or more sinks, soap or another cleaning agent, and a means for employees to dry themselves after washing. OSHA does not intend to require the use of any particular soap, cleaning agent, or drying mechanism. Employers can provide whatever washing materials and equipment they choose, as long as those materials and equipment are effective in removing beryllium from the skin and do not themselves cause skin or eye problems.

Washing reduces exposure by limiting the period of time that beryllium is in contact with the skin, and helps prevent accidental ingestion. Although engineering and work practice controls and protective clothing and equipment are designed to prevent hazardous skin and eye contact, OSHA realizes that in some circumstances exposure will nevertheless occur. For example, an employee who wears gloves to protect against hand contact with beryllium may inadvertently touch his or her face with the contaminated glove during the course of the day. The purpose of requiring washing facilities is to mitigate adverse health effects when skin or eye contact with beryllium occurs.

OSHA did not receive comment on this provision. Therefore, paragraph (i)(1) of the final standards is substantively unchanged from proposed paragraph (i)(1). Paragraph (i)(1) of the final standard for general industry requires the employer to provide readily accessible washing facilities for employees who work in beryllium work areas to remove beryllium from the

hands, face, and neck and ensure that employees who have had dermal contact with beryllium use these facilities at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

Because the standards for construction and shipyards do not require beryllium work areas, the requirements for washing facilities set forth in paragraph (i)(1) of the construction and shipyard standards differ from the general industry standard in that they require employers to provide washing facilities for each employee required to wear personal protective clothing or equipment by the final standards—that is, where employees are reasonably expected to be exposed to beryllium above the TWA PEL or STEL or where there is a reasonable expectation of dermal contact with beryllium. Otherwise, the requirements for washing facilities are the same in all three standards.

Paragraph (i)(2) of the proposed standard required employers to provide affected employees with a designated change room and washing facilities in accordance with the proposed standard and the Sanitation standard where employees were required to remove their personal clothing.

Change rooms allow employees to remove their personal clothing in order to use personal protective clothing. Minimizing contamination of employees' personal clothes will also reduce the likelihood that beryllium will contaminate employees' cars and homes, and other areas outside the workplace. Requiring employers to provide employees with change rooms to change out of work clothes, which are then segregated from their street clothes, and to leave work clothing at the workplace significantly reduces the possibility of beryllium migration outside the workplace, providing added protection from take-home beryllium exposure to workers and their families.

One commenter recommended that change rooms be required only when there is required use of personal protective clothing and equipment (Document ID 1667, pp. 5–6). OSHA intends the change rooms requirement only to apply to covered workplaces where employees must change their clothing (*i.e.,* take off their street clothes) to use protective clothing. In situations where removal of street clothes is not necessary (*e.g.,* in a workplace where only gloves are used as protective clothing), change rooms are not required. The standards do not create a requirement for employees to change their clothing. Note that paragraph (h) of all three standards requires employers to provide ''appropriate'' personal protective clothing. It is not appropriate for employees to wear protective clothing over street clothing if doing so results in contamination of the employee's street clothes. In such situations, the employer must ensure that employees wear protective clothing in lieu of (rather than over) street clothing, and provide change rooms.

Another commenter stated that the final rule should require employers to develop a program that defines approved storage areas for protective apparel and personal hygiene towels, restricts access to this area, provides for employee training when handling or reusing previously used items, and establishes an objective means for determining when an item can no longer be reused and must be laundered or discarded (Document ID 1962, p. 5). OSHA agrees that employers should develop and document procedures for limiting beryllium cross-contamination and migration, and has included such requirements in paragraph (f), Methods of Compliance, and paragraph (j), Housekeeping. These paragraphs of the final standards require each employer to develop, document, and implement procedures for limiting beryllium migration and cross-contamination in their facilities, which should address storage, handling and reuse of beryllium-contaminated items and access to storage facilities for beryllium-contaminated clothing and PPE, including towels if these are contaminated with beryllium during washing and showering.

After carefully reviewing the record, OSHA has decided to keep paragraph (i)(2) substantively unchanged. Paragraph (i)(2) of the final standard for general industry requires the employer to provide a designated change room for employees who work in a beryllium work area and are required to remove their personal clothing. Paragraph (i)(2) of the final standards for construction and shipyards requires the employer to provide a designated change room for employees who are required by the final standards to wear personal protective clothing or equipment and are required to remove their personal clothing. The changed trigger for change rooms in the construction and shipyard standards is due to the fact that there are no beryllium work areas in those standards, and requiring change rooms where employees are required to wear personal protective clothing or equipment provides a similar level of protection to the general industry standard. Change rooms must be designed in accordance with the written exposure control plan required by paragraph (f)(1) of all three standards, and with the applicable Sanitation standards in general industry (29 CFR 1910.141), construction (29 CFR 1926.51), and shipyards (29 CFR 1915.88). These Sanitation standards require change rooms to be equipped with storage facilities (*e.g.,* lockers) for protective clothing, and separate storage facilities for street clothes, to prevent cross-contamination.

As in the proposed standard for general industry, paragraph (i)(3) of the final standard for general industry requires employers in general industry to provide and ensure the use of showers if employees are or can reasonably be expected to be exposed above the TWA PEL or STEL (paragraph (i)(3)(i)(A)) and if employees' hair or body parts other than hands, face, and neck could reasonably be expected to be contaminated with beryllium (paragraph (i)(3)(i)(B)). Employers are only required to provide showers if paragraphs (i)(3)(i)(A) and (B) both apply. Paragraph (i)(3)(ii) of the final standard for general industry, like the proposed standard for general industry, requires employers to ensure that employees use the showers at the end of the work activity or shift involving beryllium if the employees reasonably could have been exposed above the TWA PEL or STEL, and if beryllium could reasonably have contaminated the employees' body parts other than hands, face, and neck. The requirement is restricted to body parts other than the hands, face, and neck because if employees have dermal contact with beryllium on their hands, faces, or necks, they must use the washing facilities required by paragraph (i)(1)(i). This language is intended to convey that showers must be used immediately after work activities involving beryllium exposure have been completed for the day. For example, if employees perform work activities involving beryllium exposure that meet the requirements for showers for the first two hours of a work shift, and then perform activities that do not involve exposure, they should shower after the exposure period to avoid increasing the duration of exposure, potential of accidental ingestion, and contamination of the work area from beryllium residue on their hair and body parts other than hands, face, and neck. If, however, employees are performing tasks involving exposure intermittently throughout the day, this provision is intended to require them to shower after the last task involving exposure, not after the completion of each such task.

The requirements of paragraph (i)(3) of the final standard for general industry are similar to requirements for provision and use of shower facilities in other substance-specific OSHA health standards, such as the standards for cadmium (29 CFR 1910.1027) and lead (29 CFR 1910.1025), which also require showers when exposures exceed the TWA PEL. OSHA's standard for coke oven emissions (29 CFR 1910.1029) requires employers to provide showers and ensure that employees working in a regulated area shower at the end of the work shift. The standard for methylenedianiline (MDA) (29 CFR 1910.1050) requires employers to ensure that employees who may potentially be exposed to MDA above the action level shower at the end of the work shift.

A majority of the comments on the proposed hygiene areas and practices provisions for general industry concerned the requirement for showers. The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) expressed support for the mandatory use of showers for workers in beryllium regulated areas where airborne exposures can reasonably be expected to exceed the TWA PEL or STEL so that proper decontamination can occur and prevent beryllium from leaving the work area, and to ensure that workers and their families are not exposed to beryllium once workers leave their place of employment (Document ID 1665, pp. 10–11). Ameren Corporation (Ameren), the United Steelworkers (USW), and Materion Corporation (Materion) also supported the requirement for showers and their use by employees working in a beryllium regulated area (that is, where airborne exposures can reasonably be expected to exceed the TWA PEL or STEL) (Document ID 1675, p. 13; 1680, p. 5; 1681, p.12).

Some commenters supported the requirement for showers, but suggested that employers should be required to provide shower facilities to workers exposed at lower exposure levels than the TWA PEL or STEL. National Jewish Health (NJH) suggested that showers should be required for workers exposed above the action level rather than the TWA PEL or STEL and in facilities where beryllium can be expected to contaminate the employees' hair or other body parts (Document ID 1664, p. 7). The North America's Building Trades Unions (NABTU) suggested that any beryllium work area should include all necessary decontamination facilities, including showers (Document ID 1679, p. 9).

OSHA notes that NJH and NABTU's comments addressed the provisions of the proposed standard for general industry, which did not include a requirement to provide PPE wherever there is a potential for dermal contact with beryllium. As discussed previously in the Summary and Explanation for paragraph (h) of the final standards, OSHA has adopted much more comprehensive requirements for employers to provide and ensure the use of personal protective clothing and equipment (PPE) wherever exposure exceeds the TWA PEL or STEL or dermal contact with beryllium is reasonably expected to occur. The Agency believes that employees working in low-exposure contexts (where exposures do not exceed the TWA PEL or STEL) and using comprehensive PPE as required in paragraph (h) are unlikely to experience beryllium contamination that requires shower facilities to effectively remove beryllium from the hair and skin. OSHA therefore concludes that the required washing facilities and change rooms for general industry employees working in beryllium work areas in combination with the comprehensive PPE requirements described in paragraph (h) of the final standards are sufficient to protect workers in areas where exposures do not exceed the TWA PEL or STEL and where there is no reasonable expectation that body areas other than hands, face and neck will be contaminated with beryllium. OSHA therefore has decided not to require the provision of showers in general industry workplaces where exposure does not exceed the TWA PEL or STEL.

The Boeing Company (Boeing) suggested requiring showers only when beryllium visibly contaminates employees' hair or body parts other than hands, face, and neck (Document ID 1667, p. 6). However, as discussed previously in the Summary and Explanation of paragraph (h), Personal Protective Clothing and Equipment, dermal contact with beryllium can lead to adverse health effects regardless of whether sufficient beryllium-containing dust has accumulated to be visible to the naked eye. Therefore, OSHA has determined that requiring showers only where beryllium contamination is visible would not adequately protect employees from prolonged dermal contact with beryllium or adequately prevent transfer of beryllium outside the workplace.

Another commenter suggested that air showers for when employees leave the work area would be more cost effective and acceptable than water-based showers (Document ID 1596, p. 1). OSHA does not believe that air showers are appropriate for removing beryllium from workers' skin. Air showers are designed to remove accumulations of dust from the surface of work clothing, PPE, and exposed skin, but cannot remove residual beryllium as effectively as washing with water and soap. In addition, air showers can disperse beryllium-containing dust into the air and cause employees additional airborne exposure, whereas water-based showers do not re-entrain dust into the air.

OSHA has not included a requirement for showers in the final standards for construction and shipyards. Workers in these industries are exposed to beryllium primarily when an abrasive that contains trace amounts of beryllium, usually coal or copper slags, is used during abrasive blasting operations. These abrasive slags contain less than 0.1% beryllium but may result in significant airborne exposure to beryllium because of the high dust levels generated during abrasive blasting. However, workers conducting abrasive blasting with these abrasives are currently protected from dermal contact with beryllium under existing OSHA standards. The OSHA Ventilation standard for construction (29 CFR 1926.57) and the OSHA Mechanical paint removers standard for shipyard employment (29 CFR 1915.34) require personal protective clothing and respiratory protection for abrasive blasters. The Ventilation standard requires employers to use only respirators approved by NIOSH under 42 CFR part 84 for protecting employees from dusts produced during abrasive-blasting operations (29 CFR 1926.57(f)(5)(i)) and abrasive-blasting respirators must be worn by all abrasive-blasting operators (29 CFR 1926.57(f)(5)(ii)). These abrasive blasting respirators cover the entire head, neck and shoulder area to protect the worker from rebounding abrasive during these operations and prevent beryllium exposure to the head and neck area. The Mechanical paint removers standard has similar requirements for abrasive blasters including the use of hoods and airline respirators, along with protective clothing (29 CFR 1915.34(c)). Compliance with these requirements should effectively prevent contamination of abrasive blasters' bodies with beryllium; thus, use of showers to remove beryllium is unnecessary for these workers.

Abrasive blasting support workers such as pot tenders and cleanup workers are also potentially exposed to beryllium during abrasive blasting

activities (Chapter IV, Technological Feasibility). However, their work is usually remote from the actual abrasive blasting or occurs prior to or after the operation is completed, resulting in lower exposures. OSHA's exposure profile for these workers shows a median exposure below the final standards' action level (0.09 μg/m³ for pot tenders and helpers and 0.07 μg/m³ for cleanup helpers) which is well below the median exposure level of 0.2 μg/m³ for abrasive blasters (Chapter IV, Technological Feasibility) and well below the trigger for provision of showers established in the final standard for general industry. While abrasive blasting support workers are not exposed to the high dust levels experienced by the abrasive blasting operator, these workers are nevertheless protected under the personal protective clothing and equipment requirements in paragraph (h) of the final standards which requires the use of appropriate personal protective clothing and equipment where exposure can reasonably be expected to exceed the TWA PEL or STEL or where there is a reasonable expectation of dermal contact with beryllium. Based on the personal protective clothing and equipment requirements under OSHA standards for abrasive blasting operators and support workers, and the low exposure levels described above and in Chapter IV, Technological Feasibility, OSHA is not requiring showers in the final standards for construction and shipyards. OSHA also notes that providing showers can be impractical in some temporary worksites, such as those often used in construction settings.

Paragraph (i)(4) (eating and drinking areas) of OSHA's proposed rule for general industry required that whenever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that surfaces in eating and drinking areas are as free as practicable of beryllium to minimize the possibility of food contamination and the likelihood of additional exposure to beryllium through inhalation or ingestion. Proposed paragraph (i)(4) further required employers to ensure that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level, and that eating and drinking areas must comply with the Sanitation standard (29 CFR 1910.141). Paragraph (i)(5)(ii) (prohibited activities) of the proposed rule, also related to eating and drinking areas, required the employer to ensure that no employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body.

A commenter with the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) recommended that OSHA develop stronger language to ensure that exposure levels are ''well below'' the action level for eating and drinking areas and that surfaces are truly as free as practicable of beryllium (Document ID 1689, pp. 12–13). OSHA agrees with the commenter that airborne beryllium should be maintained well below the action level in eating and drinking areas and has decided not to include the proposal's hygiene provision that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level in the final standards. OSHA believes that this language may be interpreted to allow airborne exposure levels up to the action level in eating and drinking areas, which is not OSHA's intent. The requirements to maintain surfaces in these eating and drinking areas as free as practicable of beryllium and to ensure that employees do not enter eating and drinking areas with personal protective work clothing or equipment unless beryllium has been removed will limit contamination and airborne exposure to beryllium and provide workers with safe areas to eat and drink.

In comments on surface cleanliness pertaining to eating and drinking areas, Boeing suggested that the standard should define specific surface contaminant levels or instead simply rely on the existing OSHA Sanitation standard (1910.141) (Document ID 1667, p. 6). Kimberly-Clark Professional (KCP) suggested that OSHA should set a future goal of establishing maximum allowable surface contamination standards for toxic substances (Document ID 1962, p. 3). Materion suggests that its ''visibly clean'' standard is analogous to OSHA's standard of ''as free as practicable'' and that its cleaning program ensures that surfaces remain ''as free as practicable'' of beryllium (Document ID 1807, p. 5). Materion and USW proposed the term ''visibly clean'' because they ''have found it to be well understood by both workers and management'' (Document ID 1808, p. 4). However, Materion also points out that the use of the term ''as free as practicable'' has been understood by workers, management and OSHA compliance officers and has been successfully applied and effective in practice: ''[f]or decades, OSHA has used the term ''as free as practicable'' in its substance specific standards . . . OSHA's use of this term has been understood by workers, management and OSHA compliance officers. OSHA has successfully applied this compliance term in many prior OSHA standards which serves to demonstrate that its use is understandable and effective in practice'' (Document ID 1808, p. 5). In post-hearing comments, KCP states its belief that ''visibly contaminated'' is an inadequate standard and should not be used as a stand-in for ''as clean as practicable'' (Document ID 1962, p. 2).

In developing the final standards, OSHA carefully considered these comments on the use of ''as free as practicable'' and alternative requirements in reference to surface cleanliness in eating and drinking areas and elsewhere in the beryllium standards, and concluded that ''as free as practicable'' is the most appropriate terminology for requirements pertaining to surface cleanliness. Issues related to use of ''as free as practicable'' and alternatives to this language are also discussed in the Summary and Explanation for paragraph (j), Housekeeping.

The requirement to maintain surfaces as free as practicable of the regulated substance is included in other OSHA health standards such as those for lead in general industry (29 CFR 1910.1025), lead in construction (29 CFR 1926.62), chromium (IV) (29 CFR 1910.1026), and asbestos (29 CFR 1910.1001). Employers therefore have the benefit of previous experience interpreting and developing methods for compliance with requirements to maintain surfaces ''as free as practicable'' of toxic substances, as well as guidance from OSHA on compliance with such requirements. As OSHA explained in a January 13, 2003 letter of interpretation concerning the meaning of ''as free as practicable'' in OSHA's Lead in Construction standard, OSHA evaluates whether a surface is ''as free as practicable'' of a contaminant by the rigor of the employer's program to keep surfaces clean (OSHA, 2003, Document ID 0550). A sufficient housekeeping program may be indicated by a routine cleaning schedule and the use of effective cleaning methods to minimize the possibility of exposure from accumulation of beryllium on surfaces. OSHA's compliance directive on Inspection Procedures for the Chromium (VI) Standards provides additional detail on how OSHA interprets ''as free as practicable'' for enforcement purposes (OSHA, 2008, Document ID 0546, pp. 45–47). As explained in the directive, if a wipe

sample reveals a toxic substance on a surface, and the employer has not taken practicable measures to keep the surface clean, the employer has not kept the surface as free as practicable of the toxic substance. Thus, OSHA believes that the term ''as free as practicable'' is clearly understood by employers through its use in other standards and as explained in letters of interpretation and is using this term in the hygiene provision of the final standards.

OSHA does not set quantitative limits for surface contamination because the best available scientific evidence on adverse health effects from dermal contact with beryllium does not provide sufficient information to link risk of adverse health effects with specific levels of surface contamination. As described above, OSHA finds that wipe sampling can be helpful in determining whether an employer is in compliance with a requirement to keep surfaces as free as practicable of toxic substances, but concludes that use of a specific target level of surface contamination should not define compliance with surface cleanliness requirements of the beryllium standards.

Based on these conclusions, paragraph (i)(4) of the final standards requires that wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that surfaces in these areas are as free as practicable of beryllium. The employer must also ensure that employees do not enter eating and drinking areas with personal protective work clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing and equipment by methods that do not disperse beryllium into the air or onto an employee's body, further protecting workers from beryllium contamination in areas where eating and drinking occurs. Eating and drinking areas must further comply with the Sanitation standards (29 CFR 1910.141(g), 1926.51(g), 1915.88(h)), which prohibit consuming or storing food or beverages in a toilet area or in any area exposed to a toxic material. In the final standards, the provisions for eating and drinking areas (paragraph (i)(4) of the general industry standard, paragraph (i)(3) of the construction and shipyard standards) and prohibited activities (paragraph (i)(5) of the general industry standard and paragraph (i)(4) of the construction and shipyard standards) have been retained with one exception and one structural change. The proposed requirement to ensure that no employee in eating and drinking areas is exposed to airborne beryllium at or above the action level has been removed for the reasons already discussed above. And the requirement concerning employees entering any eating or drinking area with personal protective clothing or equipment has been moved from the prohibited activities section of the proposed rule's hygiene provision to the eating and drinking areas section in the final standards.

Paragraph (i)(4) of the final standard for general industry and paragraph (i)(3) of the final standards for construction and shipyards do not require the employer to provide separate eating and drinking areas to employees at the worksite. Employees may consume food or beverages offsite. However, where the employer chooses to allow employees to consume food or beverages at a worksite where beryllium is present, the employer is required to maintain the area in accordance with paragraph (i)(4) of the final standard for general industry or paragraph (i)(3) of the final standards for construction and shipyards, and with the applicable Sanitation standard (29 CFR 1910.141, 29 CFR 1915.1915.88, or 29 CFR 1926.51), and the employer must ensure that employees do not enter eating and drinking areas wearing contaminated personal protective clothing or equipment.

Paragraph (i)(5)(i) of the proposed standard, setting forth prohibited activities, required the employer to ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas. OSHA did not receive comment on this provision. Therefore, paragraph (i)(5) of the final standards is substantively unchanged from proposed paragraph (i)(5)(i). Paragraph (i)(4) of the final construction and shipyard standards is substantively identical to paragraph (i)(5) of the general industry standard.

Paragraph (i)(5) of the final standard for general industry and paragraph (i)(4) of the final standard for shipyards prohibit eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas (areas where airborne exposure to beryllium is expected to exceed the TWA PEL or STEL). Paragraph (i)(4) of the final standard for construction differs slightly in that the employer is required to ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in work areas where there is a reasonable expectation of exposure above the TWA PEL or STEL. This difference arises because the final standard for construction does not have a requirement for regulated areas but instead relies on a competent person provision (paragraph (e)) to restrict employee access to areas where exposures are, or can reasonably be expected to be, above the TWA PEL or STEL. Exposure at these levels creates a greater risk of beryllium contaminating the food, drink, tobacco, gum, or cosmetics. Prohibiting eating and drinking in these areas will reduce the potential for this manner of exposure.

For the foregoing reasons, OSHA has decided to promulgate all the requirements of the proposed hygiene areas and practices provisions in the beryllium final standard for general industry except for the eating and drinking areas action level limit noted above. For the final standards for construction and shipyards, OSHA has decided to include all of the hygiene areas and practices provisions proposed for general industry except for the requirement for showers and the eating and drinking areas action level limit.

(j) Housekeeping

Paragraph (j) of the final standard for general industry requires employers to maintain all surfaces in beryllium work areas as free as practicable of beryllium; promptly clean spills and emergency releases of beryllium; use appropriate cleaning methods; and properly dispose of materials containing or contaminated with beryllium. Paragraph (j) of the final standards for construction and shipyards requires employers to follow the written exposure control plan required under paragraph (f)(1) when cleaning beryllium-contaminated areas, use appropriate cleaning methods, and provide recipients of beryllium-containing materials for use or disposal with a copy of the warning described in paragraphs (m)(2) and (m)(3), respectively.

As discussed in more detail below, the housekeeping requirements in the final standards are similar to those included in the proposal. While some stakeholders submitted divergent opinions on certain aspects of the proposed provisions, several commenters offered broad support for the inclusion of housekeeping provisions in the final rule (*e.g.,* Document ID 1664, p. 7; 1681, Attachment 1, p. 13). For example, United Steelworkers (USW) stated that ''the proposed text provides employers with clear responsibilities and provides strong provisions to ensure worker protection'' (Document ID 1681, Attachment 1, p. 13). USW also expressed appreciation for the ''precautions incorporated into this section to minimize the amount of particulate suspended in the air'' (Document ID 1681, Attachment 1, p. 13). Another stakeholder, National Jewish Health (NJH), agreed with the

proposed rule regarding housekeeping (Document ID 1664, p. 7). Similarly, the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) argued that ''housekeeping provisions are essential'' ''[b]ecause of the hazardous nature of beryllium and the significant risk of developing beryllium sensitization or disease'' (Document ID 1689, p. 13).

These comments support OSHA's view, as expressed in the NPRM, that these provisions are important because they minimize additional sources of exposure to beryllium that engineering controls do not completely eliminate. Good housekeeping measures are a cost-effective way to control worker exposures by removing settled beryllium that could otherwise become re-entrained into the surrounding atmosphere by physical disturbances or air currents and could enter an employee's breathing zone. Moreover, housekeeping provisions may be especially critical in the final beryllium standards because contact with contaminated surfaces can result in dermal exposure to beryllium. As discussed in this preamble at section V, Health Effects, researchers have identified skin exposure to beryllium as a pathway to sensitization. In addition, the housekeeping provisions in paragraph (j) of the standards for general industry, construction, and shipyards are generally consistent with housekeeping requirements in other OSHA standards for toxic metals, including cadmium (29 CFR 1910.1027, 1926.1127), chromium (VI) (29 CFR 1910.1026), and lead (29 CFR 1910.1025, 1926.62).

The Abrasive Blasting Manufacturers Alliance (ABMA) asserted that the proposed housekeeping requirements are not consistent with the abrasive blasting requirements for construction and shipyards (*e.g.,* 29 CFR 1926.57(f), 29 CFR 1915.34) (Document ID 1673, pp. 22–23). OSHA disagrees. The performance-oriented provisions in the final construction and shipyard standards for beryllium provide employers with a great deal of flexibility in cleaning beryllium-contaminated areas and spills and emergency releases of beryllium and disposing of materials designated for disposal or recycling. In essence, the text requires employers to choose cleaning methods that minimize the likelihood and level of airborne exposure (unless certain conditions are met), handle and maintain cleaning equipment in a way that minimizes exposure, and protect their employees when dry sweeping, brushing, or using compressed air to clean in beryllium-contaminated areas. When transferring materials containing beryllium to another party for use or disposal, the employer is required to advise the recipient of the beryllium content and hazards. These provisions complement, rather than contradict, the rules set out in 29 CFR 1926.57(f) and 29 CFR 1915.34, and are necessary for employee protection from beryllium-related adverse health effects.

Paragraph (j)(1)(i) of the proposed rule would have required employers to maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium and in accordance with the exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of the proposed rule. In this context, the phrase ''as free as practicable'' set forth the baseline goal in the development of an employer's housekeeping program to keep work areas free from surface contamination. For a detailed discussion of the meaning of the phrase ''as free as practicable,'' see the discussion in the Summary and Explanation for paragraph (i), Hygiene areas and practices, in this section of the preamble.

Although this requirement is often included in OSHA's substance specific regulations, a number of commenters expressed concern about its inclusion in this rulemaking. For example, USW argued that a ''requirement to maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium could lead to difficulties in assessing compliance, since 'as free as practicable' is open to interpretation''; instead, USW suggested that beryllium work areas should be required to be maintained ''visibly clean'' of accumulations (Document ID 1681, p. 13). Materion Corporation (Materion) also proposed the term ''visibly clean'' (Document ID 1808, p. 5; 1752, p. 1). However, Materion stated that OSHA has long used the term ''as free as practicable'' in its standards as a measure of cleanliness for work areas and eating areas, and the term is well understood by workers, management, and OSHA compliance officers. According to Materion, ''visibly clean'' is similar to ''as free as practicable'' and also well understood by workers and management (Document ID 1808, p. 5).

Kimberly-Clark Professional (KCP) stated that this ''ostensible equivalence'' between the ''as free as practicable'' and ''visibly clean'' standards is ''unfounded,'' in part, because ''[i]t is practicable using readily known and available methods to make many surfaces clean beyond that which is visibly apparent'' (Document ID 1962, p. 2). Instead, KCP recommended that OSHA ''establish surface contamination standards such that all subjectivity of surface cleanliness is removed'' (Document ID 1962, p. 2). KCP also argued that OSHA should require an employer's surface cleanliness protocol to be based on objective sampling and measurement. KCP maintained that there are many examples where surface sampling is used in economically feasible ways, including in the facilities governed by the Department of Energy (DOE). However, it acknowledged that the methods in other environments, including the DOE protocols for beryllium control in energy facilities, may not translate directly to industrial facilities. Nevertheless, KCP observed that ''there is sufficient ongoing successful use of such approaches to provide a framework for a more objective, data-driven protocol for surface control than 'visibly contaminated' '' (Document ID 1962, p. 3). The Boeing Company (Boeing) also requested that ''as free as practicable'' be replaced with defined surface contaminant levels (Document ID 1667, pp. 6).

Conversely, the Department of Defense (DOD) commented that employers should not be required to measure beryllium contamination on surfaces, as the relationship between level of surface contamination and health risk is unknown. It also stated that wipe samples are not an appropriate enforcement tool for determining that surfaces are ''as free as practicable'' of beryllium contamination (Document ID 1684, Attachment 1, p. 1). ORCHSE Strategies (ORCHSE) agreed that OSHA should not require measurement of beryllium contamination on surfaces (Document ID 1691, p. 18). And, the American Industrial Hygiene Association (AIHA) commented that ''the evaluation of 'visible' is subjective'' (Document ID 1686, p. 1).

After carefully considering these comments and other evidence in the record, OSHA has chosen not to require employers to measure beryllium contamination on surfaces, as suggested by KCP, or to otherwise ''define specific surface contaminant levels,'' as requested by Boeing Company. As DOD explains in its comments, the relationship between a precise amount of surface contamination and health risk is unknown. Therefore, OSHA cannot find that a particular level of contamination is safe. Rather, OSHA has determined that keeping surfaces as clean as practicable is appropriate because promptly removing beryllium deposits prevents them from becoming airborne, thus reducing employees'

inhalation exposure, and helps to minimize the likelihood of skin contact with beryllium. The Agency notes, however, that wipe samples can be a helpful tool for employers. For example, wipe samples can be used by employers to detect the presence of beryllium on surfaces and help gauge when surfaces are as free as practicable of accumulations of beryllium.

Therefore, OSHA has decided to retain the requirement that employers maintain all surfaces in beryllium work areas as free as practicable of beryllium in paragraph (j)(1)(i) of the final general industry standard. The term ''as free as practicable'' is accepted language and used in other OSHA housekeeping requirements for toxic dusts (Asbestos, 29 CFR 1910.1001 and Cadmium, 29 CFR 1910.1027). As the Agency has explained in a letter of interpretation on this term as used in the lead standard, ''the requirement to maintain surfaces 'as free as practicable' is performance-oriented. . . . The requirement is met when the employer is vigilant in his efforts to ensure that surfaces are kept free of accumulations of lead-containing dust. The role of the Compliance Safety and Health Officer (CSHO) is to evaluate the employer's housekeeping schedule, the possibility of exposure from these surfaces, and the characteristics of the workplace'' (OSHA, Jan. 13, 2003, Letter of Interpretation.) The term ''surface'' has a common meaning but is not separately defined in the standard. This term has been used multiple times in OSHA's substance specific standards and OSHA has not found that it is a source of confusion for employers. As indicated in the preamble to the proposed standard, the term includes the outer parts of objects that workers come into contact with, such as equipment, floors, and items in storage facilities, as well as objects that workers may not directly contact, such as rafters and ledges. See 80 FR 47796. Because all surfaces in beryllium work areas could potentially accumulate beryllium that could become airborne or that workers could later inhale, touch, or ingest, all surfaces in beryllium works areas must be kept as free as practicable of beryllium.

OSHA has also decided to remove the phrase ''accumulations of'' from (j)(1)(i), because OSHA believes the reference to ''accumulations'' may be misinterpreted to suggest that cleaning is only required when substantial deposits of beryllium-containing material have accumulated on surfaces. As discussed previously, dermal contact with small amounts of beryllium that are not visible to the naked eye can cause beryllium sensitization. Thus, the final standard for general industry requires the employer to maintain all surfaces in beryllium work areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.

OSHA has not included the requirement that employers maintain all surfaces in beryllium work areas as free as practicable of beryllium in the final standards for construction and shipyards because certain conditions typical in these sectors warrant different approaches in the housekeeping provisions. As discussed in the Summary and Explanation for paragraph (a), Scope and application, in this preamble, although employees in the construction and shipyard industries may be exposed to beryllium during the demolition of beryllium-contaminated buildings and metal recycling or through the dressing of non-sparking tools, the primary exposure source of beryllium at construction worksites and in shipyards is from abrasive blasting operations (Document ID 1671, Attachment 1, p. 5; 1756, Tr. 97–99). Specifically, employees in the construction and shipyard industries are typically exposed when they use abrasive blasting media that contain beryllium.

Abrasive blasting in the construction and shipyard industries often occurs outdoors (see the Final Economic Analysis (FEA), Chapter IV. The surfaces being blasted can be large structures, such as buildings or ships. The blasting process itself can be transient and may occur for short periods of time. The work can be performed in the open or in temporary work enclosures when abrading large objects or structures that cannot be transported or are fixed. These enclosures are typically constructed of tarps and regularly moved from newly abraded areas to areas needing abrasion over very large distances (Document ID 1632, p. 6).

During the abrasive blasting process, large amounts of dust become airborne and then settle on nearby surfaces. Spent blasting media containing trace amounts of beryllium is cleaned up after the blasting operation is complete and has moved to a different area of the worksite. Paragraph (j)(2) of the construction and shipyard standards requires employers to ensure that employees use methods that minimize beryllium exposure during this cleaning process. However, due to the outdoor location of many worksites in construction and shipyards, OSHA finds it is not practical to require employers to maintain all surfaces in work areas as free as practicable of beryllium in construction or shipyards as for general industry. Therefore, OSHA has not included a reference to surfaces in the provisions of in paragraph (j)(1)(i) of the final standards for construction and shipyards. OSHA has modified paragraph (j)(1)(i) of these standards to require only that the employer follow the written exposure control plan required under paragraph (f)(1) when cleaning beryllium-contaminated areas.

When beryllium is released into the workplace as a result of a spill or emergency release, paragraph (j)(1)(ii) of the final standards, like paragraph (j)(1)(ii) of the proposal, requires the employer to ensure prompt cleanup. As defined in paragraph (b) of the final standards, the term ''emergency'' means any uncontrolled release of airborne beryllium. An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes. Spills or emergency releases not attended to promptly are likely to result in additional employee exposure or skin contact.

Boeing objected to the proposed requirement that employers maintain surfaces and clean up spills or emergency releases in accordance with the written exposure control plans required by paragraph (f)(1), in part, because it did not believe OSHA should require employees to establish a written exposure control plan. Instead, Boeing suggested the Agency revise the standard to allow employers to use ''existing processes, such as a written beryllium worksite control procedure'' (Document ID 1667, p. 4). To that end, Boeing suggested that employers be allowed to ensure prompt and proper cleanup in accordance with the exposure control plan, ''or equally as effective documentation'' (Document ID 1667, pp. 6–7). As explained in the Summary and Explanation for paragraph (f), Methods of Compliance, in this preamble, OSHA disagrees with Boeing and has chosen to retain the requirement to establish, implement, and maintain a written exposure control plan. Final paragraphs (j)(1)(i) and (ii) of the standards, like proposed paragraphs (j)(1)(i) and (ii), thus require employers to perform housekeeping activities in accordance with the written exposure control plan required by paragraph (f)(1) and the cleaning methods required by paragraph (j)(2) of the standards.

Paragraph (j)(2) of the proposed rule included a few requirements regarding cleaning methods. Because OSHA recognizes that each work environment is unique, the Agency proposed

performance-oriented requirements for housekeeping to allow employers to determine how best to clean beryllium work areas. Paragraph (j)(2)(i) of the proposed standard would have required that surfaces in beryllium work areas be cleaned by high-efficiency particulate air filter (HEPA) vacuuming or other methods that minimize the likelihood and level of beryllium exposure.

Some commenters, including NJH and USW, expressed support for the proposed requirement to use HEPA-filtered vacuuming (*e.g.,* Document ID 1664, p. 7; 1681, p. 13). NJH indicated that HEPA-filtered vacuuming is one of the methods that it recommends using because ''it has been shown to minimize exposures'' (Document ID 1664, p. 7). USW added that HEPA vacuums are common in the manufacturing industry and requiring their use should not burden employers (Document ID 1681, p. 13). Southern Company also noted that where beryllium is present as a trace element in coal-fired power generation, ''surfaces are cleaned and kept free of coal dust and ash by various methods, including vacuuming or washing,'' methods that may already comply with this proposed provision (Document ID 1668, p. 6).

KCP also indicated its support for HEPA vacuums, stating that vacuuming with HEPA filters is the safest way to remove dry contaminants from surfaces (Document ID 1676, Attachment 1, p. 5). However, KCP added that HEPA vacuums do not always work well in tight areas with recesses, crevices, and complex arrangements of equipment components and that workers are likely to use a towel to clean such areas. Because workers will naturally use nearby towels, KCP recommended that OSHA specify that towels used to clean surfaces must be wet, not dry.

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) also expressed concern with the proposed provision's reliance on HEPA-filtered vacuuming. The BHSC Task Group observed that although HEPA-filtered vacuuming is considered to be the most effective method for cleaning surfaces, it is not necessarily effective in minimizing the spread of contamination because the vacuums fail in various ways during use. The BHSC Task Group further suggested that if OSHA were to prescribe HEPA-filtered equipment use, it should include a requirement for particle counting during use (Document ID 1665, p. 11).

OSHA finds that HEPA-filtered vacuuming is a highly effective method of cleaning beryllium-contaminated surfaces. However, the Agency acknowledges that any housekeeping equipment may fail and that maintaining the equipment according to the manufacturer's recommendations can be a critical part of ensuring that it functions as intended. (See summary and explanation of paragraph (j)(2)(v) which addresses maintenance of cleaning equipment.) Nevertheless, OSHA believes that when HEPA vacuums are maintained in proper working condition, it is not necessary to include a requirement for particle counting during the vacuuming. In addition, the Agency agrees with KCP that in certain circumstances other cleaning methods, such as wet wiping with towels, may also be effective in minimizing the likelihood and level of airborne exposure. Thus, paragraph (j)(2)(i) of the general industry standard retains the requirement that employers must ensure that surfaces in beryllium work areas are cleaned by HEPA-filter vacuuming or other cleaning methods that minimize the likelihood and level of airborne exposure. However, as discussed in detail below, OSHA has also added provisions to accommodate situations where cleaning with HEPA-filtered vacuums or other cleaning methods that minimize airborne exposure are not effective.

As explained above, OSHA has chosen not to include a provision requiring the cleaning of surfaces in the final construction and shipyard standards. And, as explained in the Summary and Explanation for paragraph (e), the construction and shipyard standards do not include a provision establishing beryllium work areas. Thus, references to surface cleaning and beryllium work areas have been removed from paragraph (j)(2)(i) of the construction and shipyard standards. Paragraph (j)(2)(i) in these standards requires employers to ensure the use of HEPA-filter vacuuming or other methods that minimize the likelihood and level of airborne exposure when cleaning spent blast media or performing other cleaning in beryllium-contaminated areas.

Paragraph (j)(2)(ii) of the proposed rule addressed the use of dry sweeping and brushing for cleaning in beryllium work areas. This proposed provision would have disallowed the use of dry sweeping and brushing unless the employer had tried cleaning with a HEPA-filtered vacuum or another method that minimizes the likelihood and level of exposure, and found that the method attempted was not effective under the particular circumstances found in the workplace. As explained in the proposal, OSHA included this provision to provide employers flexibility when exposure-minimizing cleaning methods would not be effective. See 80 FR 47796. However, the Agency indicated it was not aware of any circumstances in which dry sweeping or brushing would be necessary and requested comment on whether either of these cleaning methods would ever be necessary, and if so, under what circumstances. See 80 FR 47574.

Some commenters expressed general support for the prohibition on dry sweeping and brushing. For example, Ashlee Fitch, representing USW and Materion, commented that HEPA vacuums should be used whenever feasible, and stated that ''OSHA has appropriately characterized this provision relative to exceptions'' (Document ID 1680, p. 5). ORCHSE also agreed that prohibiting dry sweeping or brushing to clean surfaces in beryllium work areas is appropriate, and that employers should only be permitted to use dry sweeping and dry brushing when HEPA-filtered vacuuming have been tried and found not effective (Document ID 1691, Attachment 1, p. 5).

Commenters AFL–CIO, AWE, the BHSC Task Group, and North America's Building Trades Unions (NABTU), recommended prohibiting the use of dry sweeping under any circumstances (Document ID 1689, p. 13; 1615, p. 1, 9; 1655, p. 11; 1679, p. 9). For example, Clive LeGresley of AWE stated that AWE does not permit dry sweeping or brushing to clean surfaces and recommended banning this practice (Document ID 1615, p. 1). The BHSC Task Group recommended that dry sweeping be prohibited because it disturbs settled beryllium on surfaces, ''which can exacerbate airborne contamination'' (Document ID 1655, p. 11). It also argued that dry sweeping is not an effective cleaning method, and when dry cleaning is the only available option, dry pickup cloths rather than sweeping should be used (Document ID 1655, p. 13). The AFL–CIO recommended strengthening language in the final rule to prohibit dry housekeeping methods (Document ID 1689, p. 13). In addition, the AFL–CIO pointed out that under the DOE Chronic Beryllium Disease Prevention Program, 10 CFR 850.30 (Housekeeping), the use of dry methods for cleaning floors and surfaces in areas where beryllium is present is prohibited (Document ID 1689, p. 13). NABTU argued that there are no circumstances in which dry sweeping or brushing is necessary, that these practices are unsafe, and the use of such practices would trigger the need to decontaminate entire work areas

before any work could be performed (Document ID 1679, p. 9). AFL–CIO additionally recommended that if dry cleaning methods are necessary due to feasibility issues, ''employers should be required to conduct an exposure assessment and provide a work process description'' (Document ID 1809, p. 2). OSHA has considered AFL–CIO's comment, and finds that the requirements for exposure assessment included in paragraph (d) of the final standards adequately address AFL–CIO's recommendation for exposure assessment. If an employer uses dry methods for cleaning beryllium-contaminated surfaces or areas, exposure from these methods should be included in exposure assessment, and re-assessment of exposures must be conducted when an employer adopts or changes dry methods because this could cause new or additional exposures.

In addition, OSHA has considered AFL–CIO's recommendation to require employers who use dry methods to provide a work process description, and finds that a work process description provides no clear benefit to workers using dry methods for cleaning. However, OSHA notes that paragraph (m) of this standard, which requires training for every employee who is or can reasonably be expected to be exposed to airborne beryllium, encompasses any use of dry cleaning methods in the demarcated beryllium work areas (or, in construction and shipyard settings, in beryllium-contaminated areas). Paragraph (m)(4) includes requirements that employees can demonstrate knowledge and understanding of hazards associated with beryllium exposure, operations that could result in airborne exposure, and measures employees can take to protect themselves from airborne exposure to and contact with beryllium. OSHA intends that employees who use dry methods for cleaning beryllium-contaminated surfaces or areas must be trained on the potential for airborne exposure during such cleaning, the hazards associated with such exposure, and the measures they can take to protect themselves, including the requirements of final paragraphs (j)(2)(iv) and (j)(2)(v) discussed later in this section. OSHA finds that these training requirements serve the purpose of providing information to employees regarding the work process, hazards and methods of protection related to dry sweeping, as OSHA believes the AFL–CIO's recommendation intended.

Several stakeholders cited problems with the use of HEPA-filtered vacuums or wet methods in particular circumstances, or noted specific circumstances where they believed the use of dry sweeping was necessary (Document ID 1676, p. 5; 1668, p. 6; 1807, pp. 2–3; 1756, Tr. 42–43). For example, as noted above, KCP argued that HEPA-filtered vacuums do not always work well in tight areas with recesses, crevices, and complex arrangements of equipment components. Materion commented that it generally prohibits the use of dry brushing or broom cleaning for cleaning but, in instances such as machining operations, the use of paint brushes to clean small chips is required. Materion also noted that some manufacturing processes may use dry brushes. It added that when it permits use of a brush, it performs an exposure assessment ''to help ensure the task is well controlled'' (Document ID 1807, Attachment 1, pp. 2–3). In addition, Jerrod Weaver from the Non-Ferrous Founders' Society (NFFS) testified that dry sweeping is ''not unusual'' in the foundry industry. He explained that the use of wet sweeping or other wet cleaning methods would be dangerous in foundries because when water hits molten metal, it can cause an explosion (Document ID 1756, Tr. 42–43).

Other stakeholders offered opinions on when the use of dry sweeping and dry brushing should be constrained. For example, the Southern Company argued that when dry sweeping does not result in exposure to beryllium above the action level, it should be considered a feasible cleaning option (Document ID 1668, p. 6). Similarly, Ameren Corporation stated that ''prohibiting dry sweeping should be based on employee exposure at or above the action level, not whether it's a beryllium work area'' (Document ID 1675, p. 6). As discussed in Section V, Health Effects, and Section VI, Risk Assessment, the best available scientific evidence suggests that adverse health effects such as beryllium sensitization and CBD can result from airborne exposures below the action level of 0.1 $\mu g/m^3$. In addition, OSHA does not see this suggestion as a practical solution where employers may feel obligated to perform exposure monitoring (or exposure assessments) every time housekeeping functions are performed. OSHA, as it has done in many other standards (*e.g.,* Chromium (VI), 29 CFR 1910.1026), continues to believe that a general prohibition is warranted considering the risk even at the action level.

After carefully reviewing the evidence in the record, OSHA finds that the use of dry sweeping and dry brushing can contribute to employee exposure. However, OSHA also finds convincing evidence that wet methods and HEPA-filtered vacuums may not be safe or effective in all situations in general industry. For example, wet sweeping in certain foundry work areas may be effective but is not safe because of the physical hazard created when water comes into contact with molten metal. Therefore, the Agency has retained both the prohibition on dry sweeping and dry brushing and the exceptions to that prohibition in paragraph (j)(2)(ii) of the final standard for general industry. Although OSHA has decided not to allow these methods based on a specific exposure level, OSHA has revised (j)(2)(ii) to clarify that employers may use dry sweeping or dry brushing to clean surfaces where HEPA-filtered vacuuming or other appropriate methods that minimize likelihood and level of exposure are not safe or effective. The proposed provision merely stated that employers could utilize the dry sweeping or brushing when HEPA-filtered vacuuming or the other methods were not ''effective.'' The Agency intended this term to encompass those situations in which HEPA-filtered vacuuming or the other chosen method would not accomplish the task at hand, *i.e.,* cleaning, and situations in which the use of HEPA-filtered vacuuming or the other methods were unsafe. OSHA has modified the text of the final rule to make this intent explicit.

In sum, final paragraph (j)(2)(ii) of the general industry standard states that the employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective. In situations where HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure would be ineffective, would cause damage, or would create a hazard in the workplace, the employer is not required to use these cleaning methods. The revised paragraph (j)(2)(ii) gives employers the necessary flexibility to use dry sweeping or dry brushing in such situations.

Although OSHA is allowing for dry sweeping and brushing, the Agency anticipates that the number of circumstances where these methods are necessary will be extremely limited. Where the employer uses dry sweeping or brushing, the employer must be able to demonstrate that HEPA-filtered vacuuming or other methods, such as wet sweeping, that minimize the likelihood or exposure are not safe or effective. To comply with the final rule, it is enough for employers to demonstrate that such cleaning methods

are unsafe or ineffective—actually attempting the method on a particular worksite is unnecessary. However, as in the proposal, the employer bears the burden of providing that these methods are either unsafe or ineffective. OSHA has included a similar provision in final paragraph (j)(2)(ii) of the standards for construction and shipyards. Like the general industry provision, final paragraph (j)(2)(ii) of the standards for construction and shipyards disallows dry sweeping and dry brushing and includes an exception for circumstances where HEPA-filtered vacuuming, or other methods that minimize the likelihood of exposure are not safe or effective. Because the construction and shipyard standards do not include a provision establishing beryllium work areas, paragraph (j)(2)(i) of these standards requires the employer to ensure the use of HEPA-filter vacuuming or other methods that minimize the likelihood and level of airborne exposure when cleaning beryllium-contaminated areas. Paragraph (j)(2)(ii) states that the employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

OSHA notes that methods that minimize the likelihood and level of airborne exposure other than HEPA vacuuming may be appropriate for use in construction and shipyards. Use of wet methods, such as wet sweeping or wet shoveling, or using mechanical equipment to move wetted material, may be viable alternatives for cleaning large amounts of spent blasting media used in abrasive blasting operations.

Paragraph (j)(2)(iii) of the proposed rule would have prohibited the use of compressed air in cleaning beryllium-contaminated surfaces unless it was used in conjunction with a ventilation system designed to capture any resulting airborne beryllium. As OSHA indicated in the proposal, this provision was intended to limit airborne exposure by preventing the dispersal of beryllium into the air (80 FR 47796).

Stakeholders offered a number of comments on the use of compressed air. For example, NJH expressed support for this provision, and emphasized that compressed air should only be used in conjunction with a ventilation system (Document ID 1664, p. 7). Several commenters discussed the use of compressed air for cleaning and other processes. Materion commented that it generally prohibits the use of compressed air, but production operations may incorporate compressed air into manufacturing processes (Document ID 1807, Attachment 1, p. 3). Materion further commented that on the few occasions when it permits the use of compressed air, it performs an exposure assessment ''to help ensure the task is well controlled'' (Document ID 1807, Attachment 1, p. 3). Mr. Weaver, a representative of NFFS, testified that the use of compressed air in the foundry industry is ''not unusual'' (Document ID 1756, Tr. 42). He added that compressed air is useful for cleaning work surfaces (Document ID 1756, Tr. 42).

Some commenters, including the AFL–CIO, AWE, and United Automobile, Aerospace & Agricultural Implement Workers of America (UAW), objected to the use of compressed air for cleaning (Document ID 1615 p. 1; 1689, p. 13; 1693, p. 4). For example, the AFL–CIO noted that the DOE Chronic Beryllium Disease Prevention Program prohibits the use of compressed air and dry methods for cleaning floors and surfaces in areas where beryllium is present (Document ID 1689, p. 13). And, UAW stated that ''[c]apture hoods capable of reliably controlling particulates pushed by compressed air do not exist'' (Document ID 1693, p. 4).

OSHA has carefully considered these comments and finds that the use of compressed air to clean beryllium-contaminated surfaces may occasionally be necessary in general industry; particularly in manufacturing processes. Therefore, paragraph (j)(2)(iii) of the final standards allows for the use of compressed air to clean, but only where the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air. This provision is consistent with other recent substance-specific standards, such as the standard for respirable crystalline silica (29 CFR 1910.1053).

Because the standards for construction and shipyards do not include a provision establishing beryllium work areas, paragraph (j)(2)(iii) of these standards states that employers must not allow the use of compressed air for cleaning in beryllium-contaminated areas unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air. OSHA intends this paragraph to apply when using compressed air to clean, for example, surfaces in work areas, tarps used for abrasive blasting enclosures, abrasive blasting equipment, and material designated for recycling or disposal in order to prevent dispersal of beryllium into workers' breathing zones.

OSHA recognizes that even the limited uses permitted under these standards of dry sweeping, dry brushing, and compressed air to clean can result in employee exposure to beryllium. To help mitigate the potential health risks, OSHA included a provision in the proposed rule to further protect employees who are using these cleaning methods. Under proposed paragraph (j)(2)(iv), where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer was required to provide respiratory protection and protective clothing and equipment and ensure that each employee use this protection in accordance with paragraphs (g) and (h) of this standard. As OSHA explained in the proposal, the failure to provide proper and adequate protection to those employees performing cleanup activities would defeat the purpose of the housekeeping practices required to control beryllium exposure. See 80 FR 47796.

In its post-hearing comments, the AFL–CIO indicated support for this requirement. Specifically, the AFL–CIO argued that if dry housekeeping methods are permitted, ''workers should be provided a N–95 respirator—or a higher level of protection as required based on the exposure—and personal protective clothing'' (Document ID 1809, p. 2). After considering the record on this issue, OSHA concludes that requiring employers to provide respiratory protection and protective clothing and equipment in the limited situations where dry sweeping, brushing, or compressed air is used is essential to minimize exposure. Therefore, the Agency has included this provision in paragraph (j)(2)(iv) of the final standard for general industry. OSHA has also included a similar provision in paragraph (j)(2)(iv) of the final standards for construction and shipyards. Proposed paragraph (j)(2)(v) would have required employers to ensure that equipment used to clean beryllium from surfaces is handled and maintained in a manner that minimizes employee exposure and the re-entrainment of beryllium into the workplace environment. Re-entrainment occurs when particles that have settled on surfaces become airborne and remain suspended in the air. Beryllium particles that have been disturbed from surfaces and re-entrained contribute to employee's airborne beryllium exposure. Commenters generally supported the inclusion of this provision in the final rule. For example,

Materion stated that preventing migration of beryllium requires ''looking at all those migratory pathways where material can move around in an operation,'' keeping the material as close to the source as possible, and keeping it off of people and off of surfaces (Document ID 1755, Tr. 150). The BHSC Task Group commented that HEPA vacuums ''must be maintained per the manufacturer's recommendations and oriented in such a manner that the exhaust side of the HEPA vacuum is not blowing hazardous dust into the work area'' (Document ID 1655, p. 11). Among other things, the BHSC Task Group said this provision would cause employers to ensure that cleaning and maintenance of HEPA-filtered vacuum equipment is done carefully to avoid exposure to beryllium. This provision would also require employers to ensure that filter changes and bag and waste disposal be performed in a manner that minimizes the risk of employee exposure to airborne beryllium and accidentally dispersing beryllium back into the workplace environment. After carefully reviewing these comments, OSHA finds that the provisions of paragraph (j)(2)(v) are necessary to the protection of employees from the adverse health effects associated with beryllium exposure, and has decided to include this provision (with minor changes) in paragraph (j)(2)(v) of the final standards. OSHA notes that paragraph (j)(2)(v) complements paragraph (f)(1)(i)(F), which requires employers to establish and implement a written exposure control plan that includes procedures for minimizing the migration of beryllium.

Paragraph (j)(3)(i) of the proposed rule would have required the employer to ensure that waste, debris, and materials visibly contaminated with beryllium and consigned for disposal were disposed of in sealed, impermeable enclosures, such as bags or containers. Paragraph (j)(3)(ii) would have further required such bags or containers to be labeled in accordance with paragraph (m)(3) of the proposed rule. Finally, paragraph (j)(3)(iii) of the proposed rule would have required materials designated for recycling that are visibly contaminated with beryllium to be either cleaned to remove visible particulate, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the proposed rule.

OSHA intended these provisions to protect and inform workers who may be exposed to beryllium when handling waste or recycled materials. As discussed in the NPRM, alerting employers and employees who are involved in disposal to the potential hazards of beryllium exposure will better enable them to implement protective measures (80 FR 47771). OSHA reasoned that employers and employees should be similarly alerted if handling materials designated for recycling that have not been cleaned of visible particulate. The proposed requirements to use impermeable enclosures and/or clean materials of visible particulate were intended to reduce employees' risk of beryllium sensitization from dermal contact with beryllium in handling waste materials or materials designated for recycling. The options provided to employers in proposed paragraph (j)(3)(iii) were intended to allow employers flexibility to facilitate the recycling process.

In the NPRM, OSHA asked for feedback on proposed paragraph (j)(3) (80 FR 47574). A number of stakeholders responded. For example, NFFS argued that:

> [t]he sections regulating the manner in which waste product is labeled, packaged and shipped have already been regulated by both the [Environmental Protection Agency (EPA) (*e.g.* treatment, recycling and reuse of waste materials) and the DoT (*e.g.* shipping and placarding requirements, shipping containers for hazardous materials). Additionally, scrap and process coproducts in the non-ferrous foundry industry are treated as products and provided with appropriate labeling and SDS information as required by OSHA and the GHS/Hazard Communication standard. Requiring the non-ferrous casting industry to treat our process coproducts the same as waste and debris streams contradicts the requirements of the EPA and DoT regarding the identification, processing, packing, handling and transportation requirements of these materials'' (Document ID 1678, p. 5).

OSHA's requirement for warning labels must be consistent with the Hazard Communication Standard. Therefore, OSHA is not convinced that these are barriers to appropriately warning downstream users of beryllium contamination. In the Hazard Communication Standard (HCS), OSHA has carefully defined when other Agencies have jurisdiction for labeling requirements such as EPA and the Department of Transportation (DOT). Additionally, as OSHA further explainsed in the Summary and Explanation for paragraph (m), Communication of hazards, OSHA intends for the hazard communication requirements in the final standards to be substantively as consistent as possible with the HCS, while including additional specific requirements needed to protect employees exposed to beryllium, in order to avoid duplicative administrative burden on employers who must comply with both the HCS and this rule. To that end, OSHA allows employers to include the information required by these beryllium standards on the labels created to comply with the HCS. Thus, if NFFS's members are already supplying labels that conform to the HCS, they can add the beryllium-specific information to the existing labels. OSHA deems this information is warranted and would not contradict or cast doubt on the other information required on the label.

Some commenters, including USW, generally agreed with OSHA's proposed disposal and recycling requirements (*e.g.,* Document ID 1680, p. 6). Materion noted that a similar provision appeared in Materion and the USW's joint draft model standard (Document ID 1681, p. 12). In addition, Materion argued that OSHA should not require that all material to be recycled be decontaminated regardless of perceived surface cleanliness or require that all material disposed or discarded be in enclosures regardless of perceived surface cleanliness (Document ID 1681, p. 12). The company maintained that this requirement would be technologically and economically infeasible and extremely costly in many regards, particularly with regard to surface residue from abrasive blasting (Document ID 1681, p. 12). As discussed below, OSHA has decided for the construction and shipyard standards not to require decontamination or enclosure of materials designated for recycling or disposal due in part to concerns about the feasibility of such requirements in these sectors.

However, many other stakeholders argued in favor of cleaning or enclosing all beryllium-contaminated materials designated for recycling and enclosing such materials destined for disposal. For example, the BHSC Task Group, NJH, the National Institute for Occupational Safety and Health, Southern Company, NFFS, AIHA, NABTU, and ORCHSE disagreed with the proposal's use of the term ''visible'' when determining whether the provisions for containment and labeling included in proposed paragraph (j)(3) should apply to materials designated for recycling or disposal (*e.g.,* Document ID 1664, p. 7; 1671, Attachment 1, p. 7; 1668, p. 6; 1678, p. 5; 1686, p. 2; 1679, p. 10; 1691, p. 5). NJH and ORCHSE recommended that OSHA require all materials designated for recycling ''be decontaminated regardless of perceived surface cleanliness'' (Document ID 1664, p. 7; 1691, p. 5). NJH added that ''particles may not be visible to the naked eye'' and ''[d]econtaminating all

materials ensures that exposure is minimized.'' It also recommended that materials designated for disposal be discarded per local hazardous waste regulations (Document ID 1664, p. 7). ORCHSE argued that for the protection of municipal and commercial disposal workers, materials discarded from beryllium work areas should be in bags or other containers (Document ID 1691, p. 5). NFFS asserted that ''visibly contaminated,'' ''cleaned to remove visible particulate,'' and ''sealed, impermeable enclosures'' are vague terms (Document ID 1678, p. 5).

As discussed previously in the Summary and Explanation for paragraph (h), Personal protective clothing and equipment, in this preamble, OSHA finds that ''visibly contaminated'' is a subjective trigger for most purposes in the final standards, and dermal contact with beryllium can cause beryllium sensitization even if the beryllium is not visible to the naked eye. OSHA therefore agrees with the commenters who criticized the use of ''visibly contaminated.'' (see, *e.g.* Document ID 1686, p. 1). The Agency intends that waste, debris, and materials be disposed of as specified in paragraph (j)(3) regardless of particulate visibility. However, OSHA does not intend for this requirement to extend to articles containing beryllium that are outside of the scope the standard, but to beryllium dust generated during processing. Similarly, materials designated for recycling must be cleaned to remove particulate or placed in sealed, impermeable enclosures, such as bags or containers, and labeled in accordance with paragraph (m)(3) of the standards, regardless of particulate visibility. To make this intention clear to employers, OSHA has removed the terms ''visibly'' and ''visible'' from paragraph (j)(3) of the final standard for general industry, and has replaced them with ''as free as practicable.'' OSHA discusses the meaning of ''as free as practicable'' and addresses comments on this phrase in this Summary and Explanation of paragraph (j), Housekeeping.

OSHA also agrees with ORCHSE that materials discarded from beryllium work areas in general industry should be in bags or other containers for the protection of municipal and commercial disposal workers (Document ID 1691, p. 5). However, OSHA disagrees with NFFS's comment that ''sealed, impermeable enclosures'' is problematically vague (Document ID 1678, p. 5). OSHA intends this term to be broad and the provision performance-oriented, so as to allow employers in a variety of industries flexibility to decide what type of enclosures (*e.g.,* bags or other containers) are best suited to their workplace and the nature of the beryllium-containing materials they are disposing or designating for reuse outside the facility. OSHA finds that the terms ''sealed'' and ''impermeable'' are commonly understood and should not cause employers confusion. OSHA intends these terms to mean that the enclosures selected should not allow the materials they contain to escape the enclosures under normal conditions of use.

In addition, the BHSC Task Group stated that certain beryllium-contaminated items should not be considered for recycling. According to the BHSC Task Group, only materials scheduled for use within beryllium regulated areas at other facilities, and not by the general public, should be recycled. The BHSC Task Group recommended surface wipe sampling to determine whether items should be decontaminated again and should be resampled prior to recycling; otherwise, if not meeting established limits, they should be disposed of according to ''appropriate waste management practices'' (Document ID 1655, p. 13). After careful consideration, OSHA has decided not to adopt the BHSC Task Group's suggestion. The Agency finds that the requirement to either clean and label or enclose and label beryllium-contaminated or containing materials designated for recycling should provide protection for later recipients of these items, as discussed in more detail below.

In addition to the previously discussed changes to the proposed rule, which were directly related to comments received by OSHA, the Agency has made several changes to better implement and communicate the intention of paragraph (j)(3). First, OSHA has modified the provisions of paragraph (j)(3) to state that it applies to materials that contain beryllium as well as materials contaminated with beryllium. OSHA finds that employers and employees who work with materials that were recycled or discarded by other facilities should be made aware of any beryllium-containing materials they process. Provisions to ensure awareness of beryllium in materials received from other facilities aid employers who otherwise might not know they are required to comply with the beryllium standard, and employees who otherwise might not be appropriately protected or adequately informed about potential beryllium exposures in their workplace.

Second, the requirements of (j)(3) regarding labeling materials designated for recycling have been modified. While the proposed rule required materials designated for recycling to be labeled in accordance with paragraph (m)(3) only if employers choose to enclose rather than clean them, the final standards require employers to label materials designated for recycling in either case. This modification, like OSHA's addition of the reference to beryllium-containing materials discussed above, ensures that employers and employees who work with materials that were recycled by other facilities are aware of any beryllium-containing materials they process. OSHA also modified the requirements of proposed paragraph (j)(3) for the construction and shipyard sectors. Paragraph (j)(3) of the construction and shipyard standards requires employers who transfer materials containing beryllium to another party for use or disposal to provide the recipient with a copy of the warning described in paragraph (m)(3) of the standards, for the same reasons this requirement was retained in the final general industry standard. However, employers in construction and shipyards are not required to place beryllium-containing materials in sealed, impermeable enclosures for use or disposal by other entities. OSHA made this change from paragraph (j)(3) of the general industry standard because the Agency believes that spent media from abrasive blasting operations will constitute the great majority of beryllium-containing materials designated for disposal or recycling in construction and shipyards and it is generally not practical for employers to enclose spent blasting media in sealed, impermeable bags or containers, because of the large volume of waste material generated in these operations OSHA finds that requiring employers in construction and shipyards to include a warning label on beryllium-containing materials designated for disposal or reuse, but not requiring them to seal such materials in impermeable enclosure, appropriately informs recipients of the potential hazards of handling the materials without imposing impractical containment requirements on these employers. In addition, these separate requirements for construction and shipyards are responsive to Materion's concern regarding the technological and economic feasibility of cleaning or enclosing materials contaminated with surface residue from abrasive blasting.

In summary, paragraph (j)(3)(i) of the final standard for general industry requires that items containing or contaminated with beryllium and designated for disposal be disposed of

in sealed, impermeable bags or other sealed, impermeable containers, and requires these containers to be marked with warning labels in accordance with paragraph (m)(3) of the standards. Paragraph (j)(3)(ii) of the final standard for general industry requires materials designated for recycling that contain or are contaminated with beryllium be cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or to be placed in sealed, impermeable enclosures, such as bags or containers, that are so labeled. Paragraph (j)(3) of the construction and shipyard standards requires employers who transfer materials containing beryllium to another party for use or disposal to provide the recipient with a copy of the warning described in paragraph (m)(3) of these standards. The term ''use'' is intended to include recycling, as well as any other use the recipient may make of the beryllium-containing materials.

Finally, USW and Materion requested that OSHA make it clear that this provision does not apply to beryllium-containing scrap metals being reused within the facility (Document ID 1680, p. 6; 1661 p. 12). USW offered the example of copper beryllium machine turnings being utilized within the same facility. The union explained: ''In this example, it would not make sense to require cleaning or enclosing because they are either very clean to start with or have a thin coating of machining coolant. Requiring them to be cleaned before reuse in the facility might actually lead to greater worker exposures'' (Document ID 1680, p. 6).

OSHA did not intend to require employers to clean or enclose materials designated for reuse elsewhere in the same facility. Therefore, OSHA clarifies that paragraph (j)(3)(ii)'s requirements do not apply to scrap metals designated for reuse within the same facility.

(k) Medical Surveillance

Paragraph (k) of the final standards sets forth requirements for the medical surveillance provisions. The paragraph specifies which employees must be offered medical surveillance, as well as the frequency and content of medical examinations. It also sets forth the information that the licensed physician and CBD diagnostic center is to provide to the employee and employer. Many of the provisions in the final standards are substantively consistent with the 2012 joint draft recommended standard by Materion Corporation (Materion) and the United Steelworkers (USW) (Document ID 0754).

The purposes of medical surveillance for beryllium are: (1) To identify beryllium-related adverse health effects so that appropriate intervention measures can be taken; (2) to determine if an employee has any condition that might make him or her more sensitive to beryllium exposure; and (3) to determine the employee's fitness to use personal protective equipment such as respirators. The inclusion of medical surveillance in these final standards is consistent with section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)), which requires that, where appropriate, medical surveillance programs be included in OSHA health standards to aid in determining whether the health of employees is adversely affected by exposure to the hazards addressed by the standard. Almost all other OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026), Methylene Chloride (29 CFR 1910.1052), Cadmium (29 CFR 1910.1027), and Respirable Crystalline Silica (29 CFR 1910.1053), have also included medical surveillance requirements and OSHA finds that a medical surveillance requirement is appropriate for the beryllium standards because of the health risks resulting from exposure.

General. Consistent with the proposed standards, paragraph (k)(1)(i) of the final standards, requires employers to make medical surveillance available at no cost, and at a reasonable time and place, for each employee who meets a trigger for medical surveillance. As in previous OSHA standards, the ''no cost, and at a reasonable time and place'' requirement in the final beryllium standards is intended to encourage employee participation. Under this requirement, if participation requires travel away from the worksite, the employer will be required to bear the cost of travel, and employees will have to be paid for time spent taking medical examinations, including travel time.

OSHA clarifies that employees of beryllium vendors who qualify for benefits under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) (42 U.S.C. 7384–7385s–15) and its implementing regulations (20 CFR part 30) may also qualify for medical surveillance benefits under this final standard. Medical benefits provided to covered employees for covered beryllium diseases under the EEOICPA program are paid for by the federal government.

Employees covered by both the EEOICPA program and this final standard will not be required to choose between the programs. Rather, these dual-coverage employees may undergo medical examinations where they can receive the services and/or treatment covered under both programs. Treatment and services for covered beryllium disease of a covered beryllium employee under the EEOICPA program will be paid for by the federal government to the extent that the services provided are covered under the EEOICPA program. If this final standard requires services or treatment that are not covered by the EEOICPA program, the employer will be required to pay for these additional services.

OSHA received numerous comments during the public comment period regarding the inclusion of the medical surveillance provision for the beryllium standard. Most comments supported inclusion of medical screening or surveillance in the final beryllium standard, including those from National Safety Council (NSC), Materion, National Jewish Health (NJH), North America's Building Trades Union (NABTU), USW, the American College of Occupational and Environmental Medicine (ACOEM), the American Thoracic Society (ATS), the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), ORCHSE Strategies (ORCHSE), the National Institute of Occupational Safety and Health (NIOSH), and Public Citizen (*e.g.,* Document ID 1612, p. 3; 1661, p. 10; 1664, pp. 1, 8; 1679, pp. 11–12; 1681, pp. 13–14; 1685, p. 4; 1688, p. 2; 1689, pp. 13–14; 1691, Attachment 1, pp. 5–13; 1725, p. 33; 1964, p. 3). No commenters opposed the inclusion of a medical surveillance requirement.

In support of medical surveillance, the AFL–CIO and others indicated that medical surveillance is essential in screening for sensitization and preventing CBD (Document ID 1658, p. 3; 1689, p. 13). As noted in Section V, Health Effects, employees in the early stages of beryllium disease are often asymptomatic, and as a result, medical surveillance is critical to identify those employees who may benefit from interventions such as removal from exposure. ATS also commented that medical surveillance helps to identify those with sensitization and potentially CBD, as well as to define the risk of various work exposures, jobs, and tasks (Document ID 1688, p. 3). Commenter Evan Shoemaker said surveillance could ''inform employers that workplace controls and safeguards need updating'' (Document ID 1658, p. 3).

NJH commented that early disease detection, before symptoms occur, is the cornerstone for managing work-related disease (Document ID 1806, pp. 2–3). Studies highlighted by NJH show that medical surveillance could be important for identifying workers that might

benefit from removal from exposure. Those studies show that rates of CBD development in sensitized workers are lower for short-term than long term workers (1.4% versus 9.1% in a study by Henneberger *et al.,* 2001, Document ID 1313). Other studies it cited showed improvements in gas exchange and radiography with decreased peak air concentrations of beryllium (Sprince *et al.,* 1978, as cited in Document ID 1806) and improvements in lung function in most patients after stopping beryllium exposures (Sood *et al.,* 2004, Document ID 1331).

NJH also submitted evidence showing that once employees do develop symptoms, the knowledge that the symptoms are caused by CBD could lead to treatment to improve outcome (Document ID 1806, pp. 2–3). NJH found that identifying disease at an early stage allows the use of inhaled corticosteroids for mild symptoms, which it found to be effective for reducing expected levels of lung function decline and improving lung function and cough in employees with lower lung function (Document ID 1811, Attachment 8). Early detection of beryllium disease and identification of employees who would benefit from oral corticosteroid treatment before fibrosis develops can result in regression of signs and symptoms and possibly prevent progression of the disease (Marchand-Adam *et al.,* 2008, Document ID 0370; 80 FR 47588). NJH concluded that early detection of beryllium disease allows for exposures to be decreased and symptoms to be treated at the earliest time point, which can result in decreases in medication doses, side effects, and risk of disease progression.

In paragraphs (k)(1)(i)(A)–(C) of the proposal, OSHA specified that employers must ''make medical surveillance as required by this paragraph available'' for each employee: (1) Who has worked in a regulated area for more than 30 days in the last 12 months; (2) showing signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue; or (3) exposed to beryllium during an emergency. OSHA requested comments on these triggers and also presented alternatives to expand eligibility for medical surveillance to a broader group of employees (80 FR 47565, 47571, 47576). Under Regulatory Alternative #14, medical surveillance would have been available to employees who are exposed to beryllium above the proposed permissible exposure limit (PEL), including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would have expanded eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year.[39] OSHA requested comment on these alternatives.

OSHA received numerous comments related to each of the proposed triggers. First, a number of stakeholders commented on the proposed trigger of working in a regulated area, *i.e.,* an area in the workplace where an employee's exposure exceeds, or can reasonably be expected to exceed, either the PEL or the short-term exposure limit (STEL), for more than 30 days in a 12-month period. For example, NIOSH argued that employees exposed above an action level of 0.1 μg/m^3 for 30 days a year should be eligible for medical surveillance because ''substantial risk for [sensitization] and [chronic beryllium disease (CBD)] exists even at the [a]ction [l]evel'' (Document ID 1725, p. 32; 1755, Tr. 40). Public Citizen also advocated for an action level trigger based on risk of sensitization below the proposed PEL, arguing that triggering medical surveillance at the PEL, where significant risk remains, would be inconsistent with other OSHA health standards (Document ID 1964, p. 3). Public Citizen asked OSHA to consider the feasibility of making medical surveillance available to employees exposed at any level of beryllium for any duration of time (Document ID 1964, p. 3).

ATS and NJH supported expanding medical surveillance to all employees exposed to beryllium in beryllium work areas (above or below the action level), because of remaining significant risk at the PEL and because exposure monitoring is sporadic and may not always reflect higher exposures (Document ID 1664, p. 1; 1688, pp. 2, 4). Lisa Maier, M.D., from NJH further indicated that medical surveillance should be offered to these employees, regardless of the amount of time they spend in the work areas (Document ID 1756, Tr. 101–103). To support this recommendation, NJH referenced three studies (Henneberger *et al.,* 2001, Document ID 1313; Schuler *et al.,* 2005, (0919); and Taiwao et al, 2008, (1264)) that examine relationships between beryllium exposure and development of sensitization and CBD. NJH stated that exposure levels as low as 0.01 μg/m^3 were associated with the development of sensitization and disease (Document ID 1720; 1756, Tr. 93–94). NJH also presented evidence showing that some individuals are genetically susceptible to developing beryllium sensitization and CBD (*e.g.,* Maier *et al.,* 2003, Document ID 0484; 1720, p. 3).

The National Supplemental Screening Program (NSSP), an organization that provides medical screening for former Department of Energy workers, and ACOEM supported an action level trigger, including for employees exposed for less than 30 days a year (Document ID 1677, p. 3; 1685, p. 4; 1756, Tr. 83–84). However, Lee Newman, MD, who represented ACOEM at the public hearing, testified that he personally felt that medical surveillance should be offered to anyone who has worked in a beryllium work area with measurable beryllium exposures (Document ID 1756, Tr. 84). Dr. Newman stated that his personal opinion was based upon his ''30 years of experience of working with people [exposed to beryllium'' and ''the studies that [he and his colleagues] have done'' (Document ID 1756, Tr. 84).

In contrast, Materion argued medical surveillance should be triggered by exposures above the PEL because Johnson *et al.* (2001) (Document ID 1505) concluded that 2.0 μg/m^3 is sufficient to protect employees from developing clinical CBD, most recent scientific studies suggest that 0.2 μg/m^3 is sufficient to protect against CBD, and the coke oven emissions standard and formaldehyde standards trigger medical surveillance at the PEL (Document ID 1661, p. 10). NGK Metals Corporation (NGK) was also opposed to setting the medical surveillance trigger at the action level, claiming that this would be burdensome, costly, and cause distress in employees who receive false positive results (Document ID 1663, p. 5). The Department of Defense (DOD) argued that medical surveillance should be triggered above the PEL to monitor the effectiveness of engineering controls and respiratory protection (Document ID 1684, Attachment 2, p. 1–9).

Based on the comments and other record evidence, OSHA finds that triggering medical surveillance at the action level of 0.1 μg/m^3 better addresses residual significant risk and varying susceptibility of employees that can result in sensitization and CBD at lower exposure levels. OSHA disagrees

[39] OSHA also proposed Regulatory Alternative #21, which would have extended eligibility for medical surveillance to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1) (or any of the alternative criteria under consideration). However, under Regulatory Alternative #21, all other provisions of the standard would have been in effect only for employers and employees that fell within the scope of the proposed rule. As discussed in the Summary and Explanation for paragraph (a), Scope and application, OSHA has decided to expand the proposal's scope to cover construction and shipyards. Therefore, Regulatory Alternative #21 is moot.

with Materion that a PEL trigger for medical surveillance is sufficiently protective because OSHA's own risk assessment shows significant risk remaining at the action level and PEL (see Section VI, Risk Assessment). In addition, OSHA is aware of individuals who are genetically predisposed to developing beryllium sensitization and CBD at beryllium levels that would not cause disease in other individuals (See Section V, Health Effects). As a result, OSHA is concerned that a PEL trigger is not sufficient to identify disease at an early stage in employees who are genetically susceptible to developing disease.

Moreover, OSHA finds that an action level trigger for medical surveillance encourages employers to maintain exposures below that level, which in turns provides reasonable assurance that exposures will not exceed the PEL on days when exposures are not measured (See Summary and Explanation for paragraphs (b), Definitions, and (d), Exposure Assessment). Therefore, an action level trigger in these standards is also appropriate to address stakeholder concerns, such as those raised by ATS and NJH, that exposure assessments might underestimate actual exposures due to variability in exposure levels or other factors.

Medical surveillance triggered by the action level is the norm for OSHA health standards. Materion noted two exceptions, observing that medical surveillance is not triggered at the action level in standards for formaldehyde and coke oven emissions. However, the Coke Oven Emissions standard does not include an action level, and the trigger for medical surveillance is employment in a regulated area, which is a discretely identified area on or around the coke oven battery, for at least 30 days a year (29 CFR 1910.1029). Significantly, the Coke Oven Emissions standard requires employers to assure that no employee in the regulated area is exposed to coke oven emissions at concentrations greater than the PEL (29 CFR 1910.1029(c)). Therefore, the trigger in the Coke Oven Emissions standard, which would include employees who are exposed to levels no higher than the PEL for at least 30 days per year, is more protective than a requirement that does not trigger medical surveillance until exposures exceed the PEL for 30 days a year. With the exception of formaldehyde, OSHA standards trigger medical surveillance at exposure levels at or below the PEL, and typically at the action level.

In sum, OSHA is persuaded that a lower trigger for medical surveillance is necessary because of the remaining health risk at both the action level and PEL. However, OSHA is not persuaded by those commenters who advocated triggering medical surveillance below the action level, in part, because nearly everyone in the general population is potentially exposed to beryllium as it is a naturally occurring compound in rocks and soil. In addition, the lack of conclusive evidence of non-industrial-related beryllium-related disease in the record suggests there is a level of exposure at which the risk of developing beryllium-related disease becomes negligible, but OSHA does not have information to precisely determine that level. As a result, offering medical surveillance to all potentially exposed employees would result in some low-risk employees receiving medical examinations when they have very little likelihood of benefiting from those examinations. OSHA is especially concerned by this because some medical examination components, such as the BeLPT, are invasive. In addition, OSHA finds that triggering surveillance at a level that is achievable for some employers is important because it provides employers with an incentive to keep exposures low to avoid the costs of providing medical surveillance. Employees benefit from those lower exposures because it reduces their risk of developing disease. Triggering medical surveillance at any level of exposure eliminates the incentive to keep exposures low and thus may be counterproductive to protecting employees.

In conclusion, an action level trigger is appropriate because it is a level at which risks are measurable and found to be lower than at the PEL, especially for employees who may be more susceptible to developing disease. The action level is achievable for many employers, and those employers are likely to maintain exposures below the action level to avoid the costs associated with exposure assessments and offering medical surveillance. Maintaining exposures below the action level also benefits employees because it decreases the chances that exposures will not exceed the PEL on a day on which exposure assessments are not conducted, and it lowers the risk of developing disease. For those reasons, an action level trigger is appropriate in the beryllium standard, consistent with the majority of OSHA standards.

Comments were also received on the 30-day duration as part of the medical surveillance trigger. NIOSH supported it (Document ID 1725, p. 32; 1755, Tr. 40). However, NJH, NSSP, and ACOEM did not support OSHA's proposed duration trigger of more than 30 days a year, stating that eligible employees exposed less than 30 days a year should be offered medical surveillance (Document ID 1664, p. 9; 1677, p. 3; 1685, p. 4).

Other stakeholders did not support extending medical surveillance to employees exposed for fewer than 30 days per year. For example, DOD commented that ''[w]hile it is conceivable that workers can be sensitized to beryllium after brief exposures, it is unlikely that infrequent, brief exposures will cause either sensitization or chronic beryllium disease'' (Document ID 1684, Attachment 2, p. 1–2).

After careful consideration of these comments and other evidence in the record, OSHA finds that maintaining the 30-day exposure-duration trigger is appropriate in the final standards because the Agency's risk assessment shows increasing risk of health effects from exposure at increasing cumulative exposures, which considers both exposure level and duration (See Section VI, Risk Assessment). OSHA finds that a 30-day trigger is a reasonable benchmark for capturing increasing risk from cumulative effects caused by repeated exposures. Including a 30-day exposure-duration trigger also maintains consistency with other OSHA standards, such as Chromium (VI) (29 CFR 1910.1026), Cadmium (29 CFR 1910.1027), Lead (29 CFR 1910.1025), Asbestos (29 CFR 1910.1001), and Respirable Crystalline Silica (29 CFR 1910.1053). As discussed in more detail below, OSHA notes that the triggers in final paragraphs (k)(1)(i)(B) and (C) may address employees who could be at risk, even though they may not have had repeated exposures.

Therefore, OSHA has decided to revise the first proposed medical surveillance trigger to require the offering of medical surveillance based on exposures at or above the action level, rather than the PEL (i.e, work in a regulated area). But the Agency will retain the 30-day-per-year-exposure-duration trigger. In addition, OSHA has chosen to revise the proposed trigger to require employers to make medical surveillance available to each employee ''who is or is reasonably expected to be exposed . . . for more than 30 days a year,'' rather than waiting for the 30th day of exposure to occur. OSHA made this revision because the proposed provision, in combination with paragraph (k)(2)(i)(A), may not have resulted in timely medical examinations for new employees who are not exposed to beryllium concentrations above the action level every day. For example, a new employee exposed to beryllium once per week would not receive a

medical examination until being employed for up to 34 weeks. As noted below, several stakeholders commented that a medical exam should be offered before or within 30 days of placement (*e.g.,* Document ID 1664, p. 7; 1685, p. 4, 1689, p. 13). OSHA agrees that a medical examination should be conducted shortly after placement to allow the employee to find out if he or she has any condition that may make him or her more sensitive to beryllium exposure. For these reasons, paragraph (k)(1)(i)(A) of the final standards require that employers make medical surveillance available to each employee who is or is reasonably expected to be exposed above the action level for more than 30 days per year.

The proposal's ''regulated area'' trigger corresponded to setting the trigger at the PEL, and so has been superseded by the final rule's action level trigger. The elimination of the ''regulated area'' trigger may also affect whether employees exposed above the short-term exposure limit (STEL) receive medical surveillance. As noted above and discussed extensively in the Summary and Explanation for paragraph (e), the proposed standard defined the term ''regulated area'' to mean an area that the employer must demarcate, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's exposure exceeds, or can reasonably be expected to exceed, either of the permissible exposure limits (PELs). Proposed paragraphs (c) and (e) made clear that this definition included both the proposed 8-hour TWA PEL and the proposed STEL. Because the revised trigger in final paragraph (k)(1)(i)(A) focuses on the action level, rather than working in a regulated area, it does not directly require medical surveillance for employees who are exposed above the STEL, provided their airborne exposure levels do not exceed the action level for more than 30 days per year.

However, as explained in Chapter IV–Section 15 of the Final Economic Analysis and discussed in the Summary and Explanation for paragraph (c), Permissible Exposure Limits (PELs), the occurrence of one or more short-term exposures to elevated airborne concentration during a work shift can substantially increase a worker's 8-hour TWA exposure. For example, the TWA exposure of a worker who is exposed to a background level at the final action level of 0.1 μg/m^3 will be 0.16 μg/m^3 if that worker is exposed to a single 15-minute period at an exposure level just above 2.0 μg/m^3, the final STEL. Therefore, OSHA finds that the revised action level trigger will frequently address the STEL component of the proposed trigger because when exposures exceed the STEL, it is very likely that the action level will also be exceeded, thus triggering medical surveillance.

Signs or Symptoms. Proposed paragraph (k)(1)(i)(B)) required employers to ''make medical surveillance as required by this paragraph available'' to each employee showing signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue. As OSHA explained in the proposal, a sign-or-symptoms trigger is necessary, in part, because beryllium sensitization and CBD could develop in employees who are especially sensitive to beryllium, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests. A signs-or-symptoms trigger was also included in the draft standard submitted by Materion and USW (Document ID 0754).

One commenter, ORCHSE, argued that a symptom trigger should only apply to confirmed positive, *i.e.,* sensitized, employees because the types of symptoms listed are non-specific for CBD and would require employers to offer medical surveillance to employees who were never exposed to beryllium (Document ID 1691, Attachment 1, pp. 5–6). However, the majority of the stakeholders who opined on the signs-or-symptoms trigger supported its inclusion in the final rule. For example, NJH, ATS, and NIOSH supported a symptom trigger for medical surveillance (Document ID 1664, p. 4, 8; 1688, p. 3; 1725, p. 32). ACOEM and NJH indicated that skin symptoms should trigger medical examinations for employees exposed to beryllium (Document ID 1664, p. 4; 1685, p. 4). NJH and ACOEM also offered examples of specific symptoms or signs of skin disease, including rashes or nodules and dermatitis that is unresponsive to treatment but responsive to removal from exposure (Document ID 1664, pp. 4, 8; 1688, p. 3; 1725, p. 32). In addition, United Kingdom defense contractor, AWE, indicated that it allows its employees with ''insignificant likelihood of exposure'' to undergo a medical examination if they report symptoms (Document ID 1651, p. 10).

After carefully considering these comments, OSHA reaffirms its preliminary finding that the proposed signs-or-symptoms trigger serves as a valuable complement to the use of airborne exposure triggers as a mechanism for initiating medical surveillance. A signs-or-symptoms trigger is appropriate for employees covered by the standard because the risk of material impairment of health remains significant at the action level (see Section VI, Risk Assessment). Consequently, even employees exposed at the action level for fewer than 30 days in a year may be at risk of developing CBD and other beryllium-related diseases and adverse health effects. In addition, beryllium sensitization and CBD could develop in employees who are especially sensitive to beryllium, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests. By requiring covered employers to make a medical exam available when an employee exhibits signs or symptoms, the final standard protects all employees who may have developed CBD, including employees who have been exposed to beryllium in an emergency or for less than 30 days above the action level.

OSHA also finds that signs or symptoms of beryllium-related health effects other than CBD should also trigger medical surveillance (see Section V, Health Effects). As noted by NJH and ACOEM, these signs or symptoms can be indicative of beryllium-related skin disease or a sign of exposure that could lead to sensitization. For example, dermatitis that is unresponsive to treatment but responsive to removal from exposure may be a sign of a beryllium-related health effect. Other skin symptoms, such as reddened, elevated or fluid-filled lesions following contact with soluble beryllium compounds and ulceration or granulomas from soluble or poorly soluble beryllium compounds entering through cuts or scrapes, can also be a sign of a beryllium-related health effect (See Section V, Health Effects). Therefore, OSHA has revised paragraph (k)(1)(i)(B) to include signs or symptoms of other beryllium-related health effects.

OSHA disagrees with ORCHSE's recommendation that the final standards apply this trigger only to employees who have been confirmed positive, *i.e.,* are sensitized, for several reasons. First, limiting the sign-or-symptoms trigger in this way could prevent sensitized employees from finding out that they are sensitized. For example, as noted above, individuals who are genetically predisposed can develop beryllium sensitization and CBD at beryllium levels that would not cause disease in other individuals. Such an employee could conceivably become sensitized and develop CBD without meeting the action level or 30-day exposure trigger. Because this hypothetical employee would not otherwise be entitled to

medical surveillance, he or she might not know that they are sensitized. If this employee began suffering from signs or symptoms of CBD, he or she would not be entitled to medical surveillance under ORCHSE's proposal, precisely because they are not entitled to the BeLPT that would detect sensitization and then entitle them to further medical surveillance.

Second, as discussed in more detail below, under the final standards, employers do not automatically find out whether their employees have been confirmed positive. If an employee chooses not to inform his or her employer of this fact, the employer may never find out. See paragraphs (k)(6) and (k)(7) of the final standards.

Third, OSHA recognizes that signs and symptoms associated with adverse health effects of beryllium such as CBD and skin sensitization may be non-specific (*i.e.,* they may be caused by factors other than beryllium exposure). However, it is important to realize the context in which signs and symptoms are expected to be used in medical surveillance. Signs and symptoms are generally expected to be self-reported by employees who could potentially be exposed to beryllium and as such are not intended to serve as a means for diagnosing adverse health effects or determining their causality. Rather, they serve as a useful signal that an employee may be suffering from a beryllium exposure-related health effect. Once these signals are recognized, the employee should be offered medical surveillance and see a PLHCP who can, with sufficient information about the employee's duties, potential exposures, and medical and work histories (as required by this standard and discussed later), make determinations about the beryllium-related effects, provide medical treatment, and make other referrals or recommendations where necessary.

However, ORCHSE's comment does raise the concern that the non-specific signs and symptoms listed in the proposal, *i.e.,* shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue, might cause the employer to offer medical surveillance to employees experiencing signs or symptoms that are not related to beryllium exposure. OSHA understands that many of these non-specific symptoms can have various causes unrelated to beryllium exposure. For example, a dry cough could be related to a respiratory infection or allergies. On the other hand, the symptoms listed in the proposal can also be symptoms of CBD where they are recurring or persistent. Therefore, OSHA has removed the specific examples of signs or symptoms of CBD that were included in the proposal. OSHA finds that removing these examples makes it less likely that this will be misinterpreted to require medical surveillance for employees experiencing signs or symptoms not related to beryllium exposure. OSHA also clarifies that signs or symptoms that are indicative of CBD or other beryllium-related effects are typically persistent or recurring.

Finally, OSHA emphasizes that although this provision requires employers to offer medical surveillance if persistent or recurring symptoms related to CBD or other beryllium-related health effects are reported to or observed by the employer (*e.g.,* if an employee ''shows'' a persistent cough), it is not intended to force employers to survey their workforce, make diagnoses, or determine causality. Self-reporting by employees is supported by the training required under paragraph (m)(4)(ii) on the health hazards of beryllium and the signs and symptoms of CBD, and the medical surveillance and medical removal requirements of the final standard in paragraphs (k) and (l). Section 11(c) of the OSH Act gives employees the right to report suspected work-related health effects and prohibits employers from retaliating against employees for exercising this right. Separately, OSHA's Recordkeeping Rule gives employees the right to report work-related illnesses such as CBD or other beryllium-related health effects, and Section 1904.35(b)(1)(iv) of that rule prohibits retaliation against employees for reporting these health effects.

Emergencies. Proposed paragraph (k)(1)(i)(C) required employers to offer medical surveillance to employees exposed during an emergency. Although an emergency trigger for medical surveillance was not included in the joint draft recommended standard by Materion and USW, none of the comments on the proposal objected to its inclusion in the final rule (Document ID 0754). At least one commenter, NJH, supported a trigger for employees exposed in an emergency (Document ID 1664, p. 4).

OSHA agrees with NJH that such a trigger is appropriate because emergency situations involve uncontrolled releases of airborne beryllium, and the significant exposures that can occur in these situations justify a requirement for medical surveillance. Therefore, OSHA has decided to include this provision as part of the final standards in paragraph (k)(1)(i)(C). As in the proposal, medical surveillance triggered by airborne exposures in emergency situations must be offered regardless of the airborne concentrations of beryllium to which these employees are routinely exposed in the workplace. The requirement for medical examinations after airborne exposure in an emergency is consistent with several other OSHA health standards, including the standards for Chromium (VI) (29 CFR 1910.1026), Methylenedianiline (29 CFR 1910.1050), 1,3-Butadiene (29 CFR 1910.1051), and Methylene Chloride (29 CFR 1910.1052).

Periodic medical surveillance. As noted above, OSHA asked stakeholders to opine on which employees should be included in medical surveillance and, as discussed in more detail below, on the appropriate frequency for examinations (*e.g.,* 80 FR 47574, 47541). Several stakeholders, including Ameren Corporation (Ameren), NSSP, and ATS, submitted pre-hearing comments supporting the provision of continuing medical surveillance to employees who are confirmed positive (Document ID 1675, p. 16; 1677, p. 6; 1688, p. 3). For example, ATS commented that once an employee is sensitized, continued medical surveillance should be offered to determine if progression to CBD occurs (Document ID 1688, p. 3). Similarly, Ameren commented that sensitized employees should have the opportunity for further surveillance based on the recommendations of a pulmonologist (Document ID 1677, p. 6).

OSHA agrees that an employee who is confirmed positive should continue to receive medical surveillance to determine if progression from sensitization to CBD occurs and to monitor the severity of disease if progression does occur. As discussed below, the standards provide for medical surveillance every 2 years in certain cases, such as when the employee continues to be exposed above the action level for more than 30 days a year, when the employee continues to have signs or symptoms of CBD or other beryllium-related health effects, or when an employee is exposed to beryllium during an emergency. However, under these first three triggers, periodic surveillance would end if an employee no longer met those triggers. Thus, an employee who was confirmed positive and no longer meets these triggers might not qualify for medical surveillance again until he or she develops signs or symptoms of disease. This gap in coverage is especially concerning considering the potentially long lag time between sensitization and the development of CBD and the benefits of early detection (see Section V, Health Effects).

To allow for continued medical surveillance to this limited group of high risk employees who would not otherwise be eligible for periodic examinations, OSHA has added final paragraph (k)(1)(i)(D), which requires that medical surveillance be made available when the most recent written medical opinion to the employer recommends continued medical surveillance. Under final paragraphs (k)(6) and (k)(7), the written opinion must contain a recommendation for continued periodic medical surveillance if the employee is confirmed positive or diagnosed with CBD, and the employee provides written authorization. Under these provisions, the employer will only receive the recommendation for continued periodic medical surveillance with the employee's written consent. However, even where the employee provides his or her written consent, the written opinion must not include any specific findings or diagnoses that led to the recommendation for continued surveillance. Instead, the licensed physician or CBD diagnostic center's written opinion would simply recommend continued periodic medical surveillance. As discussed in more detail below, OSHA chose this method to convey the need for continued medical evaluations for employees who are confirmed positive or diagnosed with CBD, while protecting the employee's privacy by not revealing to the employer the specific finding that triggered the recommendation for continuing medical examinations.

OSHA notes that although this requirement was not included in either the proposed standard or the joint draft recommended standard by Materion and USW (Document ID 0754), proposed paragraph (k)(1)(i)(D) (discussed below) would have allowed for limited medical surveillance (*i.e.,* low dose computerized tomography (LDCT)) for certain high risk individuals.

Low dose computerized tomography (LDCT). The proposal included a trigger to provide LDCT to some employees who met certain criteria regarding exposure levels, exposure duration, and age. The requirement is now included under paragraph (k)(3)(ii)(F) as a test that can be selected by the PLHCP for employees based on certain risk factors. A full discussion of LDCT scans and the reasons for this change is included below under the discussion of medical examination contents.

Licensed physicians. Proposed paragraph (k)(1)(ii) required that the employer ensure that all medical examinations and procedures required by the standard are performed by or under the direction of a licensed physician. OSHA chose to require licensed physicians, as opposed to the broader category of PLHCPs, to oversee medical surveillance in this standard, and to provide certain services required by this standard (see, *e.g.,* proposed paragraphs (k)(1)(ii) and (k)(5)). OSHA has in the past allowed a PLHCP to perform all aspects of medical surveillance, regardless of whether the PLHCP is a licensed physician (see OSHA's standards regulating Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053)). As explained in the NPRM, OSHA proposed that a licensed physician perform some of the requirements of paragraph (k) in response to Materion and USW's 2012 joint draft recommended standard (80 FR 47797). OSHA preliminarily found that this requirement struck an appropriate balance between ensuring that a licensed physician supervises the overall care of the employee, while giving the employer the flexibility to retain the services of a variety of qualified licensed health care professionals to perform certain other services required by paragraph (k). However, the Agency specifically requested stakeholder comment on this proposed requirement (80 FR 47575, 47797).

OSHA received comments on this subject from a variety of stakeholders, including public health officials and representatives from industry and labor. ATS stated that due to the complex nature of CBD and sensitization, including multi-organ involvement and atypical presentations, all medical procedures should be carried out by or under the direction a licensed physician (Document ID 1688, p. 4). Similar support for medical procedures to be carried out by or under the direction of a licensed physician was expressed by NJH, Ameren, NSSP, NIOSH, and ACOEM (Document ID 1664, p. 8; 1675, p. 18; 1677, p. 7; 1755, Tr. 27; 1756, Tr. 82). Materion commented that in the joint draft recommended standard, Materion and USW intended for a licensed physician to perform certain critical aspects of medical surveillance such as diagnosis and preparation of the written medical opinion (Document ID 1661, Attachment 2, p. 7). NABTU commented that medical and nursing experts supervise medical screening of Department of Energy workers in a program that is administered by the Center for Construction Research and Training (CPWR) (Document ID 1679, p. 10).

OSHA recognizes that the requirement for a licensed physician to provide oversight and some services required under the standard departs from policy in recent standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053). In the recently promulgated Respirable Crystalline Silica standard, OSHA allowed medical services to be provided by a PLHCP, defined as an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health services required under the rule (81 FR 16818). To ensure competency while increasing flexibility for employers, OSHA found it appropriate to allow any healthcare professional to perform medical examinations and procedures made available under the standard when he or she is licensed by state law to provide those services. In the case of respirable crystalline silica, such a decision was justified because the record did not provide convincing evidence that such a requirement was not appropriate, and some stakeholders expressed concerns that healthcare professionals might be limited in certain geographical locations (81 FR 16818).

In contrast to the silica rulemaking record, the beryllium rulemaking record shows support for a licensed physician to oversee and perform certain functions of medical surveillance and lacks evidence showing that licensed physicians may be limited in certain areas. As a result, OSHA is requiring in final paragraph (k)(1)(ii) that the employer ensure that all medical examinations and procedures required by the standard are performed by, or under the direction of, a licensed physician. In the case of the beryllium standard, OSHA finds this requirement strikes an appropriate balance between ensuring that a licensed physician supervises the overall care of the employee, while giving the employer the flexibility to retain the services of a variety of qualified licensed health care professionals to perform certain other services required by paragraph (k). Therefore, final paragraph (k)(1)(ii) requires the employer to ensure that all medical examinations and procedures required by the standard are performed by, or under the direction of a licensed physician.

Frequency. Proposed paragraph (k)(2) specified when and how frequently medical examinations were to be offered to those employees covered by the medical surveillance program. Under proposed paragraph (k)(2)(i)(A), employers would have been required to provide each employee with a medical examination within 30 days after

determining that the employee had worked in a regulated area for more than 30 days in the past 12 months, unless the employee had received a medical examination provided in accordance with this standard within the previous 12 months. Under proposed paragraphs (k)(2)(i)(B) employers would have been required to provide medical examinations to employees exposed to beryllium during an emergency, and to those showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees met those criteria.

As noted above, a number of stakeholders supported a baseline examination. For example, ACOEM recommended that the criteria for inclusion in the medical surveillance program be revised to clearly indicate a baseline examination and BeLPT for employees assigned to regulated areas (Document ID 1685, p. 4). Similarly, NABTU and AFL–CIO commented that medical screening of employees should be done before they start working in a beryllium area (Document ID 1679, p. 12; 1689, p. 13). NJH also recommended a BeLPT at the beginning of employment but stated that some of their clients do the exams within 30 days to not influence hiring practices (Document ID 1664, p. 7). Ameren and NSSP commented that 30 days from initial assignment is a reasonable period to provide an examination; however, NSSP recommended a baseline BeLPT at the time of employment, while Ameren indicated that a baseline BeLPT should be at the employer's discretion based on employment history (Document ID 1675, pp. 15–16; 1677, p. 6). These comments run contrary to the proposed requirement allowing employers to withhold offering medical surveillance until after more than 30 days of exposure.

OSHA is persuaded that it is appropriate to trigger medical surveillance within 30 days after making the determinations described in final paragraphs (k)(2)(i)(A) and (B). As a result of changes made to final paragraph (k)(1)(i)(A), the initial exam required under final paragraph (k)(2)(i)(A) is now triggered within 30 days after the employer determines that the employee is or is reasonably expected to be exposed at or above the action level for more than 30 days of year. This revised trigger for medical surveillance in the final beryllium standard is consistent with Ameren and NSSP recommendations to provide an exam within 30 days of initial assignment. OSHA finds that it is a reasonable period to offer medical surveillance because new employees are not likely to experience signs of beryllium exposure during that time, and it provides employers with administrative convenience because it gives them time to make the appointment, in addition to maintaining consistency with most OSHA standards, such as the Respirable Crystalline Silica (29 CFR 1910.1053). In response to Ameren's comment, OSHA acknowledges that an employee who was not previously exposed to beryllium would not be at risk for sensitization. However, an employer may not have a complete occupational exposure history to rule out prior beryllium exposure of the employee, and the employee may not be aware that he or she was exposed. OSHA considers a baseline BeLPT within 30 days of when the employer determines that the employee is reasonably expected to be exposed for more than 30 days a year to be prudent to rule out sensitization in an employee who may have previously been exposed to beryllium unknowingly. Providing a baseline examination is also consistent with the joint draft recommended standard by Materion and USW, which recommended that medical surveillance including a BeLPT be made available to employees who are expected to meet the trigger for medical surveillance (Document ID 0754, pp. 7–8).

Final paragraph (k)(2)(i)(A) also differs from the proposal in that in the proposed paragraph the employer did not have to offer an examination if the employee had received an equivalent examination within the last 12 months. In the final rule, this was increased to two years to align that provision with the frequency of periodic examinations, which is every two years in the final standards. The reason why frequency of periodic examinations was changed from every year to every two years is discussed below. In sum, paragraph (k)(2)(i)(A) requires the employer to make a medical examination available to employees who meet the criteria of paragraph (k)(1)(i)(A), unless the employee received a medical examination provided in accordance with the standard, within the last two years.

As noted above, proposed paragraph (k)(2)(i)(B) would have required employers to provide medical examinations to employees exposed to beryllium during an emergency, and to those who are showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees meet the criteria of proposed paragraph (k)(1)(i)(B) or (C), regardless of whether these employees received an exam in the previous 2 years. OSHA is not aware of any comments from stakeholders about the time period to offer medical examinations following a report of symptoms or exposure in an emergency; however the 30-day requirement to offer medical examinations to employees experiencing signs or symptoms was included in the joint draft proposal by Materion and USW (Document ID 0754, p. 7). Moreover, OSHA finds that the 30-day trigger is administratively convenient for post-emergency surveillance as well as after CBD signs or symptoms (and other beryllium-related effects like rashes) are reported, insofar as it is consistent with other OSHA standards and with other triggers in the beryllium standards. OSHA is therefore retaining paragraph (k)(2)(i)(B), as proposed, in the final rule. Proposed paragraph (k)(2)(ii) would have required employers to provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of proposed paragraph (k)(1)(i)(A) or (B). The Agency requested comment on the frequency of this medical surveillance (80 FR 47574).

Ameren agreed with the proposed frequency of annual examinations, and USW commented that the proposed medical surveillance requirements would allow for timely detection of sensitization and health outcomes (Document ID 1675, p. 16; 1681, p. 13). AWE commented that it offers annual spirometry testing to its employees with ''significant likelihood for exposure'' (Document ID 1615, p. 10). DOD also provides annual medical surveillance for its beryllium-exposed employees (Document ID 1684, Attachment 2, p. 1–5). NIOSH commented that OSHA should require an annual questionnaire for symptoms (Document ID 1725, p. 32). However, other commenters argued that annual surveillance was not routinely required. For example, NJH and ACOEM supported offering medical examinations to eligible employees every two years (Document ID 1664, p. 4; 1685, p. 4); NJH indicated that after initial testing, biennial medical surveillance is adequate to identify any new cases of sensitization that may develop in the workplace. In addition, NJH, NSSP, and NGK were opposed to annual BeLPTs (Document ID 1664, p. 4; 1677, p. 3; 1663, p. 5). ATS and NIOSH recommended examinations every 1 to 3 years for sensitized individuals to determine if progression is occurring (Document ID 1688, p. 3; 1725, pp. 2, 32). Finally, NABTU agreed with the proposed frequency for screening but noted that Department of Energy

workers participating in a medical screening program administered by CPWR are examined every three years (Document ID 1679, pp. 10–12).

After careful consideration of the record on this issue, OSHA agrees with commenters like NJH who recommended that a BeLPT every two years is appropriate. In addition, based on its review of beryllium health effects, which shows that CBD generally progresses slowly (See Section V, Health Effects), the Agency finds that a two-year frequency period is also appropriate for the remaining parts of the medical examinations. This two-year period is consistent with NJH's suggestion to offer medical examinations biennially after the initial exam and with ATS and NIOSH's recommendations for examinations every 1 to 3 years for sensitized individuals. However, OSHA disagrees with NIOSH that a yearly questionnaire for symptoms is needed because the standards already permit employees to receive medical surveillance by self-reporting signs and symptoms of CBD.

To align the requirements for BeLPTs with the medical and work history, the physical examination, and pulmonary function testing, OSHA is requiring that all those components of the examination be offered every two years. OSHA concludes that this approach is more convenient for employers to administer, while maintaining adequate protection of employees. Offering examinations every two years accomplishes the main goals of medical surveillance for employees exposed to beryllium, which are to detect beryllium sensitization before employees develop CBD, and to diagnose CBD and other adverse health effects at an early stage. Requiring examinations to be offered every two years also strikes a reasonable balance between the resources required to provide surveillance and the need to diagnose health effects at an early stage to allow for interventions.

In addition, OSHA finds that it is appropriate to extend the requirement for biennial surveillance under final paragraph (k)(2)(ii) for employees who continue to meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. As discussed above, the recommendation for continued medical surveillance is based on a confirmed positive finding or a diagnosis of CBD. Employees such as those who are confirmed positive benefit from periodic surveillance to determine if sensitization progresses to CBD and monitor possible CBD progression.

Finally, OSHA revised proposed paragraph (k)(2)(ii) to specify that medical examinations were to be made available ''at least'' every two years. This change clarifies OSHA's intent that the employer need not wait precisely two years to make medical surveillance available to employees who continue to meet the criteria of (k)(1)(A), (B), or (D) of this standard.

Under the final standards, employees exposed in an emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the biennial examination requirement unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B), because OSHA expects that most effects of airborne exposure will be detected during the medical examination provided within 30 days of the emergency, pursuant to paragraph (k)(2)(i)(A). This is consistent with the proposal. An exception to this is beryllium sensitization, which OSHA finds may result from exposure in an emergency, but may not be detected within 30 days of the emergency. OSHA received no comments on this issue. To address possible delayed sensitization in employees exposed in an emergency, final paragraph (k)(3)(ii)(E) requires biennial BeLPTs for employees who have not been confirmed positive, including those exposed in emergencies. This paragraph is discussed in more detail later in this section of the preamble.

Proposed paragraph (k)(2)(iii) required the employer to offer a medical examination at the termination of employment, if the departing employee met any of the criteria of proposed paragraphs (k)(1)(i)(A), (B), or (C) at the time the employee's employment was terminated. This proposed requirement was waived if the employer provided the departing employee with an exam during the six months prior to the date of termination. OSHA explained that the provision of an exam at termination was intended to ensure that no employee terminates employment while carrying a detectable, but undiagnosed, health condition related to beryllium exposure (80 FR 47798). A similar provision was included in the draft joint recommended standard by Materion and USW (Document ID 0754, p. 8).

Commenters generally supported the inclusion of this provision in the final standard. NJH and NSSP agreed with the proposed requirement to perform a BeLPT at the time of termination and Ameren stated that a BeLPT is not needed if the employee was tested within the last six months (Document ID 1664, p. 7; 1675, p. 16; 1677, p. 6). However, NABTU indicated that the BeLPT need not be repeated if the employee's last test was done within the previous 60 days because the experience of their medical professionals indicates that a different test result is unlikely to occur within that time period (Document ID 1805, Attachment 1, p. 5). After considering these comments, OSHA reaffirms its preliminary decision to require employers to make medical surveillance available at the time of termination to eligible employers. Final paragraph (k)(2)(iii) requires the employer to make a medical examination available to each employee who meets the criteria of final paragraph (k)(1)(i)—the action level/30-day-exposure based trigger, shows signs or symptoms of CBD, or is exposed during an emergency—at the termination of employment, unless the employee received an exam meeting the requirements of the standards within the last 6 months. OSHA also finds that it is appropriate to extend the requirement to employees who meet the criteria of final paragraph (k)(1)(i)(D), *i.e.,* each employee whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance. Like the other employees covered by this provision, those employees could potentially have beryllium-related disease that was not present or detectable at their last examination or that has advanced.

As indicated in the proposal, OSHA finds that providing a BeLPT at the time of termination, unless the employee was tested within the last six months or the employee was confirmed positive, is important to ensure that no employee is unknowingly sensitized at the time he or she leaves the job. In addition, OSHA finds that the other components of the examination, such as a medical and work history, the physical examination, and lung function testing are also important to determine if an employee may have developed physical signs of disease or if existing disease may have progressed since the last examination. OSHA disagrees with NABTU that another BeLPT should be conducted if the employee's last BeLPT was done more than two months ago. Requiring another BeLPT if the employee has not had one within the past six months is an abundantly cautious approach considering that public health officials, such as NJH, recommend a BeLPT every two years, since that time period is considered adequate to identify any new cases of sensitization that may develop in the workplace (Document ID 1664, p. 4). Therefore, OSHA concludes that

offering a BeLPT at termination, if the employee has not had one in the past six months, is an approach that adequately protects the employee's health.

Contents of Examination. Proposed paragraph (k)(3) detailed the contents of the examination. Proposed paragraph (k)(3)(i) required the employer to ensure that the PLHCP advised the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination. As OSHA explained in the proposal, the benefits of participating in medical surveillance may include early detection of adverse health effects, and aiding intervention efforts to prevent or treat disease. However, there may also be risks associated with medical testing for some conditions, such as radiation risks from CT scans for lung cancer (80 FR 47798). The employer must make sure the PLHCP communicates those risks to the employee. This requirement was included in the draft proposed rule submitted to the Agency by Materion and USW (Document ID 0754, p. 8). In the absence of public comments on this issue, the requirement remains substantively unchanged from the proposal in final paragraph (k)(3)(i). OSHA did, however, make one minor change to clarify the intent of this provision. Under the final standards, the PLHCP who advises the employee must be the PLCHP who is conducting the examination. Proposed paragraphs (k)(3)(ii)(A)–(D) specified that the medical examination must consist of: A medical and work history, with emphasis on past and present exposure, smoking history, and any history of respiratory dysfunction; a physical examination with emphasis on the respiratory system; a physical examination for skin breaks and wounds; and a pulmonary function test, performed in accordance with guidelines established by the American Thoracic Society including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV_1). Exam contents under the proposal also included a standardized BeLPT and, in some cases, a computerized tomography (CT) scan, both of which are discussed in more detail below. OSHA asked for comment on the contents of the medical surveillance exam in the proposal (80 FR 47574). Among other things, the Agency asked whether the required tests were appropriate, if additional tests should be included, and whether the skin should be examined for signs and symptoms of beryllium exposure or other medical issues, as well as for breaks and wounds. Stakeholders from the medical community and industry responded to OSHA's request for comment on the proposed contents for medical examinations. Ameren, NSSP, and NABTU agreed with the tests that OSHA proposed, including skin examinations (Document ID 1675, p. 16; 1677, p. 6; 1679, p. 12). ORCHESE was opposed to examining the skin for wounds and breaks because although skin injuries could allow for increased beryllium absorption, they are temporary conditions that could heal within days, thus making the finding observed during the exam irrelevant (Document ID 1691, Attachment 1, p. 7). NIOSH and ATS supported medical and work histories or questionnaires, but neither they nor NJH supported routine physical examinations and lung function testing of beryllium exposed employees (Document ID 1664, p. 8; 1688 p. 3; 1725, p. 32). ATS and NIOSH commented that physical examinations and lung function testing are not effective for identifying sensitization or CBD. NJH recommended that physical examinations and pulmonary function tests be offered to employees who do not have CBD but are experiencing symptoms, while NIOSH said that required tests should be determined by the PLHCP, based on responses to the questionnaire. Lung function (spirometry) testing is the only type of examination that AWE routinely does on its employees with ''significant likelihood for exposure'' (Document ID 1615, p. 10). DOD includes a history, physical exam, a chest X-ray, and spirometry in its surveillance program, and agreed that the skin should be examined (Document ID 1684, Attachment 2, p. 1–5). 3M agreed that an employee's fitness to wear a respirator should be evaluated, but they argued that incorporating requirements of the medical evaluation under the respiratory protection program (29 CFR 1910.134(e)) would be a better tool for evaluating fitness to wear a respirator than the proposed medical surveillance requirements. In support of this statement, it asserted that pulmonary function tests are a poor predictor for fitness to wear a respirator (Document ID 1625, pp. 3–5).

OSHA recognizes, as ATS, NIOSH, and NJH commented, that physical examinations and lung function testing are not effective for detecting sensitization or CBD. However, OSHA still finds that these tests should be included as part of medical surveillance examinations of beryllium exposed workers because they accomplish important goals of medical surveillance as part of an occupational health program. As indicated above, the major purposes of medical surveillance for beryllium-exposed employees go beyond identifying disease and include identifying conditions that put employees at increased risk from beryllium exposure and determining the employee's fitness to use personal protective equipment such as respirators. The medical examination for beryllium complements the medical evaluation under the respiratory protection program that must still be conducted before an employee is fitted for a respirator or uses the respirator in the workplace (29 CFR 1910.134(e)(1)). Physical examinations and lung function tests are objective measures that are valuable in accomplishing the goals of medical surveillance for beryllium and to determine fitness to use personal protective equipment. For example, listening to heart and lung sounds with a stethoscope and conducting lung function testing might identify an impairment in an employee who is not experiencing symptoms but might be at risk with use of a negative pressure respirator. Such impairments in employees lacking symptoms may not be identified in the medical evaluation for respirator use, which typically involves administering a questionnaire and may not involve an examination. Another example of how the required tests under the beryllium standard accomplish goals of medical surveillance is that an employee who is found to have a loss in lung function can be warned that lung function loss can be compounded if that employee develops CBD.

Skin examinations are also important because skin rashes could be a sign of dermal sensitization or also a sign that exposures that put the employee at risk of becoming sensitized have occurred. However, OSHA agrees with ORCHESE that conditions such as breaks and wounds are temporary and has therefore revised the proposed paragraph so that final paragraph (k)(3)(ii)(C) requires a physical examination for skin rashes, rather than an examination for breaks and wounds. OSHA notes that PLHCPs will nonetheless detect skin injuries during the skin examination, and when doing so can take that as an opportunity to educate the employee on the importance of using protective clothing, because beryllium absorption can be increased through broken skin.

OSHA also revised proposed paragraph (k)(3)(ii)(A), which would have required, among other things, ''a medical and work history, with emphasis on past and present exposure'' so that final paragraph (k)(3)(ii)(A)

includes emphasis on past and present airborne exposure to or dermal contact with beryllium. OSHA added dermal contact to this list because, as noted by NJH and ACOEM, dermal contact can result in skin effects and sensitization (Document ID 1664, p. 5, 1685, p. 3). As discussed in Section V, Health Effects, dermal contact with beryllium can lead to respiratory and dermal sensitization and it is therefore an appropriate factor to consider as part of the medical and work history. With these changes, final paragraphs (k)(3)(ii)(A)–(D) require the medical examination to include: (1) Medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory dysfunction; (2) a physical examination with emphasis on the respiratory system; (3) a physical examination for skin rashes; and (4) a pulmonary function test, performed in accordance with guidelines established by the ATS including forced vital capacity (FVC) and a forced expiratory volume in one second (FEV_1).

Under proposed paragraph (k)(3)(ii)(E), an employee would have been offered a BeLPT or an equivalent test at the first examination, and then at least every two years after the first examination, unless the employee was confirmed positive. As OSHA explained in the preamble to the proposal, the proposed requirement to test for beryllium sensitization was intended to apply whether or not an employee was otherwise entitled to a medical examination in a given year (80 FR 47799). For example, for an employee exposed during an emergency who would have normally been entitled to 1 exam within 30 days of the emergency but not annual exams thereafter, the employer would still have been required to provide this employee with a test for beryllium sensitization every 2 years. OSHA further explained that this proposed biennial requirement would have applied until the employee was confirmed positive. The Agency preliminarily found that the biennial testing required under proposed paragraph (k)(3)(ii)(E) was adequate to monitor employees at risk of developing sensitization while being sufficiently affordable for employers.

The record showed strong support for use of BeLPT, with limited exceptions. NIOSH supported the BeLPT to identify sensitized employees, citing recent evidence that the BeLPT has a sensitivity of 66 to 86% and a specificity of >99%, which it stated is superior or comparable to other common medical screening test (Document ID 1725, pp. 32–33). In responding to comparisons of the BeLPT against World Health Organization (WHO) (Wilson) criteria (see next paragraph), NIOSH concluded that current evidence supports the use of the BeLPT to benefit both the individual employee and to identify improvements that could be made in work areas to prevent other workers from becoming sensitized (Document ID 1725, p. 33). BeLPT is also supported by or used in medical screening by medical authorities, unions, and industry stakeholders including Materion, NJH, Ameren, NSSP, USW, ACOEM, ATS, and ORCHSE (Document ID 1661, Attachment 2, pp. 7–8; 1664, p. 4; 1675, p. 16; 1677, pp. 5–6; 1681, p. 25; 1685, p. 4; 1688, p. 3; 1691, Attachment 1, p. 12). Ameren also commented that a BeLPT should be provided for employees diagnosed with sarcoidosis because of the potential for a misdiagnosis of CBD (Document ID 1675, p. 16). USW supported periodic BeLPTs because workers with a history of exposure remain at risk in the future (Document ID 1681, pp. 13–14). NJH supported biennial BeLPTs, which is consistent with the draft joint recommended standard by Materion and USW (Document ID 0754; 1664, p. 4).

In contrast, based on a false positive rate reported in a review done by AWE in 1990, AWE commented that it does not routinely use BeLPT in its medical surveillance program (Document ID 1615, p. 11). DOD did not support the BeLPT, arguing that it has not been shown to meet WHO guidelines as a screening tool (often referred to as the Wilson Criteria, which evaluates factors such as reliability of the assay and its usefulness to identify disease at an early stage in which treatment would be beneficial) (Document ID 1958, p. 8).

After carefully considering these comments, OSHA agrees with NIOSH that the BeLPT is appropriate based on its sensitivity and low false positive rate that is comparable or superior to other screening tests. Unlike DOD, OSHA finds that the BeLPT does meet a number of the Wilson criteria because it is an acceptable, reliable test that allows for a serious disease to be diagnosed at an early stage, when employees with symptoms could benefit from treatment, or in the case of occupational exposures, interventions such as removal from exposure. OSHA agrees with Ameren that a BeLPT is an important component for diagnosing lung disease in beryllium-exposed employees to prevent a misdiagnosis. And OSHA reaffirms that it is important to conduct the BeLPT at least every two years to screen for beryllium sensitization, until the employee is confirmed positive. As in the proposal, the biennial requirement to test for beryllium sensitization applies regardless of whether an employee is otherwise entitled to a medical examination in a given year. OSHA concludes that this continuing requirement is important because sensitization can occur after exposures end.

OSHA finds that in general, the biennial testing required under paragraph (k)(3)(ii)(E) is adequate to monitor employees that have the potential to develop sensitization while being sufficiently affordable for employers. However, one change to this provision compared to the proposed standard is to allow the test to be offered ''at least'' every two years, rather than every two years as proposed. This change clarifies OSHA's intent that the employer need not wait precisely two years to make the BeLPT available to employees.

Final paragraph (3)(ii)(E) contains a number of other differences compared to the proposed requirements. Consistent with the definition in the proposed standards, the proposed paragraph considered two abnormal test results necessary to confirm a finding of beryllium sensitization when using the BeLPT (''confirmed positive''). Therefore, the proposal would have required that the BeLPT be repeated within one month of an employee receiving a single abnormal result. As discussed in more detail in the Summary and Explanation for paragraph (b), Definitions, commenters including ACOEM and ATS indicated that retesting should also be done following borderline BeLPT results, and as ACOEM noted, one borderline and one positive test or three borderline tests have a high predictive value for sensitization (Document ID 1685, p. 4; 1688, p. 2). In response to such comments, OSHA changed the definition of confirmed positive to two abnormal test results, an abnormal test result and a borderline test result, or three borderline test results. Therefore, to make this paragraph consistent with the revised definition, the text was changed to indicate that a follow-up BeLPT must be offered within 30 days for results that are ''other than normal'' unless the employee has been confirmed positive. This language makes it clear that not only abnormal BeLPT results, but also borderline BeLPT results must be followed up according to the definition for confirmed positive. When an other than normal result is obtained, testing is to be repeated within 30 days, unless the employee is confirmed positive. This means that follow-up can stop as soon as it is determined that the

employee is confirmed positive (*e.g.,* after receiving an abnormal and borderline test or three borderline tests).

The proposed paragraph indicated that the requirement for a repeat BeLPT was waived if a more reliable and accurate test were to become available that could confirm beryllium sensitization based on one test result. OSHA requested comments on the availability of more reliable and accurate tests than the BeLPT for identifying beryllium sensitization (80 FR 47575). ORCHSE took issue with the statement that retesting would not be required if a more reliable and accurate test became available that could confirm beryllium sensitization based on one test result. It interpreted the statement to mean that an employee who tested positive would not receive a second BeLPT or second test that is more reliable and accurate than the BeLPT, leaving the employee with only one abnormal test that was unconfirmed (Document ID 1691; Attachment 1, pp. 7–8).

To streamline the paragraph and avoid misunderstandings of the Agency's intent, OSHA removed the language waiving a second confirmatory test if a more accurate and reliable test became available that did not require retesting for confirmation of sensitization. Instead, final paragraph (k)(3)(E) requires a standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. This revision clarifies that only other than normal BeLPT results must be followed up within 30 days. Because the paragraph refers to follow-up testing for other than normal ''BeLPT'' results, the requirement would not apply to a more accurate and reliable test that would not require an abnormal result to be confirmed.

OSHA acknowledges that the ''more accurate and reliable'' alternative remains hypothetical as there are currently no tests for beryllium sensitization that allow for a confirmed diagnosis of sensitization based on one test. However, if developed and validated as described below, such a test would be an improvement because it would eliminate the need for an employee to go back to have blood drawn a second and possible third time. OSHA's intent was to allow the current BeLPT requirement to be replaced with a more accurate and reliable test that would not require retesting to confirm sensitization, if such a test were ever developed. To clarify the Agency's intent, final paragraph (k)(3)(ii)(E) now specifies that a standardized BeLPT ''or equivalent test'' is to be offered. OSHA considers an ''equivalent test'' to be a test that would accurately identify sensitization based on one test result. Thus, the original intent of that requirement is unchanged, but OSHA clarifies that an ''equivalent test'' could also be a validated test that is superior to the BeLPT for other reasons. For example, NJH commented that alternative tests to the BeLPT are being developed that could require less blood and less sample manipulation and provide earlier results (Document ID 1664, p. 9).

NJH commented on validating tests for beryllium sensitization that might be superior to a BeLPT (Document ID 1664, p. 9). It noted that validation could occur in a College of American Pathologists (CAP)/Clinical Laboratory Improvement Amendments (CLIA) laboratory. Once the assay is determined to be robust and reproducible, clinical validation should then be performed using samples from patients known to be sensitized and from unexposed controls. OSHA agrees and as explained in the Summary and Explanation for paragraph (b), Definitions, before any test could be considered ''equivalent'' to a BeLPT for identifying sensitization but based on a single test result, the test must undergo rigorous validation to ensure that it has comparable or increased sensitivity, specificity, and positive predictive value within one test result than the BeLPT. OSHA also recommends that before any test for sensitization is considered equivalent to a BeLPT, it should be widely accepted by authoritative sources, such as CDC/NIOSH, ACOEM, and ATS, based on the validation criteria described above. Such an approach is conceptually consistent with that in the draft recommended standard by Materion and USW that required the CDC to approve a more reliable test that could eliminate the need to confirm a positive finding. The joint draft recommended standard by Materion and USW required that the BeLPT be performed in a laboratory licensed by the CDC (Document ID 0754). In contrast, OSHA's proposed provision did not require that a BeLPT be conducted by a laboratory that was licensed or accredited. OSHA requested comment on whether testing should be performed by a laboratory accredited by an organization such as CLIA (80 FR 47575).

Commenters including NJH, Ameren, NSSP, Materion and USW, ACOEM, and ORCHSE supported the inclusion of a requirement that laboratories performing BeLPT be accredited by CAP and/or CLIA (Document ID 1664, pp. 8, 9; 1675, p. 19; 1677, p. 7; 1680, p. 7; 1685, p. 5; 1691, Attachment 1, p. 13). For example, NJH commented that a CAP/CLIA certification represents the standard for oversight for clinical testing to ensure proper quality control and testing (Document ID 1664, p. 9). ACOEM further added that those laboratories should undergo periodic proficiency testing (Document ID 1685, p. 5). Materion and USW also recommended that all laboratories that conduct BeLPT have a standard procedure and algorithm and that their BeLPT be approved by the FDA, but that these issues should not delay promulgation of the rule (Document ID 1680, p. 7). However, NJH indicated that while it would be preferable, standardization of interpretation algorithms across laboratories is challenging because it is influenced by many variables such as serum and reagent lots, sample quality, use of round versus flat bottomed plates, and technician skill (Document ID 1664, p. 8). NSSP commented that all current BeLPT laboratories have certifications from CAP and/or another accreditation organization approved under CLIA and have participated in inter-laboratory split specimen testing (Document ID 1677, p. 7).

After reviewing these comments and the remainder of the record on this issue, OSHA is convinced that requiring that the BeLPT be conducted by CAP/CLIA-certified laboratories would improve quality of BeLPT results. Based on comments from NSSP, all laboratories conducting BeLPTs are currently accredited. OSHA therefore finds that accredited laboratories are currently available and including such a requirement in the standards would not delay promulgation of the rule. The Agency also finds that CAP/CLIA certification helps improve proficiency in terms of obtaining accurate results that are appropriately interpreted and ensures that quality control procedures are followed. Therefore, to improve the accuracy and reliability of BeLPTs, the standards require that samples be analyzed by a laboratory certified under CAP/CLIA guidelines to perform the BeLPT.

As a result of the changes discussed above, final paragraph (k)(3)(E) specifies that the examination must include a standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be

offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed by a laboratory certified under the College of American Pathologists (CAP)/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

Proposed paragraph (k)(3)(ii)(F) would have required a CT scan to be offered to employees who had been exposed to beryllium at concentrations above 0.2 μg/m³ for more than 30 days in a 12-month period for 5 years or more. As OSHA explained in the preamble, the five years of exposure did not need to be consecutive (80 FR 47799). As with the requirement for sensitization testing explained above, the CT scan would have been required to be offered to an employee who met the criteria of paragraph (k)(1)(i)(D) without regard to whether the employee was otherwise required to receive a medical exam in a given year. OSHA explained that the CT scan would have been offered to employees who met the criteria of paragraph (k)(1)(i)(D) for the first time beginning on the start-up date of this standard, or 15 years after the employee's first exposure to beryllium above 0.2 μg/m³ for more than 30 days in a 12-month period, whichever was later. OSHA proposed the requirement for CT screening based in part on the Agency's consideration of the draft recommended standard submitted by industry and union stakeholders (Document ID 0754, p. 8).

OSHA requested comment on the proposed CT scan requirements, as part of the content of the medical examinations (80 FR 47574). In addition, OSHA asked stakeholders to opine on two regulatory alternatives related to CT scans: (1) Regulatory Alternative #18, which would have dropped the CT scan requirement from the proposed rule, and (2) Regulatory Alternative #19, which would have increased the frequency of periodic CT scans from biennial to annual scans (80 FR 47571).

A number of stakeholders responded to the Agency's request for comments on the proposed CT scan requirements. Two such commenters, Public Citizen and NJH, referenced criteria for low-dose CT lung cancer screening set forth by the U.S. Preventive Services Task Force (USPSTF), an independent, volunteer panel of national experts in prevention and evidence-based medicine (Document ID 1664, p. 4; 1964, p. 4). In December, 2013, the USPSTF recommended annual screening for lung cancer with LDCT for adults aged 55 to 80 years with a 30-pack-year smoking history and who either currently smoke or have quit within the past 15 years. Under USPSTF's criteria, screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery (Moyer *et al.,* 2014, Document ID 1791). The USPSTF recommendation was based on the findings of the National Lung Cancer Screening Trial (NLST), which was a large study of the effectiveness of using x-ray and LDCT screening for early detection of lung cancer.

The NLST enrolled asymptomatic men and women (n = 53,454), aged 55 to 74, that were current smokers or former smokers within the last 15 years and had a smoking history of at least 30 pack-years. The participants underwent annual lung cancer screening with either LDCT or chest radiography for three years. The results showed a statistically significant 20-percent relative reduction in lung cancer mortality with LDCT screening (Aberle, *et al.,* 2011, Document ID 1701). However, the trial also showed that LDCT screening results in a high false-positive rate; 24.2 percent of the total LDCT screening tests were classified as positive, with 96.4 percent of these positive results ultimately being false positives. In addition, 39.1 percent of the 26,722 (or about 10,450) participants in the LDCT screening group had at least one positive screening result out of three LDCT scans during the study (Alberle, *et al.,* 2011, Document ID 1701). Given that only 649 cancers were diagnosed after a positive screening test, and assuming that each of these cancers was in a different participant, it follows that only 6.2 percent of those with at least one positive test were ultimately diagnosed with lung cancer. This means that 36.7 percent of participants in the LDCT screening group had at least one false positive result. Most positive initial screening results in the NLST—many of which were false positives—were followed up with a diagnostic evaluation that included further imaging and, infrequently, invasive procedures (Alberle, *et al.,* 2011, Document ID 1701).

Given these findings, the USPSTF noted, in its recommendation for lung cancer screening for high-risk individuals, the importance of shared decision making. The USPSTF advised:

> Shared decision making is important for the population for whom screening is recommended. The benefit of screening varies with risk because persons who are at higher risk because of smoking history or other risk factors are more likely to benefit. Screening cannot prevent most lung cancer deaths, and smoking cessation remains essential. Lung cancer screening has substantial harms, most notably the risk for false-positive results and incidental findings that lead to a cascade of testing and treatment that may result in more harms, including the anxiety of living with a lesion that may be cancer. Overdiagnosis of lung cancer and the risks of radiation are real harms, although their magnitude is uncertain. The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms (Moyer, *et al.,* 2014, Document ID 1791, p. 333).

In addition to the USPSTF, several other organizations have recommended similar lung cancer screening protocols for high-risk individuals, including the American Cancer Society, American College of Chest Physicians, American Society of Clinical Oncology, American Lung Association, National Comprehensive Cancer Network, and the American Association for Thoracic Surgery. Each organization's specific screening recommendations are summarized by the U.S. Centers for Disease Control and Prevention: *http://www.cdc.gov/cancer/lung/pdf/guidelines.pdf.*

With regard to occupational exposure, OSHA is not aware of any definitive recommendations based on a large, well-conducted, randomized, controlled study examining the benefit of lung cancer screening with LDCT among occupationally-exposed workers. In its pre-hearing comments, NIOSH noted that the screened population must be at sufficiently high risk for lung cancer in order to assure that the benefit of LDCT screening for early detection exceeds the harm (Document ID 1671, Attachment 1, p. 8). NIOSH cited a report by the Finnish Institute of Occupational Health (FIOH) that recommended LDCT screening in asbestos-exposed individuals if their personal combination of risk factors, particularly smoking history, yields a risk for lung cancer equal to that needed for entry into the NLST. NIOSH noted that the absolute risk for lung cancer in the NLST and the threshold absolute risk for lung cancer proposed by FIOH as a trigger for LDCT screening was 1.34% over 6 years (Document ID 1671, Attachment 1, p. 8).

OSHA also received comments in the record pointing to the LDCT lung cancer screening recommendations of the National Comprehensive Cancer Network (NCCN), a nonprofit alliance of 27 cancer centers (Document ID 1805, Attachment 1; Document ID 1959). In addition to recommending screening for individuals (current smokers or former smokers that have quit within the last 15 years) who are 55 to 74 years of age

with a smoking history of at least 30 pack-years, the NCCN recommended LDCT screening for individuals age 50 years or older with a smoking history of at least 20 pack-years and with one or more additional risk factors; these risk factors include a history of COPD or pulmonary fibrosis, a history of cancer, a family history of lung cancer, radon exposure, or occupational exposure to the carcinogens asbestos, arsenic, beryllium, cadmium, chromium, nickel, silica, or diesel fumes (Document ID 1815, Attachment 39). Like the USPSTF, NCCN noted that individuals who qualify under these LDCT screening recommendations should engage in shared decision making with their physician and discuss the benefits and harms of LDCT screening for lung cancer (Document ID 1815, Attachment 39).

Thus, the studies and recommendations discussed above indicate that age and smoking history are crucial risk factors that determine when the benefits of LDCT screening are likely to outweigh the risks from radiation exposure and false-positive results. The radiation exposure received from periodic LDCT scans increases the risk of lung and breast cancer, as well as leukemia. Public Citizen estimated the risk of these cancers that could result when workers are screened as described in OSHA's proposed rule (Document ID 1964, pp. 4–6). Public Citizen also estimated the total radiation dose received to range from 900 to 2,400 mrems, depending on age at which screening begins. The excess cancer risks resulting from these exposures, based on Public Citizen's use of the National Academies BIER VII report, ranged from 3.7 to 29.9 deaths per 1,000 workers for solid organ cancers, and from 0.5 to 2.3 deaths per 1,000 for leukemia (Document ID 1964, p. 6). These risk estimates are comparable to OSHA's estimated lung cancer mortality risk resulting from exposure to beryllium at the PEL of 0.2 μg/m^3 over a working life (see Section VI, Risk Assessment). False-positive results carry the risk of additional radiation exposure from repeat scans, as well as unnecessary anxiety for the workers and his or her family, unnecessary invasive procedures that may have risks of medical complications, and unnecessary medical expenses (Document ID 1806, pp. 1–2; 1964, pp. 7–8).

A number of rulemaking participants agreed that the lung cancer risks from beryllium exposure are, for the vast majority of workers, unlikely to be so high that LDCT screening would be beneficial, including NJH, ATS, ORCHSE, NIOSH, Public Citizen, NGK, and the Aluminum Association (Document ID 1664, pp. 1, 4; 1688, p. 2; 1691, Attachment 1, p. 1; 1671, Attachment 1, pp. 8–9; 1964, p. 4; 1663, p. 3; 1666, pp. 3–4). For example, NJH commented that the risk of lung cancer associated with exposure to beryllium at the final rule's PEL of 0.2 μg/m^3 was likely to be lower than that from the radiation exposure received from LDCT screening, particularly for workers under age 50 (Document ID 1664, p. 4). NJH also stated that the majority of beryllium-exposed workers are former smokers and many would not fit the criteria for the USPSTF recommendations (Document ID 1664, p. 4). ORCHSE argued that ''[e]xtrapolation of the results of the non-occupational National Lung Screening Trial for implementation in the occupational setting is premature, and fraught with a number of potential issues and concerns [*e.g.,* over-diagnosis, false positives, radiation dose, follow-on invasive procedures and attendant complications]. The requisite 30 pack-year trigger recommended for screening is associated with risks orders of magnitude higher than that associated with beryllium exposure'' (Document ID 1691, Attachment 1, p. 1). Similarly, in post-hearing comment, Public Citizen remarked that it would be a ''dangerous mistake'' to provide LDCT screening for the majority of non-smoking beryllium-exposed workers who are at low risk for lung cancer and thus would not benefit from such screening (Document ID 1964, p. 10).

The suggestion that beryllium exposure alone would lead to lung cancer risks too low to warrant LDCT screening was illustrated by NIOSH in an analysis of risk information. NIOSH used the mortality study by Schubauer-Berigan *et al.* (2011 b, Document ID 0521) to estimate the exposure levels to beryllium that would result in a risk level at least as high as that suggested by FIOH as a trigger for LDCT screening (*i.e.,* an absolute increased risk of 1.34 percent over a 6-year period). To reach risk levels of this magnitude, NIOSH found that a 40-year-old would have had to have been exposed to a mean daily weighted average exposure of 12 μg/m^3 to achieve a lung cancer risk level sufficient to justify LDCT, and a 50-year-old worker would have had to have been exposed to a mean daily weighted average exposure of 2 μg/m^3, a daily exposure equal to the previous PEL. It was not possible for NIOSH to estimate the required level of beryllium exposure necessary above age 60 to reach a risk level equal to that suggested by FIOH because the background rate of lung cancer already exceeded that level. Although there are uncertainties around the NIOSH estimates (for example, use of 10-year rather than 6-year age intervals, which would understate the required level of beryllium exposure), OSHA finds that the NIOSH analysis demonstrates that LDCT screening would benefit non-smoking workers exposed to beryllium only where the workers were exposed to very high concentrations of beryllium, *i.e.,* levels at and above the previous PEL.

Many of the rulemaking commenters who objected to the proposed requirement for LDCT screening also believed that the absence of any studies showing the effectiveness of LDCT screening on beryllium-exposed workers was further reason not to require LDCT screening based only on a history of beryllium exposure (Document ID 1664, p. 1; 1688, p. 2; 1691, Attachment 1, p. 1; 1756, pp. 123–125; 1806, pp. 1–2). For example, Dr. Newman, who represented ACOEM at the public hearing, in response to a question testified that

> . . . we don't have any data on beryllium—specifically looking at beryllium workers with the cluster of risk factors [*i.e.,* smoking plus Be exposure] that you've described. And I think that absent that it means that there is more of a question mark around . . . how far should OSHA go at this point with low dose CT (Document ID 1756, pp. 124–125).

In contrast to these commenters, inclusion of LDCT screening into the final rule was supported by USW in written comments and at the informal public hearing. Sara Brooks of the USW commented that

> The proposed inclusion of a low dose CT scan as part of medical surveillance is entirely justified. The low dose CT scan can effectively detect lung cancer at an early stage and has been demonstrated to reduce lung cancer mortality among high risk individuals. Since lung cancer is recognized as an outcome caused by beryllium exposure, inclusion of the low dose CT scan in the proposed rule is appropriate (Document ID 1681, Attachment 1, p. 14).

Dr. Steven Markowitz of the City University of New York, testifying on behalf of USW, supported OSHA requiring LDCT screening for beryllium-exposed workers, citing the NLST finding that screening reduced lung cancer mortality by 20 percent. He also noted that

> [t]he use of LDCT is rapidly increasing because of just how common lung cancer is. And this is an effective non-invasive technique. And that there can really [be] a display of leadership by including LDCT now in the proposed medical standard for beryllium (Document ID 1755, Tr. 110).

In post-hearing comment, Dr. Markowitz suggested limiting the proposal's requirement to apply to workers age 50 or more, and pointed out that this was consistent with OSHA's past practice (*i.e.,* medical surveillance requirements under the Cadmium standard, 29 CFR 1910.1027) and with NCCN recommendations (Document ID 1959, p. 1). Second, he argued that the assertion that LDCT should not be included in the rule based on the lack of studies showing efficacy of LDCT on beryllium-exposures workers was ''without merit'' (Document ID 1959, p. 1). He pointed out that many of the risk factors used by the medical community as a basis for recommending LDCT (*e.g.,* family medical history, presence of chronic obstructive lung disease) lack empirical evidence relating the effectiveness of LDCT to the presence of these risk factors. Thus, Dr. Markowitz argued that ''[t]he decision to undergo (by the individual) or to recommend (by the physician) LDCT for lung cancer screening is based on that individual's overall level of risk of lung cancer, not on the particular mix and magnitude of individual risk factors that constitute overall risk'' (Document ID 1959, p. 1). He also argued that because cancers caused by beryllium exposure are similar to the types of lung cancers from other causes, beryllium exposure is not more or less amenable to LDCT screening than are smoking history or other risk factors (Document ID 1959, p. 2). Dr. Markowitz concluded that the absence of studies on beryllium-exposed workers and LDCT screening ''should not be a decisive factor in determining whether LDCT should be included in the final OSHA standard on beryllium.'' (Document ID 1959, p. 3).

OSHA agrees in general that beryllium exposure should be considered as a risk factor when deciding whether LDCT screening is appropriate, and agrees that it is not appropriate to wait for specific studies to be conducted before considering that a history of beryllium exposure should be factored into a decision to undergo LDCT screening. This is, in fact, consistent with the NCCN's criteria for LDCT screening that include occupational exposures along with age, smoking history, and other risk factors. However, LDCT screening is not triggered under these criteria based on occupational exposures and age alone; there must also be a history of smoking (albeit a lower trigger than when considering only age and smoking). As discussed above, there is no evidence in the record that exposure to beryllium alone at the level used in the proposal to trigger LDCT screening results in a cancer risk sufficiently high to warrant LDCT screening.

For the final rule, OSHA considered increasing the threshold of beryllium exposure such that LDCT screening would be triggered at much higher exposures to beryllium (*e.g.,* average exposure above 2 $\mu g/m^3$ for over several years), as was suggested by the NIOSH analysis. OSHA rejected this approach for three reasons. First, as pointed out by ORCHSE (Document ID 1691, Attachment 1, p. 6), it is unlikely that exposure records would be available for many workers to show that the trigger was met, except where workers had long employment tenure with their present employer. Second, establishing such a high exposure trigger for LDCT screening would, in fact, exclude workers with a history of lesser beryllium exposure even when other risk factors are present such that LDCT would be beneficial. Finally, OSHA is reluctant to fix a hard exposure trigger in the standard given that, as pointed out by USW, LDCT technology is likely to advance and increase the efficacy of screening to where screening becomes beneficial for those with lesser risk of lung cancer than is reflected by current recommendations.

Therefore, OSHA concludes that the best approach is to require LDCT screening for beryllium-exposed workers based on the recommendation of the physician conducting or overseeing the medical examination, after all relevant risk factors have been considered, and has accordingly reflected this approach in the final standards. For these reasons, paragraph (k)(3)(ii)(F) of the final standards requires the medical examination to include an LDCT scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, age, sex, and presence of existing lung disease.

The seventh and final item required as part of the medical examination under the proposal was any other test deemed appropriate by the PLHCP. OSHA explained that other types of tests and examinations not mentioned in this standard, including X-ray, arterial blood gas, diffusing capacity, and oxygen desaturation during exercise, may also be useful in evaluating the effects of beryllium exposure (80 FR 47799). In addition, OSHA noted that medical examinations that include more invasive testing, such as bronchoscopy, alveolar lavage, and transbronchial biopsy, have been demonstrated to provide additional valuable medical information. The Agency preliminarily found that the PLHCP was in the best position to decide which medical tests are necessary for each individual examined. Although a requirement for other tests deemed appropriate by the PLCHP was not included in the draft joint recommended standard by Materion and USW (Document ID 0754), similar requirements have been included in previous OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053).

No stakeholders objected to the proposal's requirement that the medical examination include other tests deemed appropriate by the PLHCP. However, some commenters offered examples of tests that might be useful in certain situations. For example, for employees diagnosed with CBD, NJH recommended that the test battery include pulmonary function tests including diffusing capacity, exercise tolerance tests, chest X-ray or CT scan, bronchoscopy with lavage and biopsy, and bronchoalveolar lavage BeLPT (Document ID 1806, p. 12).

After reviewing the comments on this issue, OSHA reaffirms that allowing the PLHCP to select other tests is appropriate because there are no particular tests—beyond those listed in paragraph (k)(3)(ii)(A)–(E)—that are necessarily applicable to all employees covered by the medical surveillance requirements. This provision gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate for individual employees. While the tests conducted under this paragraph are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding related to beryllium exposure or the PLHCP may decide that the test battery needs to be expanded once an employee has been diagnosed with CBD. Although the tests suggested by NJH have been demonstrated to provide additional valuable medical information, OSHA considers the PLHCP to be in the best position to decide if any additional medical tests, especially the more invasive tests, are necessary for each individual examined. Under this provision, if a PLHCP decides another test related to beryllium exposure is medically indicated, the employer must make it available. OSHA intends the phrase ''deemed appropriate'' to mean that additional tests requested by the PLHCP must be both related to beryllium exposure and medically necessary, based on the findings of the medical examination.

Information Provided to the PLHCP. Proposed paragraph (k)(4) detailed which information must be provided to the PHLCP. Specifically, the proposed standard required the employer to ensure the examining PLHCP has a copy of the standard, and to provide to the examining PLHCP the following information, if known to the employer: A description of the employee's former and current duties that relate to the employee's occupational exposure ((k)(4)(i)); the employee's former and current levels of occupational exposure ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that clothing and equipment ((k)(4)(iii)); and information the employer has obtained from previous medical examinations provided to the employee, that is currently within the employer's control, if the employee provides a medical release of the information ((k)(4)(iv)). A similar requirement was contained in the draft joint recommended standard by Materion and USW (Document ID 0754, p. 8). However, Materion and USW's standard did not require written authorization from the employee for the employer to release medical information to the PLHCP. OSHA has included similar provisions, with the exception of the employee's medical release, in previous OSHA standards, such as Chromium (VI) (29 CFR 1910.1026) and Respirable Crystalline Silica (29 CFR 1910.1053).

OSHA did not receive any comments on the proposed requirement to provide information to the PLHCP. Therefore, the Agency is including it in the final standards with three modifications. First, OSHA has updated paragraph (k)(4)(i) to require the employer to provide a description of the employee's former and current duties that relate to both the employee's airborne exposure to and dermal contact with beryllium, instead of merely requiring the provision of information related to airborne exposures, as in the proposal. As indicated above with regard to the medical examination's medical and work history requirements, OSHA finds that this change is appropriate because the record indicates that dermal contact with beryllium can lead to respiratory and dermal sensitization.

Second, OSHA revised the requirement that the employer obtain a ''medical release'' before providing the PLHCP with information from records of employment-related medical examinations. ORCHSE recommended that paragraph (k)(4)(iv) be revised to indicate that the requirement to provide medical information to the PLHCP be waived if the employee refuses to sign a medical release (Document ID 1691, Attachment 1, pp. 10–11). After considering this comment, OSHA finds that a change to the provision is not needed because the employer can demonstrate a good faith effort in meeting this requirement by documenting the employee's refusal to provide a medical release. However, the Agency has chosen to use the phrase ''written consent'' instead of ''medical release'' in the final standards. This non-substantive change brings the language in this provision in line with the language used in final paragraphs (k)(6) and (k)(7), discussed below.

Third, OSHA revised the provision to indicate that the employer must ensure that the same information provided to the PLHCP is also provided to the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard. OSHA made this change because the CBD diagnostic center will need the same information as the PLHCP in order to effectively evaluate the employee.

OSHA concludes that making this information available to the PLHCP and CBD diagnostic center will aid in the evaluation of the employee's health as it relates to the employee's assigned duties and fitness to use personal protective equipment, including respirators, when necessary. Providing the PLHCP and CBD diagnostic center with exposure monitoring results, as required under paragraph (k)(4)(ii), will assist them in determining if an employee is likely to be at risk of adverse effects from airborne beryllium exposure at work and indicate that information in the written medical report for the employee. A well-documented exposure history will also assist the PLCHP in determining if a condition (*e.g.,* dermatitis, decreased lung function) may be related to beryllium exposure.

Written medical reports and opinions. Paragraph (k)(5) of the proposed standard provided for the licensed physician to give a written medical opinion to the employer, but relied on the employer to give the employee a copy of that opinion; thus, there was no difference between information the employer and employee received. The final standards differentiate the types of information the employer and employee receive by including two separate paragraphs within the medical surveillance section that require a written medical report to go to the employee, and a more limited written medical opinion to go to the employer. The former requirement is in paragraph (k)(5) of the final standards; the latter requirement is in paragraph (k)(6) of the final standards. This summary and explanation for those paragraphs first discusses the proposed requirements and general comments received in response during the rulemaking. OSHA then explains in this subsection of the preamble its decision in response to these comments to change from the proposed requirement for a single opinion to go to both the employee and employer and replace it with two separate and distinct requirements: (1) A full report for the employee, which includes medical findings, any recommendations on the employee's use of respirators, protective clothing, or equipment or limitations on airborne exposure to beryllium, and any recommendations for referral to a CBD diagnostic center, continued periodic surveillance, and medical removal; and (2) an opinion for the employer, which focuses primarily on any recommended limitations on respirator, protective clothing, or equipment use, and with the employee's consent, recommendations for referral to a CBD diagnostic center, continued periodic surveillance, and medical removal. The ensuing two subsections will then discuss the specific requirements and the record comments and testimony relating to those specific requirements.

Proposed paragraphs (k)(5)(i)(A)–(C) would have required the employer to obtain from the licensed physician a written medical opinion containing: (1) The licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further airborne exposure to beryllium; (2) any recommended limitations on the employee's airborne exposure to beryllium, including the use and limitations of protective clothing or equipment, including respirators; and (3) a statement that the PLHCP explained the results of the medical examination to the employee, including tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions related to use of protective clothing or equipment. Proposed paragraph (k)(5)(ii) would have required the employer to ensure that neither the licensed physician nor any other PLCHP revealed to the employer specific findings or diagnoses unrelated to airborne beryllium exposure or contact with soluble beryllium compounds. Finally, proposed paragraph (k)(5)(iii) would have required the employer to provide the employee with a copy of the opinion within two weeks of receiving it.

OSHA asked stakeholders to consider what if any information the PLHCP should give to the employer. Specifically, the Agency asked whether it should revise the medical surveillance provisions of the proposed standard to allow employees to choose what, if any, medical information goes to the employer from the PLHCP. For example, OSHA explained, the employer could instead be required to obtain a certification from the PLHCP stating (1) when the examination took place, (2) that the examination complied with the standard, and (3) that the PLHCP provided the licensed physician's written medical opinion to the employee. Such an approach would require the employee to provide written consent for the medical opinion or any other medical information about the employee to be sent to the employer. OSHA asked stakeholders to comment on the relative merits of the proposed standard's requirement that employers obtain the PLHCP's written opinion or an alternative that would provide employees with greater discretion over the information that goes to employers. OSHA also asked that commenters explain the basis for their position and the potential impacts of such an approach (80 FR 47575).

OSHA received a number of comments related to the proposed provisions and the issues raised. Many of these comments related to the proposed contents of the PLHCP's written medical opinion and its transmission to the employer. Some commenters offered suggestions to address privacy concerns regarding the content of the proposed licensed physician's written medical opinion and the proposed requirement that the opinion be given to the employer instead of the employee. For example, David Weissman, M.D., the director of the Respiratory Health Division at NIOSH, objected to providing a specific diagnosis to employers and urged OSHA to adopt a policy consistent with the International Code of Ethics for Occupational Health Professionals established by the International Commission on Occupational Health (Document ID 1725, p. 33; 1815, Attachment 82). The policy recommends reporting only information on fitness for work and medically related limitations to management. NIOSH, AFL–CIO, and NABTU also recommended the ACOEM guidance on confidentiality as a model for the types of information submitted to the employer (Document ID 1679, p. 13; 1689, p. 14; 1725, p. 33). The ACOEM guidelines state:

> Physicians should disclose their professional opinion to both the employer and the employee when the employee has undergone a medical assessment for fitness to perform a specific job. However, the physician should not provide the employer with specific medical details or diagnoses unless the employee has given his or her permission (Document ID 1815, Attachment 60, p. 1).

Exceptions to this recommendation listed under the ACOEM guidelines include health and safety concerns.

Dr. Weissman also expressed concerns about employers' ability to ensure the confidentiality of the medical information obtained from workers (Document ID 1725, pp. 33–34). He argued that if OSHA were to require diagnoses of beryllium sensitization to be shared with employers, provisions would be needed to ensure that sensitive information was protected (Document ID 1725, p. 34). He maintained that ''[s]uch provisions are especially needed because employers are not necessarily covered entities under the Health Insurance Portability and Accountability Act (HIPPAA) Privacy Rule'' (Document ID 1725, p. 34). In fact, some employers who commented during the silica rulemaking expressed concerns about having to maintain confidential medical information (81 FR 16832).

Commenters representing employee interests also objected to giving the opinion to the employer, and offered solutions. For example, AFL–CIO fellow Mary Kathryn Fletcher testified that OSHA should consider the MSHA requirements for black lung, which requires health care providers to give their opinion directly to the employee (Document ID 1756, Tr. 201–202; 30 CFR 90.3).

OSHA has accounted for stakeholder privacy concerns in devising the medical disclosure requirements in the rule. OSHA understands that the need to inform employers about a licensed physician's recommendations on work limitations associated with an employee's exposure to beryllium must be balanced against the employee's privacy interests. As discussed in further detail below, OSHA finds it appropriate to distinguish between the licensed physician's recommendations and the underlying medical reasons for those recommendations. In doing so, OSHA intends for the licensed physician to limit disclosure to the employer to what the employer needs to know to protect the employee, which does not include an employee's diagnosis.

OSHA concludes that the employer primarily needs to know about any recommended work-related limitations or recommendations without conveying the medical reasons for the limitations. Thus, consistent with the weight of opinion in this rulemaking record and with evolving notions about where the balance between preventive health policy and patient privacy is properly struck, OSHA is taking a more privacy- and consent-based approach regarding the contents of the licensed physician's written medical opinion for the employer. The approach is similar to the approach that OSHA took in the recently promulgated Respirable Crystalline Silica standard, but more privacy-based compared to the proposed beryllium requirements and OSHA standards promulgated before the Respirable Crystalline Silica standard. These changes, which are reflected in paragraph (k)(6) of the standards, and the comments that led to these changes, are more fully discussed below.

Reinforcing the privacy concerns, stakeholders testified about job loss concerns when employees are diagnosed with an illness. For example, NABTU's Chris Trahan testified that workers in the construction industry get laid off if an employer finds out they are ill (Document ID 1756, Tr. 237–238). Mike Wright, Director of the Environmental Health and Safety Department, USW, testified that he has repeatedly seen employers fire employees who are in the early stages of occupational disease (Document ID 1751, p. 284). Dr. Weissman testified that if medical results are given directly to the employer, employees may fear that it would result in loss of their jobs and that would discourage them from participating in medical surveillance (Document ID 1755, Tr. 47–48). In commenting on a proposed standard provision that required an employer to get a signed release before sending medical information to a PLHCP, ORCHSE expressed concerns that employees are not compelled to sign releases (Document ID 1691, p. 10). The ORCHSE comment suggests that employees are reluctant to automatically have their medical information shared with medical professionals, much less their own employers. These comments mirror concerns voiced in the recent silica rulemaking. As part of that rulemaking, Dr. Weissman testified that fear of medical information being shared with employers is one of the biggest reasons that miners give for not participating in medical surveillance, and a number of employees testified that they would not participate in medical surveillance that lacked both employee confidentiality and anti-

retaliation and discrimination protection (81 FR 16831–16832). In addition, the Construction Industry Safety Coalition commented that some employers might refuse to hire an employee with silicosis for fear that they would be held liable or have to offer workers' compensation if the disease progressed (81 FR 16832)).

A number of stakeholders, including Southern Company, Ameren, and NSSP highlighted the importance of reporting beryllium-related findings to the employer for reasons such as evaluating the effectiveness of workplace programs and making workplace changes to protect employees (Document ID 1668, p. 7; 1675, p. 18; 1677, p. 7). NJH reflected similar views and also indicated that the employer would need medical information for medical follow-up and removal and to help the employee file for workers' compensation (Document ID 1664, p. 8). Materion opposed withholding medical information from employers. It commented that Materion has a cooperative process where employees are involved in problem identification and resolution, and when an employee is diagnosed with sensitization or CBD, senior and safety personnel conduct an investigation (Document ID 1755, Tr. 172–173; 1807, pp. 4–5). It indicated that the approach has resulted in improvements aimed at preventing other workers from developing CBD in the future (Document ID 1807, pp. 4–5).

Although USW agreed that patient confidentiality is essential, it argued in comments submitted before the hearing that the employer needs certain information to comply with the standard, identify over-exposures, and accommodate the needs of affected employees; it commented that the proposed rule struck the appropriate balance by giving the employer needed information while prohibiting the reporting of medical findings not related to beryllium exposure (Document ID 1681, p. 26). However, at the hearings USW presented a slightly different view, as Mike Wright testified:

> So in this circumstance, we'd like the employer to know that there's an operation that has caused illness. In a union setting, we can usually protect people, but we only represent a fraction of the workforce. In a nonunion setting, and even in the union setting, people who report an occupational illness put their jobs at peril. So we tend to resolve that dilemma in terms of privacy (Document ID 1756, Tr. 285).

When questioned how privacy concerns could be balanced with improving the work environment, Dr. Weissman testified that medical providers could provide aggregated medical data to employers that would let employers know there may be a problem but not identify the specific employees affected (Document ID 1755, Tr. 47–49). He also said that employers could foster a strong culture of safety so that employees would be more likely to share medical findings. Dr. Maier, from NJH, suggested a similar approach of analyzing combined data based on job task with employees de-identified (Document ID 1756, p. 145). However, Terry Civic, Director of Safety Health and Regulatory Affairs from Materion, and Dr. Newman argued that such an approach may not be able to maintain employee confidentiality in many cases, such as when very few employees are involved with a process or are employed by a small company (Document ID 1755, Tr. 173–174; 1756, Tr. 145).

Mr. Wright presented another view when he testified that risk can be determined in many ways, including air sampling and analyses of work processes. He went on to say that waiting for an employee to get sick is the least effective way of determining risk (Document ID 1756, Tr. 284–285). Chris Trahan of NABTU expressed similar thoughts in her testimony (Document ID 1756, Tr. 240). Rebecca Reindel, Senior Safety and Health Specialist from AFL–CIO, added:

> Employers don't need to hear about a disease in order to implement engineering controls. It's unlikely that a disease is necessarily going to trigger engineering controls more than what OSHA requires in its standards (Document ID 1756, Tr. 240).

OSHA acknowledges that identifying workers with beryllium-related disease has led to an increased understanding of exposures related to beryllium disease and development of controls to protect workers, and OSHA recognizes the efforts of employers who have promoted a strong health and safety culture and contributed to the knowledge on beryllium. However, OSHA also recognizes that many employees may fear possible repercussions of the release of medical information to their employers.

Moreover, OSHA agrees with commenters who said that employers should be basing their actions on exposure assessments and implementing controls, and it encourages employers to regularly evaluate their beryllium programs. The standards for beryllium require employers to review and evaluate the written exposure control plan if the employer is notified that an employee is eligible for medical removal, is referred to a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium (paragraph (f)(1)(ii)(B)). OSHA also encourages analyses of aggregated data when employers have the resources to do that and are able to maintain employee confidentially, which is not always possible. However, in the case where an employee may have disease related to beryllium exposure and the employer is effectively implementing controls to maintain exposures within the PEL, the only further action required by the employer would be to follow the licensed physician's recommendations to protect the employee who may be especially sensitive to exposure and may need special accommodations such as continuing medical examinations at a CBD diagnostic center or medical removal if requested by the employee. The employer does not need the specific health findings that contributed to those recommendations.

OSHA examined a number of other factors in determining what the possible outcomes could be of not providing medical findings to employers. One possible outcome is that employers would not be able to report or record illness according to OSHA's standard on recording and reporting occupational injuries and illnesses (29 CFR 1904). OSHA notes that if employees do not participate in medical surveillance because of discrimination or retaliation fears, illnesses associated with beryllium would also generally not be identified. Although not disclosing medical information to employers appears inconsistent with the objective of recording illnesses, the net effect of that decision to guard employee privacy is improving employee protections due to more employees participating in medical surveillance.

An additional possible outcome relating to what information goes to the employer is that withholding information, such as conditions that might place an employee at risk of health impairment with further exposure, may leave employers with no medical basis to aid in the placement of employees. For example, DOD opposed withholding medical information from employers because the information lets the employer know if the worker can continue to work without undue risk (Document ID 1684, Attachment 2, pp. 1–7). However, in the recent silica rulemaking, a number of stakeholders commented that because of the significance of job loss or modifications, employees that are able to perform work duties should make their own decisions on whether to continue working and that such decisions should be made with guidance from the PLHCP (81 FR

16833). OSHA finds that this is also true for beryllium-exposed employees. As a result of participating in medical surveillance, those employees will receive information about any health condition they have that might put them at further risk with exposure to beryllium and allow them to make employment choices to benefit their health.

Such an approach is not inconsistent with Materion's approach of letting employees make some employment decisions after learning that they are sensitized or have CBD, although Materion strongly supports providing employers with sensitization information (Document ID 1807, pp. 4–5; Attachment 6, pp. 75–76). At Materion, the confirmed positive finding is reported to management so an investigation can be conducted, and the Materion Medical Director informs the employee about the rates of progression from sensitization to CBD based on Materion's most recent epidemiological data. If the employee is diagnosed with CBD by his or her personal pulmonologist, the employee can choose to provide the information to Materion's Medical Director. Materion reported that employees ''often do [disclose their diagnosis of CBD] in choosing to apply for Materion benefits under its CBD policy'' (Document ID 1807, p. 4). Under the CBD policy, employees who are physically able to perform the job are given the choice of remaining in their current job, taking a job with lower beryllium exposures, or receiving benefits for 12 months. OSHA agrees with Materion's approach of letting employees decide how to proceed if they are confirmed positive or diagnosed with CBD, but disagrees that the employer must receive specific health findings before that can happen.

In review of this evidence, OSHA concludes that if employees decide to make employment changes to protect their health, there are ways to communicate recommended limitations or medical removal, without revealing the specific medical finding leading to those recommendations. Because of evolving views on medical privacy, such as those set forth in ACOEM's Confidentiality Guidelines, OSHA does not find that medical reasons for limitations or medical removal should be automatically reported to employers. In addition, providing confidential medical information to all employers presents challenges in some cases. Unlike Materion, many employers do not have medical departments and may not therefore be aware of medical privacy laws or have the resources to maintain medical records under strict confidentiality.

Another factor that OSHA considered was the value of giving health information to all employers, when some companies, such as small businesses, may not have in-house health and safety personnel to answer employee questions or emphasize the importance of protective measures, such as work practices or proper use of respirators. In such cases, employees are not likely to benefit from having their medical findings given to employers, who may have no deeper knowledge about health risks than the employee. OSHA expects that the training required under the standards will give employees knowledge to understand protective measures recommended by the PLHCP, and will make it more likely they will authorize PLHCP recommendations to be disclosed to the employer.

As was the case in the silica rulemaking, OSHA agrees that employees exposed to beryllium have the most at stake in terms of their health and employability, and they should not have to choose between continued employment and the health benefits offered by medical surveillance, which they are entitled to under the OSH Act. OSHA agrees that employees should make employment decisions, following discussions with the PLHCP that include the risks of continued exposure. Before that can happen, however, employees need to have confidence that participation in medical surveillance will not threaten their livelihoods. After considering the various viewpoints expressed during the rulemaking on these issues, OSHA concludes that the best way to maximize employee participation in medical surveillance, therefore promoting the protective and preventative purposes of this rule, is by limiting required disclosures of information to the employer to only the bare minimum of what the employer needs to know to protect employee health—recommended restrictions on respirator and protective clothing and equipment use and, only with consent of the employee, the licensed physician's recommended limitations on airborne exposure to beryllium and recommendations for evaluation at a CBD diagnostic center, continued medical surveillance, and removal from airborne exposure to beryllium. Thus, OSHA views this consent-based approach to reporting of medical surveillance findings critical to the ultimate success of this provision, which will be measured not just in the participation rate, but in the benefits to participating employees—early detection of beryllium-related disease so that employees can make decisions to mitigate adverse health effects and to possibly retard progression of the disease.

In sum, OSHA concludes that the record offers compelling evidence for modifying the proposed content of the licensed physician's written medical opinion for the employer. The evidence includes employee privacy concerns, as well as evidence on the limited utility for giving specific medical findings to employers. OSHA is particularly concerned that the proposed requirements would have led to many employees not participating in medical surveillance and thus not receiving its benefits. OSHA therefore has limited the information to be given to the employer under this rule, but is requiring that the employee receive a separate written medical report with more detailed medical information.

The requirements for the type of information provided to the employer are consistent with those in the Respirable Crystalline Silica standard (29 CFR 1910.1053), but are different from requirements in the majority of OSHA standards that were promulgated before that standard. The requirements in other standards remain in effect for those standards. The requirements for this rule are based on the evidence obtained during this rulemaking for beryllium, in particular that many employees, especially those who are not represented by a labor union or who work in a company that does not foster a strong health and safety culture, would not take advantage of medical surveillance without stronger privacy protections.

Licensed Physician's written medical report for the employee. OSHA did not propose a separate report given directly by the licensed physician to the employee, but as discussed in detail above, several commenters requested that a report containing medical information be given to the employee only. OSHA agrees and in response to those comments, final paragraph (k)(5) requires the employer to ensure that the PLHCP explains the results of the medical examination and that the licensed physician provides the employee with a written medical report within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). In other words, the examination does not end (and trigger the 45-day disclosure period) until all of the follow-up BeLPTs have been administered. This deadline is consistent with the deadline for the licensed physician's written medical

opinion for the employer, which is discussed below.

The contents of the licensed physician's written medical report for the employee are set forth in final paragraphs (k)(5)(i)–(v). They include: The results of the medical examination, including any medical condition(s), such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as is defined in paragraph (b) of the standard), that may place the employee at increased risk from further airborne exposure; any medical conditions related to airborne exposure that require further evaluation or treatment; any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on airborne beryllium exposure. If the employee is confirmed positive or diagnosed with CBD, the written medical report must also contain any recommendations for referral to a CBD diagnostic center, continued medical surveillance, and medical removal from airborne beryllium exposures, as described in paragraph (l) of the standard. Paragraph (l) specifies that medical removal applies only to work scenarios where airborne exposures exceed the action level. Paragraph (k)(5)(iii) also states that the licensed physician may recommend evaluations at a CBD diagnostic center based on any other reason deemed appropriate. For example, the physician might recommend an evaluation at a CBD diagnostic center because he or she suspects that results from the BeLPT are questionable based on signs or symptoms in the employee or other clinical findings that are consistent with CBD and wants a specialist in beryllium disease to examine the employee. However, OSHA notes that recommendations for referrals for evaluations at CBD diagnostic centers under this standard should only be given for health-related reasons that pertain to beryllium.

The health-related information in the licensed physician's written medical report for the employee is generally consistent with the proposed written medical opinion for the employer, with a few notable exceptions. The proposal required the written medical opinion to indicate ''whether the employee had any medical condition that would place the employee at increased risk of CBD from further [airborne] exposure.'' Although including a statement in the opinion that ''the employee has a medical condition that places him or her at increased risk of CBD'' implies that the employee is sensitized to beryllium, the proposal did not require that a specific finding such as ''confirmed beryllium sensitization'' be included in the opinion. Because only the employee will be receiving the written medical report, the written medical report will include any specific diagnoses, such as CBD or beryllium sensitization. OSHA added ''CBD'' as a condition to be included in the written medical report to the employee because employees who have CBD may be at risk of increased progression of the disease if they continue to be exposed. Including a confirmed positive finding or CBD diagnosis will also give the employee a record of his or her eligibility for medical removal. An additional change from the proposed to final requirement is that the proposed phrase of ''would place the employee at risk of CBD from further [airborne] exposure'' was changed to ''may place the employee at increased risk from further airborne exposure.'' The change of the word ''would'' to ''may'' was for clarification because the word ''would'' implies a certainty that does not exist.

The phrase ''risk of CBD'' was also changed to ''risk'' to clarify that risks may be increased by conditions other than CBD-related disease. For example, the employee may have lung function loss related to a disease such as chronic obstructive pulmonary disease and that lung function loss might be compounded if the employee develops CBD. As noted in the introduction to the Summary and Explanation, the word ''airborne'' was included as a modifier to the term ''exposure'' in many cases in the final standards to clarify that OSHA did not intend a change from the proposal. In this provision, OSHA included the term ''airborne'' to reaffirm its intent that the report must discuss any detected medical conditions that may place the employee at increased risk from further airborne exposure, rather than dermal exposure. OSHA finds that this distinction is appropriate because it is inhalation exposure and not dermal contact that increases the risk of CBD development in a sensitized employee or increases the risk of progression in an employee who has CBD. (For this same reason the word ''airborne'' was added to final paragraph (k)(5)(ii)(B).)

Finally, the proposed phrase ''including the use and limitations of protective clothing and equipment, including respirators'' was changed to ''use of respirators, protective clothing or equipment'' in final paragraph (k)(5)(ii)(A). That change reflected an edit to remove superfluous language and the intent of that requirement has not changed. OSHA intends this provision to cover situations where the physician might have recommendations on the use of respirators, protective clothing or equipment in general, *e.g.,* that the employee should wear long sleeves to limit the possibility of dermal exposure. OSHA also intends for the provision to address recommended limitations on an employee's use of respirators, protective clothing or equipment, *e.g.,* that the employee cannot safely wear a negative pressure respirator.

In addition to these changes, OSHA added a number of recommendations that the licensed physician is to include in the written medical report to the employee if the employee is confirmed positive or diagnosed with CBD: (1) Referral for an evaluation at a CBD diagnostic center (paragraph (k)(5)(iii)), (2) continued medical surveillance (paragraph (k)(5)(iv)), and (3) medical removal from airborne exposure to beryllium as described in paragraph (l) (paragraph (k)(5)(v). Aside from a confirmed positive or CBD diagnosis, if otherwise deemed appropriate by the licensed physician, the written medical report must also contain a referral for an evaluation at the CBD diagnostic center.

Each of these recommendations reflects another requirement of the final standard. For example, proposed paragraph (k)(6)(i) and (ii) indicated that an evaluation at a CBD diagnostic center was to occur when an employee was confirmed positive and agreed to the examination. OSHA updated the requirement to make it clear that an evaluation at a CBD diagnostic center should not be limited to employees who have been confirmed positive and want to find out if they have CBD, and should be extended to employees already diagnosed with CBD. Such employees would benefit from having a pulmonologist familiar with beryllium disease select appropriate tests to monitor progression of the disease. OSHA therefore expanded the trigger for referral to a CBD diagnostic center to include CBD in addition to sensitization in final paragraphs (k)(5)(iii), (k)(6)(iii), and paragraph (k)(7)(i).

The referral for continued medical surveillance for employees who are confirmed positive or have been diagnosed with CBD reflects the addition of paragraph (k)(1)(i)(D) that allows employees whose most recent medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance to continue receiving medical examinations, even if they do not qualify under any other trigger; a more detailed discussion is included under the summary and explanation for final paragraph (k)(1)(i)(D).

Finally, the triggers for a medical removal recommendation in paragraph (k)(5)(v) reflect the triggers under paragraph (l)(1)(i) and are discussed in more detail in the summary and explanation for final paragraph (l), medical removal protection. OSHA added these recommendations to the written medical report to make it clear to the licensed physician and employee that each of these recommendations is to occur when an employee is confirmed positive or diagnosed with CBD. A similar approach is applied in the Respirable Crystalline Silica standard, where the PLHCP is to include a statement that the employee should be examined by a specialist if that employee has X-ray evidence of silicosis.

The requirements for the health-related information to be included in the written medical report for the employee are consistent with the overall goals of medical surveillance: To identify beryllium-related adverse health effects so that the employee can consider appropriate steps to manage his or her health; to let the employee know if he or she can be exposed to beryllium in the workplace without increased risk of experiencing adverse health effects; and to determine the employee's fitness to use respirators. By providing the licensed physician's written medical report to employees, those who might be at increased risk of health impairment from airborne beryllium exposure will be able to consider interventions (*i.e.,* health management strategies) with guidance from the licensed physician. Such strategies might include employment choices to limit airborne exposures or using a respirator for additional protection.

The requirement for a verbal explanation from the PLHCP in paragraph (k)(5) allows the employee to confidentially ask questions or discuss concerns with the PLHCP. It also allows the PLHCP to inform the employee about any non-occupationally related health conditions so that the employee can follow-up as needed with his or her personal healthcare provider at the employee's expense. The requirement for a written medical report ensures that the employee receives a record of all findings. Employees would also be able to provide the written medical report to future health care providers.

Licensed physician's written medical opinion for the employer. As discussed in detail above, some commenters objected to OSHA's proposed content for the written medical opinion for the employer based on employee privacy concerns. OSHA shares these privacy concerns and is thus revising the contents of the written medical opinion. In developing the contents of the written medical opinion for the employer, OSHA considered what type of information needs to be included to provide employers with information to protect employee health, while at the same time protecting employee privacy as much as possible. NIOSH commented that the employer should only be provided with information on the employee's fitness for duty, in addition to restrictions and eligibility for medical removal benefits, as applicable (Document ID 1725, page pp. 33–34). AFL–CIO recommended that OSHA use the language from the respirable crystalline silica rule promulgated in March of 2016, and referred OSHA to the final brief it submitted for the silica rulemaking since the justifications for increased confidentiality apply to beryllium (Document ID 1809, p. 1; 1786). In the silica standard, OSHA required that only limitations on respirator use be included in the written medical opinion without the employee's consent. The decision was largely influence by physician testimony that giving the employer information on an employee's ability to use a respirator, but not specific medical information, strikes the appropriate balance between the employee's privacy and the employer's right to know because employees who are not fit to wear a respirator and then do so can be at risk of sudden incapacitation or death (81 FR 16835; see also Document ID 1786; pp. 89–90; 1805, Attachment 2, p. 133).

Based on the record evidence, OSHA has determined that for the beryllium standards, the written medical opinion for the employer must contain only the date of the examination, a statement that the examination has met the requirements of this standard, and any recommended limitations on the employee's use of respirators, protective clothing, and equipment; and a statement that the PLHCP explained the results of the examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment. These requirements are set forth in paragraph (k)(6)(i) of the standards.

OSHA is persuaded to include recommended limitations on the employee's use of respirators, protective clothing, and equipment, with no other medically-related information, in the written medical opinion for the employer without further consent from the employee. The Agency notes that the limitation on respirator use is consistent with information provided to the employer under the Respiratory Protection standard (29 CFR 1910.134). OSHA concludes that only providing information on respirator and protective clothing and equipment limitations in the written medical opinion for the employer is consistent with the ACOEM confidentiality guidelines that address the reporting of health and safety concerns to the employer (Document ID 1815, Attachment 60, p. 1). The date and statement about the examination meeting the requirements of this standard are to provide both the employer and employee with evidence that compliance with the medical surveillance requirements are current. Employees will be able to show this opinion to future employers to demonstrate that they have received the medical examination.

Paragraph (k)(6)(ii) states that if the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. Paragraphs (i)(6)(iii)–(v) state that if an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain recommendations for evaluation at a CBD diagnostic center, continued medical surveillance, and medical removal from airborne exposure to beryllium as described in paragraph (l). If otherwise deemed appropriate by the licensed physician and the employee authorizes the information to be included in the written medical opinion, the opinion must also contain a referral for an evaluation at the CBD diagnostic center. As noted above, referrals for evaluations at CBD diagnostic centers under this standard should only be given for health-related reasons that pertain to beryllium.

OSHA intends for this provision to allow the employee to give authorizations for the written medical opinion for the employer to contain only the referral for evaluation at a CBD diagnostic center, only the recommendation for continued periodic surveillance, or only the recommendation for medical removal, or both. This will allow employees to choose one or more options that best fit their needs. For example, an employee may choose to only let the employer know that he or she wants continued medical surveillance but not at the CBD diagnostic center because he or she is satisfied with the care provided by the current PLHCP. In another case, an employee may decide that he or she

wants only the recommendation for evaluation at a CBD diagnostic center reported to the employer because the employer wants to be evaluated by someone who is more specialized in beryllium disease before making any major employment decisions. In a third case, the employee may only want the recommendation for removal from airborne exposure reported to the employer because the employee is very concerned about his or her health and wants to be immediately removed without an evaluation at the CBD diagnostic center. OSHA expects that the written authorization could easily be accomplished through the use of a form that allows the employee to check, initial, or otherwise indicate which (if any) of these items discussed above the employee wishes to be included in the written medical opinion for the employer. OSHA concludes that allowing the employee to decide what if any additional information can be reported to the employer is warranted based on the seriousness and irreversibility of beryllium disease and the major impact that the decision may have on the employee's health and employment.

OSHA is convinced that routinely including recommended limitations on airborne exposure, evaluations at a CBD diagnostic center, and especially medical removal in the written medical opinion for the employer absent employee consent could adversely affect employees' willingness to participate in medical surveillance. The requirements for this paragraph are consistent with recommendations to let employees make their own health decisions. OSHA stresses that information given to the employer should not include an underlying diagnosis—only the specific recommendation or referral called for under the standards. OSHA considers this a reasonable approach that balances the need to maintain employee confidentiality with the employer's need to know that it may want to reevaluate its beryllium program. Reporting that a referral or medical removal is recommended, when authorized by the employee, allows the employer to reevaluate its written exposure control plan, as required under paragraph (f)(1)(ii)(B).

OSHA finds that this new format for the licensed physician's medical opinion for beryllium will better address concerns of ORCHSE, who feared it would be in violation if the written medical opinion for the employer included information that OSHA proposed the licensed physician or PLHCP not report to the employer, such as an unrelated diagnosis (Document ID 1691, p. 11). OSHA finds that removing the prohibition on unrelated diagnoses and instead specifying the only information that is to be included in the written medical opinion for the employer remedies this concern because it makes the contents of the opinion easier to understand and less subject to misinterpretation.

OSHA recognizes that some employees might be exposed to multiple OSHA-regulated substances at levels that trigger medical surveillance and requirements for written opinions. For example, Newport News Shipbuilding indicated that their employees already undergo medical surveillance for arsenic (Document ID 1657, p. 2). The licensed physician can opt to prepare one written medical opinion for the employer for each employee that addresses the requirements of all relevant standards, as noted in preambles for past rulemakings, such as Chromium (VI) (71 FR 10100, 10365 (2/28/06)). However, the combined written medical opinion for the employer must include the information required under each relevant OSHA standard. For example, if the PLHCP opts to combine written medical opinions for an employee exposed to both inorganic arsenic and beryllium, then the combined opinion to the employer must contain the information required by paragraphs (n)(6)(i) of the inorganic arsenic standard (29 CFR 1910.1018) and the information required by paragraphs (k)(6)(i) (and paragraphs (k)(6)(ii)–(v) with written authorization from the employee) of the beryllium standards.

NABTU noted that the black lung rule for coal miners protects confidentiality by prohibiting mine operators from requiring miners to provide a copy of their medical information (Document ID 1679, p. 13; 30 CFR 90.3). NABTU requested that the beryllium rule protect confidentiality by prohibiting employers from asking employees or the PLHCP for medical information (Document ID 1679, p. 13). Consistent with the Respirable Crystalline Silica standard, OSHA is not including such a prohibition in the beryllium standard because employers may have legitimate reasons for requesting medical information, such as BeLPT results. For example, employers might request such information for doing an investigation or helping employees file compensation claims. If employees are not concerned about discrimination or retaliation, or need the employer's help in filing a claim, they could provide the health information to the employer. Paragraph (k)(6)(vi) requires the employer to ensure that employees receive a copy of the written medical opinion for the employer within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee. The reason for the 45-day deadline to provide the written medical opinion is discussed below. OSHA is requiring that employees receive a copy of the written medical opinion for the employer, in addition to the written medical report, because they can present the written medical opinion as proof of a current medical examination to future employers. This is especially important in industries with high turnover because employees may work for more than one employer during a two-year period and this ensures that tests are not performed more frequently than required.

On the topic of transient employment, NSC asked OSHA to consider workers employed by staffing agencies and assigned to multiple host employers and possibly employees of contractors to the host employer, who might not receive medical surveillance because of the transient nature of their employment (Document ID 1612, p. 3). OSHA's July 15, 2014, memorandum titled *Policy Background on the Temporary Worker Initiative* indicates that both the host and staffing agency are responsible for the health and safety of temporary employees. For example, the policy memorandum indicates that host employers are well suited for assuming responsibility for compliance related to workplace hazards, while staffing agencies may be best positioned to provide medical surveillance. Under this policy, staffing agencies are expected to offer medical surveillance to eligible employees, and they could send a copy of the written medical opinion to the host employer so that the host employer would know about any limitations that might be recommended by the licensed physician. Similarly contract employers whose employees work at different job sites are expected to offer medical surveillance to their eligible employees. Also, OSHA revised the triggers for medical surveillance in paragraphs (k)(1)(i)(A) and (k)(2)(i)(A) so that employees must be offered medical surveillance within 30 days of when the employer determines they are reasonably expected to be exposed above the action level for 30 or more days a year. The revised trigger allows for more timely medical examinations than the proposed trigger, which would have allowed for the employee to be exposed for 30 days before the employer had to offer medical surveillance. As a result, more temporary workers who are

employed for short periods of time will meet the trigger for medical surveillance.

As indicated above, the standards require that employers ensure that employees get a copy of the PLHCP's written medical report and opinion and that they get a copy of the written opinion within 45 days of each medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) (paragraphs (k)(5), (k)(6)(i), (k)(6)(vi)). By contrast, the proposed rule would have required that the employer obtain the licensed physician's written medical opinion within 30 days of the medical examination and then provide a copy to the employee within 2 weeks after receiving it. NJH commented that 45 days is a better time period for notifying employers because it can take more than 2 weeks to process the BeLPT (Document ID 1664, p. 8). ORCHSE expressed concern about the 30-day timeline, stating that the employer would be in violation if the physician took more than 30 days to deliver the report (Document ID 1691, pp. 11–12).

In light of NJH and ORCHSE's comments, OSHA has revised the proposed 30-day timeline to allow for 45 days. OSHA expects that the new 45-day period will give the licensed physician sufficient time to consider the results of any tests, including a follow-up BeLPT, done as part of the examination. OSHA finds that delivering the report to the employer within 45 days will still ensure that the employee and employer are informed in a timely manner and allows the employer to take any necessary protective measures within a reasonable time period. To ensure timely delivery of reports and opinions containing the correct information and demonstrate a good faith effort in meeting these requirements of the standard, the employer could inform licensed physicians about the time deadline and other requirements of the beryllium standard in a written agreement and follow up with the physician if there is concern about timely delivery or content of these documents. Because the licensed physician will be providing the employee with a copy of the written medical report, he or she could give the employee a copy of the written medical opinion at the same time. This would eliminate the need for the employer to give the employee a copy of the PLHCP's written medical opinion for the employer, but the employer would still need to ensure timely delivery.

OSHA has also revised this provision to account for the time to administer any follow-up BeLPT tests required under paragraph (k)(3)(ii)(E) of these standards. As discussed above, if the results of the BeLPT are other than normal, paragraph (k)(3)(ii)(E) requires a follow-up BeLPT to be offered within 30 days, unless the employee has been confirmed positive. In order to allow for the licensed physician to consider BeLPT results and prepare the written medical opinion, the Agency must allow time for the BeLPT to be administered, processed, and interpreted. Therefore, OSHA has decided to require the employer to obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard).

Evaluation at a CBD Diagnostic Center. OSHA proposed that within 30 days after an employer learned that an employee was confirmed positive, the licensed physician was to consult with the employee to discuss referral to a CBD diagnostic center that was mutually agreed upon by the employer and employee (proposed paragraph (k)(6)(i)). Following the consultation, if the employee decided to be clinically evaluated at a CBD diagnostic center, the employer was to provide the examination at no cost to the employee (proposed paragraph (k)(6)(ii)).

OSHA asked stakeholders to comment on the proposed requirement for evaluation at a CBD diagnostic center, especially whether the requirements for mutual agreement by the employee and employer is necessary and appropriate and how the diagnostic center should be chosen if the employer and employee cannot agree. OSHA also asked whether the standard should specify that evaluation at a diagnostic center must be at a reasonable location (80 FR 47574–47575).

The term CBD diagnostic center is defined in paragraph (b), Definitions, of the standards. As provided in paragraph (b) and explained in the Summary and Explanation, the CBD diagnostic center can be a hospital or other facility that has an on-site pulmonary specialist who can interpret biopsy pathology and bronchoalveolar lavage (BAL) results. The diagnostic center must also have onsite facilities that can do a clinical evaluation for CBD that includes pulmonary function testing according to ATS guidelines, transbronchial biopsy, and BAL, with the ability to transfer BAL samples to a laboratory for diagnostic evaluation within 24 hours.

Ameren supported a specialist exam but asserted that an examination by a pulmonologist was sufficient and that the pulmonologist could be allowed to work with a CBD diagnostic center to treat a sensitized employee (Document ID 1675, p. 17). Southern Company argued that rather than requiring an evaluation at a CBD diagnostic center, the standard should instead specify the types of exams required (Document ID 1668, pp. 2–3). DOD commented that employees should be referred to a board-certified pulmonologist who is capable of doing bronchoscopy, bronchial biopsy, and broncho-alveolar lavage (Document ID 1684, Attachment 2, p. 1–6), NSSP, NABTU, ACOEM, and ATS advocated for an examination at a CBD center for sensitized employees (Document ID 1677, p. 6; 1679, p. 12; 1685, p. 5; 1688, p. 3).

OSHA is not persuaded by Southern Company's argument that the final standards should detail specific tests for confirmed positive employees, instead of requiring an examination at a CBD diagnostic center. As described above, the types of evaluations required for an employee who has a confirmed positive finding or is diagnosed with CBD must be determined on a case-by-case basis, and therefore determining appropriate testing requires a pulmonologist with the expertise described in the definition for CBD diagnostic center. In addition, many of the procedures that a pulmonologist may recommend are invasive and therefore involve risks. As a result, these tests should only be performed by a pulmonologist familiar with beryllium disease at a facility that meets the definition of a CBD diagnostic center, after the pulmonologist has carefully considered the employee's medical and occupational history. For these reasons, OSHA reaffirms that it is essential that eligible employees be evaluated at a CBD diagnostic center. Requiring that the diagnostic center be able to perform all the functions described under the Definitions section also makes the exam more convenient for the employer and the employee because the employee will not have to go to multiple facilities in order to undergo different procedures.

Southern Company disagreed with the proposed requirement that both the employee and employer agree upon the CBD diagnostic center, asserting that the requirement could conflict with selection of a physician under workers' compensation laws, because OSHA does not have a mechanism to settle disputes, and because similar requirements are not included in other OSHA standards (Document ID 1668, pp. 6–7). Ameren and ORCHSE also opposed the requirement for mutual agreement on a CBD diagnostic center and recommended that location be considered when the employee and employer cannot reach agreement

(Document ID 1675, p. 17; 1691, p. 10). NJH supported mutual agreement on the CBD diagnostic center between the employee and employer and stated that location, expertise of the center, and feasibility should all be accounted for when agreement cannot be reached (Document ID 1664, p. 8).

OSHA acknowledges the concerns of these stakeholders, but maintains that the employee should be given a choice in the selection of a CBD diagnostic center because of the risks involved with procedures that the employee may have to undergo and because of the life-changing decisions that the employee might have to make based on the results of the evaluation. The employer and employee should make a good faith effort to agree on a CBD diagnostic center that is acceptable to them both. In making the decision, the first consideration is identifying qualified CBD diagnostic centers. The next considerations in the decision should include requirements under other laws and geographical location. OSHA expects that once these criteria are considered, there will not be unlimited options, which will help the employee and employer come to a decision.

Although OSHA was not convinced that changes needed to be made based on public comments, OSHA did find changes were required to make the final provision consistent with other requirements of the final standard. First, OSHA changed the trigger for referral to a CBD diagnostic center to include both confirmed positive and a CBD diagnosis for consistency with paragraphs (k)(5)(iii) and (k)(6)(iii). The reasoning for this change is described above in the discussion of paragraph (k)(5)(iii). Second, OSHA removed the requirement for a consultation between the physician and employee within 30 days after the employer learned that the employee was confirmed positive. Under paragraph (k)(6)(D), the employer already must ensure that the PLHCP explains findings to the employee, including conditions related to airborne beryllium exposures that require further evaluation or treatment within 30 days of the medical examination. The discussion about recommended referral can occur as part of that conversation, and OSHA does not find that a separate consultation with the physician or PLHCP is necessary.

The third major change to this provision was detailing how the employer would be informed that the employee is eligible for an evaluation at a CBD diagnostic center. The change reflects updates made to paragraph (k)(6) to allow the employee more privacy and control over the type of information the employer receives. Under final paragraph (k)(6), the employee must authorize the written medical opinion to contain recommendations for an evaluation at a CBD diagnostic center, and the licensed physician would then provide the employer that recommendation in the written medical opinion. Under paragraph (k)(5), the employee's written medical report is to contain medical findings, including a confirmed positive test result and a CBD diagnosis. The report must also contain a referral for an evaluation at a CBD diagnostic center if the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate. The employee has the option of providing the employer with a copy of the written medical report indicating a confirmed positive finding or diagnosis of CBD, or recommending referral. OSHA is providing the option for a written medical report listing a confirmed positive finding or diagnoses of CBD to be offered as proof of eligibility for an evaluation at a CBD diagnostic center, in the event that a licensed physician did not recommend a referral to a CBD diagnostic center in either the written medical report or the written medical opinion.

As the result of the changes discussed above, final paragraph (k)(7) requires that employers provide a no-cost evaluation at a CBD-diagnostic center that is mutually agreed upon by the employee and employer within 30 days of receiving a medical opinion that recommends the referral (paragraph (k)(7)(i)(A)) or within 30 days after the employee presents the employer with a written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center (paragraph (k)(7)(i)(B)). As is the case with the PLHCP's examination, the employer is responsible for providing the employee with a medical examination at a CBD diagnostic center, at no cost, and at a reasonable time and place.

Under paragraph (k)(7)(ii) of the standards the employer must ensure that the CBD diagnostic center explains medical findings to the employee and gives the employee a written medical report within 30 days of the examination. Like the licensed physician's written medical report, the written medical report from the CBD diagnostic center must contain the results of the examination, including conditions such as sensitization or CBD that might increase the employee's risk from airborne exposure to beryllium; any medical conditions related to beryllium that require further follow-up; any recommendations on the employee's use of respirators, protective clothing, or equipment; and any recommended limitations on beryllium exposure. If the employee is confirmed positive or diagnosed with CBD, the written medical report must also contain recommendations for continued periodic medical surveillance and recommendations for removal from exposure to beryllium, as described in paragraph (l). The reasons why the CBD diagnostic center is to give the employee this information are the same as discussed above, under the requirements for the licensed physician's written medical report for the employee. This provision was added to the final standards to ensure that the employee gets a written record from the CBD diagnostic center and to allow the employee to consult with the CBD diagnostic center about the findings.

Paragraph (k)(7)(iii) requires that the CBD diagnostic center provides the employer with a written medical opinion within 30 days of the medical examination. The written medical opinion must contain the date of the examination, any recommended limitations on the employee's use of respirators, protective clothing, or equipment, and a statement that a PLHCP explained the results of the medical examination to the employee. It must also contain a statement that the examination met the requirements of the standard, if a periodic examination was conducted for an employee who chooses examinations conducted at the CBD diagnostic center as specified under paragraph (7)(iv). If the employee provides written authorization, the written medical opinion for the employer must also contain any recommended limitations on the employee's airborne exposure to beryllium. If an employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain recommendations for continued medical surveillance, and/or medical removal from exposure to beryllium, as described in paragraph (l).

This provision was not in the proposed standard or the joint draft recommended standard by Materion and USW but was added to the final standards to allow for transmittal of CBD diagnostic center recommendations to the employer without revealing the specific medical reason for those recommendations. The structure parallels the written medical opinion from the licensed physician, which was developed based on stakeholder requests to increase confidentiality of

medical findings. A separate written medical opinion from the CBD diagnostic center is needed because the recommendations may differ from those of the licensed physician and usually comes from a different provider. For example, the employee may have wanted only a recommendation for evaluation at a CBD diagnostic center to be included on the written medical opinion from the physician, but, after evaluation at a CBD diagnostic center, may decide to include the recommendation for medical removal from exposure on the CBD diagnostic center's written medical opinion.

Paragraph (k)(7)(iv) requires the employer to ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee. As discussed above with regard to paragraph (k)(6)(vi), requiring the provision of all written medical opinions to employees can permit employees to provide that information to future employers without divulging private medical information and also present the opinion as proof of a current examination that meets the requirements of the beryllium standard.

The deadlines for submittal of the written medical opinion and report are shorter for the CBD diagnostic center (30 days) than the licensed physician (45 days). The reasoning is because CBD diagnostic centers are not expected to routinely conduct BeLPTs, which as noted above, take 2 weeks to process. They will not, therefore, be affected by the same time limitations as licensed physicians.

In the NPRM, OSHA asked stakeholders to comment on whether sensitized employees should be given the opportunity to be examined at a CBD diagnostic center more than once and how frequently those employees should be evaluated (80 FR 47574). This provision was not included in the draft standard or the joint draft recommended standard by Materion and USW (Document ID 0754).

NABTU commented that a sensitized employee should continue to be periodically evaluated at a CBD diagnostic center because it cannot be predicted when a sensitized employee will develop CBD (Document ID 1679, p. 12). NSSP, ACOEM, and ATS agreed with continued periodic surveillance at a CBD diagnostic center for sensitized employees (Document ID 1677, p. 6; 1685, p. 5; 1688, p. 3). ATS recommended that sensitized employees be evaluated every one to three years and NSSP recommended that the original physician, CBD diagnostic center, and employee determine the frequency of medical examinations. Finally, Ameren stated that the standard should allow for follow-up based on pulmonologist recommendations (Document ID 1675, p. 16).

OSHA agrees that continued evaluation at a CBD diagnostic center is appropriate for sensitized employees and employees diagnosed with CBD. Specialized evaluation is needed to determine the appropriate tests to monitor for possible progression from sensitization to CBD and to monitor the progression of CBD if it does occur. Therefore, after considering the record, OSHA added the requirement for continued evaluation at a CBD diagnostic center for these employees.

This new requirement is contained in paragraph (k)(7)(v), which specifies that after an employee has received a clinical evaluation at a CBD diagnostic center described by paragraph (k)(7)(i) of the standards, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center. The evaluations must continue to be done at a CBD diagnostic center mutually agreed upon by the employee and employer and provided at no cost to the employee. To allow for continued medical surveillance for those employees who would not otherwise be entitled under (k)(1) or (k)(2), the employee must authorize the recommendation for continued periodic medical surveillance to be included in the most recent written medical opinion from the CBD diagnostic center (paragraph (k)(7)(iii)). Under paragraph (k)(2)(ii), the CBD diagnostic center can recommend continued surveillance every two years. OSHA is not including a provision for more frequent examinations because, as indicated above, surveillance done every two years is appropriate to monitor for sensitization and CBD progression in most employees.

Proposed paragraph (k)(7) had required that employers were to convey the results of beryllium sensitization tests to OSHA for evaluation and analysis at the request of OSHA. The employer was to remove all personally identifiable information (*e.g.,* names, social security numbers) before sending the results to OSHA. A similar provision was included in the joint draft recommended standard by Materion and USW. OSHA asked for comment on this provision, specifically if such a requirement would be burdensome for employers and whether it would be more appropriate to send the information to other organizations (80 FR 47575).

Some commenters did not support the inclusion of this requirement in the final rule. For example, Ameren commented that the proposed requirement would be burdensome because it would be cumbersome to get signed releases for this information (Document ID 1675, p. 20). ORCHSE also argued that employees would have a difficult time complying with this requirement because employees would not likely sign a release (Document ID 1691, p. 13). DOD also claimed that the requirement would be burdensome and said that it would be better to send the results to NIOSH but not routinely (Document 1684, Attachment 2, pp. 1–7–1–8). On the other hand, NJH supported this requirement because it believed the information would help OSHA identify industries where sensitization is occurring (Document ID 1664, p. 9). However, NJH added that small companies may need help complying with this requirement (Document ID 1664, p. 9). In addition, NJH and ATS recommended that the rule specify that employers routinely and systematically analyze medical screening results along with job and exposure data to identify employees who may be at risk of sensitization and working conditions contributing to sensitization and CBD risk (Document ID 1664, p. 8; 1688, 4).

Consistent with the concerns of Ameren and ORCHSE regarding getting releases from employees, OSHA has given much thought to maintaining confidentiality of medical findings as discussed in detail above. As a result of changes made in the standards to enhance employee privacy, the Agency eliminated the proposed paragraph for the written medical opinion to the employer to include a statement about whether the employee had a condition that would put him or her at risk of developing CBD with further beryllium exposure. That provision suggested that the written medical opinion might include findings such as beryllium sensitization. In the final standard, it is explicit that the employer will not receive information about sensitization or CBD in the written medical opinion to the employer, and the employer will only receive that information when an employee presents the employer with the employee's written medical report. As a result, many employers may not have that information to submit to OSHA or to otherwise conduct a systematic analysis of medical screening results. As discussed above, even if employers were provided aggregated medical findings, it may still be difficult

to maintain confidentiality when companies are small or few employees are involved in a process.

OSHA has other ways to obtain medical findings if needed. For example, as noted in the Summary and Explanation for paragraph (n), Recordkeeping, OSHA's Access to Employee Exposure and Medical Records standard (29 CFR 1910.1020) requires employers to ensure that most employee medical records are retained for the duration of employment plus 30 years for employees employed more than one year, and requires that those records be made available to OSHA upon request (29 CFR 1910.1020 (d)(1)(i) and (e)(3)). OSHA therefore deleted proposed paragraph (k)(7) from the final standard.

(l) Medical Removal

Paragraph (l) of the standards for general industry, shipyards, and construction provide for medical removal protection (MRP). This paragraph applies only to workers with airborne exposure to beryllium at or above the action level who are diagnosed with CBD or confirmed positive and provide documentation of their diagnosis of CBD or confirmed positive status or a physician's recommendations for removal from exposure to beryllium to their employers. Under this paragraph, employees must provide eligible employees with a choice of removal from exposure at or above the action level or remaining in their job with airborne exposure at or above the action level and wearing a respirator. If the employee chooses removal, the employer is required to remove the employee to comparable work in a work environment where the airborne exposure is below the action level, if such work is available. If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first. The employee's earnings under MRP can be diminished by the amount of compensation received from certain other sources.

OSHA included medical removal provisions in the proposed rule as a protective, preventative health mechanism that was intended to work in concert with the proposed medical surveillance provisions. As OSHA explained in the proposal, the Agency preliminarily found that medical removal is an important means of protecting employees who have become sensitized or developed CBD, and is an appropriate means to enable them to avoid further exposure. *See* 80 FR 47802. The Agency further explained that the inclusion of MRP in the proposal was in keeping with the recommendation of beryllium health specialists in the medical community and with the draft recommended standard provided by union and industry stakeholders (Document ID 0754).

OSHA solicited comments on the health effects that should trigger MRP and the proposed provisions for MRP. In addition, the Agency included several specific questions to guide stakeholders in their response, including whether beryllium sensitization and CBD are appropriate triggers for medical removal, whether there were other medical conditions or findings that should trigger medical removal, and the amount of time for which a removed employee's benefits should be extended. OSHA also included questions regarding the costs and benefits of MRP (*see* 80 FR 47575).

During the public comment periods and informal public hearing, numerous stakeholders submitted comments supporting the inclusion of MRP in this rulemaking (*e.g.,* Document ID 1664, pp. 3–4, 9; 1680, pp. 1, 7; 1681, p. 14–15; 1683, p. 3; 1688, p. 2; 1689, pp. 8, 13–14; 1690, pp. 1, 3–4; 1691, Attachment 1, pp. 13, 15; 1755, Tr. 26, 168; 1756, Tr. 142–143; 1809, p. 1; 1963, pp. 13–14). The commenters who commented on the issue supported MRP in general terms; none opposed inclusion of MRP in the final rule. Some of these stakeholders noted that they supported MRP because it promotes participation in medical surveillance programs. For example, National Council on Occupational Safety and Health (National COSH) argued that MRP benefits are crucial to a successful medical surveillance program (Document ID 1690, pp. 3–4). National COSH maintained that ''workers will not willingly participate in medical surveillance or disclose early signs and symptoms of disease if doing so means they lose their job and can no longer pay their bills. For this reason, an effective medical surveillance program for CBD must include . . . [MRP] benefits'' (Document ID 1690, p. 3). NIOSH similarly argued that ''[f]ear of job loss and associated loss of income and other benefits is an important barrier to translating medical screening and surveillance findings into secondary prevention. Inclusion of medical removal provisions is critical to addressing that barrier'' (Document ID 1755, Tr. 26). The American Association for Justice agreed, observing that ''MRP benefits are an essential tool to ensure that workers with signs and symptoms of disease step forward without fear of reprisal and seek medical advice'' (Document ID 1683, p. 3).

Other commenters indicated that the option for removal was necessary for workers' health. For example, the USW argued that the inclusion of MRP is necessary to provide a safe and healthful workplace (Document ID 1963, p. 13). USW further commented that Section VIII (Significance of Risk) of the NPRM shows that existing evidence within the docket indicates that workers who are sensitized to beryllium or are in the early stages of chronic beryllium disease can significantly benefit from MRP (Document ID 1963, p. 13). National Jewish Health (NJH) generally agreed with USW's opinion, stating that ''removal from exposure is the best form of prevention'' (Document ID 1664, p. 4).

Other stakeholders indicated that the inclusion of a medical removal provision might lower exposures in the workplace as a whole. For example, USW testified that MRP provides employers with a financial incentive to keep beryllium exposures low (Document ID 1755, Tr. 167–68). Mike Wright from USW observed that this incentive helped to lower exposure levels in the context of the lead standard:

> But what really, I think, best protected workers was medical removal protection because employers did not want to pay people to stay at home until their blood leads got down. So I think if you look at the real benefits of MRP, it isn't simply that it removes workers from exposure, who might be harmed by further exposure. It is that it really provides an incentive for employers to keep exposures low in the first place. And that's been our experience (Document ID 1755, Tr. 167–68).

After careful consideration of these comments, OSHA has decided to include MRP in the final standards. As noted by commenters, MRP serves three main interrelated purposes. First, it increases employee participation and confidence in the standards' medical surveillance program. Under paragraph (k)(1)(i)(B), employers must offer medical examinations to employees showing signs or symptoms of CBD. The success of that program will depend in part on employees' willingness to report their symptoms, submit to examinations, respond to questions, and comply with instructions. Guaranteeing comparable work or earnings, seniority, and other rights and benefits for a period of time can help allay an employee's fear that a CBD diagnosis or

being confirmed positive will negatively affect earnings or career prospects. MRP encourages employees to report their symptoms and seek treatment, as OSHA has previously recognized when including medical removal in regulations governing the exposure to Lead (43 FR 52952, 52973, November 14, 1978), Benzene (52 FR 34460, 34557, September 11, 1987), and Cadmium (57 FR 42102, 42367–42368, September 14, 1992). This reasoning was also cited by the Department of Energy in support of the medical removal provisions of its Chronic Beryllium Disease Prevention Program, stating that the availability of medical removal benefits encourages worker participation and cooperation in medical surveillance (64 FR 68893).

Second, by requiring the employer to remove employees with the highest risk of suffering material impairment of health (if the employee chooses removal), MRP may benefit sensitized employees and those with CBD. OSHA notes that there remains some scientific uncertainty regarding the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD. For example, Steven Markowitz, MD, a medical consultant for USW, acknowledged during the informal public hearing that ''there's a paucity of evidence that removal from exposure results in improvement of CBD'' (Document ID 1755, Tr. 101). Nonetheless, most members of the medical community support removal from beryllium exposure as a prudent step in the management of beryllium sensitization and CBD. As noted above, physicians at NJH recommend that individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry should have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour TWA, which is 10 times below the action level of 0.1 micrograms per cubic meter (*http://www.nationaljewish.org/healthinfo/conditions/beryllium-disease/environment-management/*) (Document ID 0637). Furthermore, OSHA received comments from Lisa Maier, MD and Margaret Mroz, MSPH from NJH during the public comment period supporting MRP for workers with sensitization or CBD (Document ID 1664; 1806, pp. 3–4). Specifically, Ms. Mroz commented that ''eliminating or reducing exposure can lead to improvement in symptoms'' for beryllium workers and that ''[r]emoval or reduction in exposure may prevent the development of CBD'' (Document ID 1806, p. 3–4). And, during the informal public hearing, Dr. Lee Newman, testifying on behalf of the American College of Occupational and Environmental Medicine (ACOEM), commented that ''removal from exposure is the right thing to do for somebody who is at a stage of being beryllium sensitized or any stage beyond that'' (Document ID 1756, Tr. 143). Thus, even though CBD and sensitization are considered to be irreversible, OSHA finds removal may still benefit sensitized employees and those with CBD.

Finally, MRP may provide employers with an additional incentive to keep employee exposures low. Precisely because MRP will impose additional costs on employers, MRP can increase the protection afforded workers by the beryllium standards not only directly by improving medical surveillance but also indirectly by providing employers with economic incentives to comply with other provisions of the standard. The costs of MRP are likely to decrease as employer compliance with other provisions of the standard increases. Employers who comply with other provisions of the standard may have to remove relatively few employees. With only a small number of employees requiring removal, complying employers are more likely to be able to find positions available to which removed employees can be transferred. By contrast, employers who make only cursory attempts to comply with the central provisions of these standards are likely to find that the greater their degree of noncompliance, the greater the number of employees requiring medical removal and the greater the associated MRP costs. Thus, as OSHA explained in the preambles to its substance-specific standards on Cadmium and Lead, the inclusion of MRP in a final rule can serve as a strong stimulus for employers to protect worker health and rewards employers who through innovation and creativity derive new ways of protecting worker health not contemplated by these standards (57 FR 42102, 42368 (Sep. 14, 1992); 43 FR 54354, 54450 (Nov. 21, 1978)).

OSHA has the authority to include MRP in this standard. Indeed, the Court of Appeals for the D.C. Circuit recognized the Agency's authority to adopt such provisions more than 35 years ago in its review of the Agency's Lead standard (Lead I, 647 F.2d at 1229–1236). There, the Court found that MRP ''appears to lie well within the general range of OSHA's powers,'' and reasonable in the case of lead because it would help prevent impermissibly high blood lead levels and mitigate potential employee concerns about cooperating with the medical surveillance program (Id. at 1232, 1237). And, in the three and a half decades since the Lead I decision, OSHA has adopted MRP in five other substance-specific health standards: Cadmium (29 CFR 1910.1027), Benzene (29 CFR 1910.1028), Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene chloride (1910.1052).

Paragraph (l)(1) of the proposed standard detailed the eligibility requirements for medical removal. The provision explained that an employee would be eligible for medical removal if he or she works in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for sensitization. OSHA specifically asked for comments on whether beryllium sensitization and CBD are appropriate triggers for medical removal and whether there are other medical conditions or findings that should trigger medical removal.

Stakeholders generally supported the proposed triggers. ORCHSE Strategies (ORCHSE) argued that confirmed beryllium sensitization and CBD are appropriate triggers for medical removal (Document ID 1691, Attachment 1, p. 15). ORCHSE explained that since CBD is a chronic, progressive lung disease with no known cure, it is imperative that signs of health impairment be found early and exposure be terminated to avoid further impairment (Document ID 1691, Attachment 1, p. 15). NJH also commented that confirmed beryllium sensitization and CBD are appropriate triggers for medical removal (Document ID 1664, p. 9). Ameren, North America's Building Trades Unions (NABTU), Materion Corporation (Materion), and USW agreed (Document ID 1675, p. 20; 1679, p. 14; 1680, p. 7; 1681, pp. 14–15). USW commented that medical removal could prevent the progression of disease in workers diagnosed with sensitization or CBD (Document ID 1681, p. 15). However the Department of Defense argued that CBD but not beryllium sensitization is an appropriate trigger for medical removal and that sensitization is an appropriate trigger for advising employees about risk and requiring use of personal protective equipment if the employee chooses to return to work (Document ID 1684, Attachment 2, p. 1–8). The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) indicated support for the action level exposure trigger (Document ID 1809, p. 1; 1809, Attachment 2, Tr. 930–931; 942–943).

After reviewing the record on this issue, OSHA has decided that a CBD diagnosis and a confirmed positive test for sensitization are appropriate triggers for medical removal. OSHA disagrees

with the DOD and concludes that sensitization is an appropriate trigger for medical removal because removal from exposure may prevent the onset of CBD. Therefore, OSHA is retaining the triggers of both sensitization and CBD.

Final paragraph (l)(1), consistent with the proposal, states that the employee is eligible for medical removal if the employee works in a job with exposure at or above the action level, but contains more specificity about the types of documentation that are submitted to the employer to demonstrate eligibility for medical removal. This change was made to track employee privacy protections included in the licensed physician's medical opinion in paragraph (k)(6) and the CBD diagnostic center's medical opinion in paragraph (k)(7)(iii). Under paragraphs (k)(5) and (k)(7)(ii), the standards now specify that the licensed physician or CBD diagnostic center provides only the employee a medical report that contains detailed medical findings, such as confirmed positive findings or a diagnosis of CBD. In cases where the employee is confirmed positive or diagnosed with CBD, the physician or CBD diagnostic center also includes recommendations for removal from exposure in the written medical report. However, under paragraphs (k)(6) and (k)(7)(iii), employers do not receive a written medical opinion that contains an employee's medical information (other than any recommended limitations on the employee's use of respirators) without the employee's written consent. The written opinion to the employer may contain a recommendation for removal from exposure, without the medical reason for the recommendation, only if the employee authorizes that recommendation to be included in the opinion. This allows an employee who is eligible for medical removal and chooses that option to provide official documentation requesting removal, without disclosing a specific medical condition.

Thus, paragraph (l)(1) allows an employee's eligibility for removal to be established by four different types of documentation:

- The employee may provide a (k)(5) or (k)(7)(ii) written medical report indicating a confirmed positive finding or diagnoses of CBD and recommending removal because of that finding or diagnosis.
- The employee may provide a (k)(5) or (k)(7)(ii) written medical report in which the confirmed positive finding or diagnosis has been obscured or removed, but still contains the recommendation of removal because of that finding or diagnosis. An employee might do this if, consistent with the approach of paragraph (k), the employee wishes to keep the details of the condition private.
- The employee may provide any reliable medical documentation establishing a confirmed positive finding or diagnosis of CBD, regardless of whether it was issued in compliance with paragraph (k)(5). An employee might do this if, for example, the documentation predates this standard. This documentation would be a ''written medical report'' for purposes of (l)(1)(i)(A).
- The employer receives a (k)(6) or (k)(7)(iii) written medical opinion recommending removal from the licensed physician or CBD diagnostic center.

OSHA added the language ''in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard'' to (l)(1)(i)(B) and ''in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of the standard'' to (l)(1)(ii) to be clear that medical removal is required under those provisions only when the removal recommendation is based on a confirmed positive finding or a diagnosis of CBD.

Paragraph (l)(2) of the proposal laid out the options for employees who are eligible for MRP. Specifically, paragraph (l)(2) required eligible employees to choose removal, as described under paragraph (l)(3), or to remain in a job with exposure at or above the action level as long as they wear a respirator in accordance with paragraph (g) of this standard. While both ORCHSE and Public Citizen supported the MRP provision, neither supported making removal optional (Document ID 1691, Attachment 1, p. 13; 1756, Tr. 189). ORCHSE specifically stated that utilizing respiratory protection as a means of protecting workers violates the hierarchy of controls and removal is most prudent for worker protection (Document ID 1691, Attachment 1, p. 13).

After careful consideration of these comments, OSHA has decided to allow employees to choose between removal and remaining in a job with airborne exposure at or above the action level, provided that the employee uses respiratory protection for exposures at or above the action level, as contemplated in the proposal. OSHA recognizes that removal may reduce the risk of the onset of CBD and lead to reduction of symptoms. However, CBD is unlike triggers for MRP in some other OSHA standards, such as lead and benzene, because CBD is not reversible. Thus, without the respirator option, mandatory removal would require that the employee switch careers permanently. OSHA believes the worker should be given a voice in such a fundamental life decision where the confirmed positive employee may be able to minimize the risk of CBD through the consistent and careful use of respiratory protection in a workplace where feasible controls are implemented to maintain exposures within the PEL. Indeed, mandatory permanent removal might lead workers to hide their symptoms or not seek treatment, which is directly contrary to the purpose of MRP. For these reasons, the Agency finds mandating removal is not appropriate in this rulemaking. Therefore, paragraph (l)(2) of the final standards requires employers to provide eligible employees with the employee's choice of: (i) Removal as described in paragraph (l)(3) of these standards; or (ii) remaining in a job with airborne exposure at or above the action level, provided that the employee uses respiratory protection that complies with paragraph (g) of these standards whenever exposures are at or above the action level.

Although paragraph (l)(2) of the final standards tracks OSHA's intent as expressed in the proposal, the final provision contains several clarifying changes. First, final paragraph (l)(2) explicitly places the responsibility for providing the choices on the employer, while the proposal merely implied that the employer would do so. OSHA believes that this clarification eliminates the possibility of confusion. Second, final paragraph (l)(2)(ii) refers to paragraph (g) of these standards, instead of referring to the Respiratory Protection standard (29 CFR 1910.134). OSHA made this second change to bring this provision into line with a similar provision in paragraph (e) of the final standards; it does not affect the employer's obligations as set forth in the proposed rule. Third, final paragraph (l)(2)(ii) expressly requires employers to ensure that employees use the respiratory protection whenever airborne exposures meet or exceed the action level. Again, this requirement was implied in the proposal, but OSHA believes that making the requirement express helps employers understand their obligations under these standards.

Proposed paragraph (l)(3) contained requirements that would have applied if an eligible employee elected removal. Under the proposal, when an employee chooses removal, the employer would have been required to remove the employee to comparable work if such work was available. Proposed paragraph (l)(3)(i) explained that comparable work is a position for which the employee is already qualified or can be trained

within one month, in an environment where beryllium exposure is below the action level. As explained in the preamble to the proposal, this provision would not have required an employer to place an employee on paid leave under proposed paragraph (l)(3)(iii) if the employee refused comparable work offered under paragraph (l)(3)(i).

If comparable work was not immediately available, paragraph (l)(3)(ii) of the proposal would have required the employer to place the employee on paid leave for six months or until comparable work becomes available, whichever occurs first. Proposed paragraph (l)(3)(ii) further explained that if comparable work became available before the end of the six month paid leave period, the employer would have been obligated to offer the open position to the employee. However, OSHA explained that if the employee declined the position, the employer would have had no further obligation to provide paid leave.

Proposed paragraph (l)(3)(iii) would have continued a removed employee's rights and benefits for six months, regardless of whether the employee was removed to comparable work or placed on paid leave. The six-month period would have begun when the employee was removed, which means either the day the employer transferred the employee to comparable work, or the day the employer placed the employee on paid leave. For this period, the provision would have required the employer to maintain the employee's base earnings, seniority, and other rights and benefits of employment as they existed at the time of removal. OSHA explained that this provision is typical of medical removal provisions in other OSHA standards, such as Cadmium (29 CFR 1910.1027), Benzene (29 CFR 1910.1028), Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene Chloride (29 CFR 1910.1052).

As detailed above, there is widespread support among stakeholders for the inclusion of removal and wage protection for eligible employees in this rulemaking. The provisions included in the proposal were consistent with the recommendation of beryllium health specialists in the medical community and with the draft recommended standard provided by Materion and USW (Document ID 0754). However, not all commenters agreed with the proposed provisions. One commenter, NABTU, argued that ''[i]f an employer who has placed an employee at risk cannot offer alternative employment [within six months], then a better solution would be to provide MRP until the employee has obtained new and equivalent employment, provided that the employee is making *a good faith effort at finding new employment* [emphasis added].'' (Document ID 1679, p. 15).

OSHA is sympathetic to NABTU's position—some employers, especially small employers, may lack the flexibility and resources to provide comparable positions for MRP-eligible employees (Document ID 0345, p. 24), and as a result, employees' base earnings and benefits would only be maintained for a six-month period. However, OSHA also recognizes that the requirement to maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for even a six-month period may be difficult for some employers. After weighing these two concerns, OSHA finds that the requirement to provide medical removal protection for a six-month period strikes a reasonable balance between protecting employees and limiting the burden on employers. Therefore, OSHA has decided to retain these provisions in the final standard with minor edits, as follows.

First, OSHA reorganized and edited paragraph (l)(3)(i) to clarify and emphasize the employer's responsibilities. Like the proposed provision, final paragraph (l)(3) applies where an eligible employee chooses removal. If a comparable job is available where exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, final paragraph (l)(3)(i) requires the employer to remove the employee to that job. Although each of these requirements was expressly stated in the NPRM in either the regulatory text or the preamble (80 FR 47802), OSHA has chosen to make its intent express in the final regulatory text. For example, the NPRM implied in regulatory text and explained in the preamble that an employer's obligation under proposed paragraph (l)(3)(i) arose where comparable work was available, but the final text makes the trigger for this obligation explicit (see 80 FR 47802; proposed paragraph (l)(3)(ii) (which applied ''if comparable work is not available)).

Second, OSHA omitted the proposed requirement in paragraph (l)(3)(i) that ''[t]he employee must accept comparable work if such work is available'' from final paragraph (l)(3)(i). As stated in the preamble to the proposal, OSHA included this statement in proposed paragraph (l)(3)(i), in part, to make clear that if the employee declines an offer of comparable work, then the employer was not obligated to place the employee on paid leave under paragraph (l)(3)(ii) (80 FR 47802). However, because OSHA regulates employers, this requirement is better expressed as a clarification to the employer's responsibilities. OSHA concludes that the opening clause to proposed and final paragraphs (l)(3)(ii), which indicates that an employer's obligation to maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal arises ''[i]f comparable work is not available'' makes this sufficiently clear.

Third, OSHA eliminated proposed paragraphs (l)(3)(iii), which stated that ''whether the employee is removed to comparable work or placed on paid leave, the employer shall maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.'' In the final rule, proposed (l)(3)(iii)'s requirements have been incorporated into final paragraphs (l)(3)(i) and (ii). OSHA believes that this simplification will clarify the Agency's intent.

OSHA has also omitted the phrase ''paid leave'' from final paragraph (l)(3)(ii) because, with the incorporation of proposed paragraph (l)(3)(iii)'s temporal and benefits requirements into final paragraph (l)(3)(ii), it is unnecessary to specify what an employee who has been removed but is not working in a comparable job would be doing. In addition, OSHA wishes to give employers the flexibility to work with removed employees to create alternatives to merely placing the employee on paid leave. For example, employers might choose to offer the employee the opportunity to train for more than one month so that he or she could qualify for a different job. Provided that the employer otherwise complied with final paragraph (l)(3)(ii), such an arrangement would be permissible under the final standards.

Finally, proposed paragraph (l)(4) provided that an employer's obligation to provide MRP benefits to a removed employee would be reduced if, and to the extent that, the employee receives compensation from a publicly or employer-funded compensation program for earnings lost during the removal period, or receives income from another employer made possible by virtue of the employee's removal. OSHA retained this requirement unchanged in final paragraph (l)(4). OSHA clarifies that benefits received under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) do not constitute wage replacement; therefore, EEOICPA benefits would not offset the employee's MRP benefits.

OSHA did not receive any comments specifically directed to this provision, but, as noted above, several stakeholders commented that they supported the MRP provisions contained in the proposal as a whole (*i.e.,* Document ID 1664, pp. 3–4, 9; 1680, pp. 1, 7; 1681, pp. 14–15; 1683, p. 3; 1688, p. 2; 1689, pp. 8, 13–14; 1690, pp. 1, 3–4; 1691, Attachment 1, pp. 13, 15; 1755, Tr. 26, 168; 1756, Tr. 142–143; 1809, p. 1; 1963, pp. 13–14). After considering all comments and the record as a whole on MRP, OSHA finds that a provision for MRP is a necessary part of the final rule. As discussed above, MRP protects an employee's rights and benefits during the first six months of removal, and OSHA structured the MRP provisions to provide for ways to reduce in certain circumstances an employer's obligation to compensate employees for earnings lost. OSHA emphasizes, however, that MRP is not intended to serve as a workers' compensation system. The primary reason the Agency is including MRP in this standard is to provide eligible employees a six-month period to adjust to the comparable work arrangement or to seek alternative employment, without any further exposure at or above the action level. The Agency finds that this provision accomplishes that goal while providing for allowing the employer to control costs in many cases. In addition, this provision is consistent with other standards such as Formaldehyde (29 CFR 1910.1048), Methylenedianiline (29 CFR 1910.1050), and Methylene Chloride (29 CFR 1910.1052).

For the reasons discussed above, OSHA finds that maintaining the MRP provision, with the clarifying changes noted above, in the final rule provides workers the incentive to participate in the medical surveillance program and provides workers with sensitization or CBD the opportunity and means to minimize further exposure to beryllium.

(m) Communication of Hazards

Paragraph (m) of the standards for general industry, construction, and shipyards sets forth the employer's obligations to comply with OSHA's Hazard Communication Standard (HCS) (29 CFR 1910.1200) relative to beryllium, and to take additional steps to warn and train employees about the hazards of beryllium. Employees need to know about the hazards to which they are exposed, along with the associated protective measures, in order to understand how they can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and safety data sheets (SDSs). These written forms of communication will be most effective when employees understand the information presented and are aware of how to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects. Several commenters, including Ameren Corporation (Ameren) and United Steelworkers (USW), generally supported inclusion of a hazard communication requirement in the beryllium standards (*e.g.,* Document ID 1675, p. 7; 1681, p. 15).

As a general matter, the HCS requires a comprehensive hazard evaluation and communication process, aimed at ensuring that the hazards of all chemicals are evaluated, and also requires that the information concerning chemical hazards and necessary protective measures is properly transmitted to employees. The HCS achieves this goal, in part, by requiring chemical manufacturers and importers to review available scientific evidence concerning the physical and health hazards of the chemicals they produce or import to determine if they are hazardous. For every chemical found to be hazardous, the chemical manufacturer or importer must develop a container label and an SDS, and provide both documents to downstream users of the chemical. All employers with employees exposed to hazardous chemicals must develop a hazard communication program and ensure that all containers of hazardous chemicals are labeled and employees are provided access to SDSs and are trained on the hazardous chemicals in their workplace. Because OSHA preliminarily found beryllium to be a hazardous chemical, the Agency determined that hazard communications provisions should be included in the proposal. OSHA intends for the hazard communication requirements in the final standards to be substantively as consistent as possible with the HCS, while including additional specific requirements needed to protect employees exposed to beryllium, in order to avoid duplicative administrative burden on employers who must comply with both the HCS and this rule. Proposed paragraph (m)(1)(i) required chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS (29 CFR 1910.1200) for beryllium. Stakeholders did not offer any comments on this provision. After reviewing the full record, including all available evidence, and as discussed in this preamble at Section V, Health Effects, and Section VI, Risk Assessment, OSHA finds that beryllium is a hazardous chemical for purposes of the HCS. Therefore, the Agency includes paragraph (m)(1)(i) of the final standards for general industry, construction, and shipyards to require chemical manufacturers, importers, distributors, and employers to comply with their duties under HCS. The final provision in these standards is substantively unchanged from the proposed provision. Paragraph (m)(1)(ii) of the proposal required employers to address at least the following, in classifying the hazards of beryllium: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation. According to the HCS, employers must classify hazards if they do not rely on the classifications of chemical manufacturers, importers, and distributors (see 29 CFR 1910.1200(d)(1)). Commenters did not object to this provision. Therefore, after considering the record, including the general comments in favor of the proposed hazard communications provisions and the evidence presented in Section V, Health Effects, and Section VI, Risk Assessment, regarding the enumerated hazards of exposure to beryllium, OSHA has decided to retain this proposed provision substantively unchanged in final paragraph (m)(1)(ii) of the standards for general industry and shipyards. However, OSHA has revised the language to bring it into conformity with other substance specific standards so it is clear that chemical manufacturers, importers, and distributors are among the entities required to classify the hazards of beryllium (See 77 FR 17748–50).

OSHA has chosen not to include an equivalent requirement in the final standards for construction and shipyards since employers in construction and shipyards are downstream users of beryllium products (blasting media) and would not therefore be classifying chemicals (Chapter IV of the Final Economic Analysis).

Proposed paragraph (m)(1)(iii) required employers to include beryllium in the hazard communication program established to comply with the HCS, and ensure that each employee has access to labels on containers and safety data sheets for beryllium and is trained in accordance with the HCS and paragraph (m)(4) of this section. Stakeholders did not object to any part of this provision. After reviewing the record, OSHA reaffirms that employees

exposed to beryllium need additional training and information. Therefore, OSHA has decided to include the approach set forth in the proposed rule in the final paragraph (m)(1)(iii) of the final standards for general industry and shipyards and final paragraph (m)(1)(ii) of the standard for construction. The final provisions are substantively unchanged from the proposal.

Paragraph (m)(2)(i) of the proposed standard required employers to provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area. Proposed paragraph (m)(2)(ii) of the standards required employers to ensure that warning signs are legible and readily visible, and that they bear the following legend:

DANGER
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

A number of stakeholders offered opinions on these provisions. Some stakeholders, like the USW, supported the proposed provisions (*e.g.,* Document ID 1681, p. 15). Other stakeholders offered specific critiques regarding the proposed required language for the signs. For example, NGK Metals Corporation (NGK) and Materion Corporation (Materion) strongly opposed having cancer warnings displayed on warning signs. These commenters requested that OSHA strike out the cancer warning based on the results of a recent study by Boffetta, *et al.* (2014) (Document ID 0403) that does not show an elevated risk of cancer to workers exposed to beryllium (Document ID 1663, p. 3; 0403; 1958, pp. 3–5). Materion added that the cancer warning masks the true risk, CBD, and that the wording on warning signs should be changed to ''Causes Damage to Lungs'' to reflect the true hazard (Document ID 1958, pp. 4–5).

OSHA has decided to retain the hazard statement about cancer as a requirement for the warning signs. As discussed in this preamble at Section V, Health Effects, and Section VI, Risk Assessment, OSHA has reviewed the scientific literature for beryllium carcinogenicity, including the Boffeta study, and has concluded that beryllium is carcinogenic. The Agency's finding is based on the best available epidemiological data, reflects evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations. Furthermore, the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen (Document ID 0651; 0389, pp. 1–3; 1304; 0345, p. 4). In light of this evidence, OSHA finds the comments opposing the cancer warning language on signs unpersuasive. However, with regard to Materion's suggested language, OSHA agrees that a warning that beryllium can cause damage to lungs is appropriate and retains that language, as proposed, in the final standards for general industry and shipyards.

A few other stakeholders also suggested edits or additions to the proposed sign legend. For example, NGK recommended that the phrase, WEAR RESPIRATORY PROTECTION AND PROTECTIVE EQUIPMENT IN THIS AREA be changed to WEAR RESPIRATORY PROTECTION AND PROTECTIVE EQUIPMENT PRIOR TO ENTERING THIS AREA, on warning signs to emphasize that personal protective equipment (PPE) must be put on before entering the restricted work area (Document ID 1663, p. 3). OSHA agrees that employees need to don PPE prior to entering the regulated area, but finds the suggested language requiring respiratory protection and PPE ''in this area'' is sufficient to alert the workers to put their equipment and respirators on prior to entering the restricted work area. Therefore, OSHA has decided to retain the text ''in this area'' as stated in the final standards for general industry and shipyards. OSHA also notes that this language is consistent with the HCS and other previous health standards, such as Benzene (29 CFR 1910.1028).

One stakeholder proposed a provision particular to shipyards. In hearing testimony, Ashlee Fitch of USW commented that warning signs ''demarking abrasive blasting operations with beryllium-containing materials'' should be posted (Document ID 1756, p. 245). OSHA has chosen not to incorporate this suggestion. The signs required by paragraph (m)(2) of this final rule are intended to serve as a warning to employees and others who may not be aware that they are entering a regulated area, and to remind them of the hazards of beryllium so that they take necessary protective steps before entering the area. These signs are also intended to supplement the training that employees must receive regarding the hazards of beryllium, since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary before entering these dangerous areas (see paragraph (m)(4) of this rule and 29 CFR 1910.1200(h) for training requirements). OSHA does not believe it is necessary for the signs to denote the precise activity occurring within the regulated area in order to accomplish these goals. However, employers may choose to include additional information on the signs required under this rule, provided that the additional information included is not confusing or misleading and does not detract from required warnings.

Thus, paragraph (m)(2)(i)) of the final standards for general industry and shipyards requires employers to provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area. Pursuant to final paragraph (m)(2)(ii), employers must ensure that these warning signs legible and readily visible and include the specified legend. The only alteration to the legend from the proposal is the addition of the words, ''REGULATED AREA'' following the word, ''DANGER.'' OSHA has not included these regulated area signage requirements in the final standard for construction, because the construction standard does not contain requirements for establishing regulated area and uses the competent person (paragraph (e) of the construction standard) to limit access to areas where exposures have the potential to be above the PEL. In summary, OSHA finds that the use of warning signs is important to make employees who are regularly scheduled to work at these sites aware of beryllium hazards, to alert employees who have limited access to these sites of beryllium hazards, and to warn those who do not require access to regulated areas to avoid those areas. Access must be limited to authorized personnel to ensure that those entering the area are adequately trained and equipped, and to limit exposure to those whose presence is absolutely necessary. By limiting access to authorized persons, employers can minimize employee exposure to beryllium in regulated areas and thereby minimize the number of employees who may require medical surveillance or may be subject to the other requirements associated with working in a regulated area.

Proposed paragraph (m)(3) required that labels be affixed to all bags and containers of clothing, equipment, and materials visibly contaminated with beryllium. OSHA also included a requirement that the labels contain the following statement:

DANGER

CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

The USW supported the proposal's requirement that bags and containers storing materials visibly contaminated with beryllium have specific warning labels to alert workers of the dangers of beryllium exposure (Document ID 1681, p. 15). However, as discussed in the Summary and Explanation on paragraph (h) on personal protective clothing and equipment, several commenters objected to the use of the term ''visibly contaminated.'' For example, the Non-Ferrous Founder's Society (NFFS) commented that the definition of ''visibly contaminated with beryllium'' was not provided in the proposed rule and was vague (Document ID 1679, p. 5). OSHA agrees that the term is ambiguous and has chosen to remove the term visibly from the final standards. OSHA has therefore relied on terminology that is commonly used in other substance specific standards for metals, such as Chromium (VI) (29 CFR 1910.1026). NGK also recommended that OSHA insert the word ''particulate'' (Document ID 1663, pp. 3–4). OSHA declines to adopt this suggestion. The addition of the term ''particulate'' is unnecessary and may cause confusion since the final standards cover beryllium in all forms, compounds, and mixtures. Several stakeholders also weighed in on other aspects of these provisions. For example, NGK and Materion offered comments on the proposed wording of the required labels, which restated their requests that the cancer warnings be struck from the proposed language (Document ID 1663, pp. 3–4; 1958, pp. 3–5). OSHA has decided to retain the cancer warning labeling requirements in the final rule for the reasons discussed in response to their comments on paragraph (m)(2) above.

ORCHSE Strategies (ORCHSE) also commented on the labeling requirements of containers and bags in paragraph (m)(3). First, it argued that the provision would require the precautionary statements ''Avoid creating dust'' and ''Do not get on skin'' for all bags and containers which it maintained is inconsistent with the HCS precautionary statements (Document ID 1691, Attachment 1, p. 23). OSHA acknowledges that these ''precautionary statements'' are not from Appendix C of the HCS. However, OSHA is requiring alternate language for the unique situation for bags of contaminated clothing or equipment where workers handling these materials may not have access to other more in-depth forms of information. The Agency is therefore requiring that employers place appropriate warning language on bags and containers containing beryllium-contaminated materials. This provision is consistent with other substance-specific health standards.

Second, ORSCHSE argued that the proposed labeling requirements are inconsistent with the HCS. It stated that paragraph (m)(1) required compliance with the HCS, which covers warning labels for hazardous chemicals other than beryllium, ''so using the same standard for beryllium labels would promote consistency throughout the workplace.'' Therefore, it suggested that paragraph (m)(3) be deleted, because paragraph (m)(1) already requires observation of ''all requirements'' of the HCS. Additionally, ORCHSE commented that the HCS does not require labeling for carcinogens on bags and containers unless the concentration is 1% or more (Document ID 1691, Attachment 1, pp. 23–24).

After considering these comments and the record on this issue, OSHA has decided to retain proposed paragraph (m)(3) with the minor alteration described above. The final provision, which appears in paragraph (m)(3) of the final standards for general industry and shipyards and paragraph (m)(2) of the final standard for construction, requires employers to label each bag and container of clothing, equipment, and materials contaminated with beryllium. The required label must, at a minimum, include the language specified in the proposal. The warning label language for the signal word (danger) and hazard statements (may cause cancer) are consistent with the GHS. However, OSHA has decided that the precautionary statements needed to be slightly different due to the nature of the exposure and the fact that sensitization can result from short term exposures (see Health Effects section V of this preamble).

While ORCHSE correctly notes that the HCS contains a concentration cutoff (0.1% for category 1 carcinogens, and 1% for category 2 carcinogens), that cutoff is difficult to apply in the case of clothing or other material that has been contaminated with beryllium-containing dust. As a practical matter, it may be difficult to determine whether the cutoffs have been exceeded with dust contamination. Moreover, the cutoffs were developed for mixtures that are products and more homogeneous in nature, rather than materials contaminated with dust. If contaminated clothing or other materials are handled in a way that generates dust, exposures of concern might occur more readily than with homogenous mixtures of similar concentration. OSHA believes the clearer approach is to require all contaminated materials with a uniform labelling scheme, as it has for other substance-specific standards (*e.g.,* Lead, 29 CFR 1910.1025; Cadmium, 29 CFR 1910.1027; Coke Oven Emissions, 29 CFR 1910.1029). Including this provision will ensure that downstream workers who might receive the contaminated material have notice of the contamination. As discussed in the summary and explanation for paragraph (b) the term ''materials'' includes waste, scrap, debris, and any other items contaminated with beryllium.

The Agency finds that the final labeling requirements will help ensure that all affected employees, not only the employees of a particular employer, are apprised of the presence of beryllium-containing materials and the hazardous nature of beryllium exposure. With this knowledge, employees can take steps to protect themselves through proper work practices established by their employers. Employees are also better able to alert their employers if they believe exposures or skin contamination can occur.

Proposed paragraph (m)(4) contained requirements for employee information and training. The proposed provisions applied to each employee who is or can reasonably be expected to be exposed to airborne beryllium. ORCHSE strongly urged OSHA to rewrite this provision to align with the HCS training, arguing that ''there is no need to include chemical hazard training requirements in a substance specific standard'' (Document ID 1691, Attachment 1, p. 20). While OSHA agrees that the HCS is designed to cover all chemical hazards in the workplace, an employer may choose to train by specific chemical or by hazard. In this substance specific standard, OSHA find that employees need to be trained on the hazards specifically associated with beryllium, in addition to the training they receive under the HCS. These types of requirements are not uncommon in substance specific hazards. For example, the Lead standard requires annual training on the specific hazards associated with lead exposure (see 29 CFR 1910.1025 (l)(1)). Consequently, OSHA is not persuaded by ORCHSE that OSHA should substantially change the training provisions in the final rule.

The Boeing Company (Boeing) suggested that OSHA add the text ''within the scope of this standard'' to the end of this requirement (Document ID 1667, p. 7). It contended that its

recommended language would ''set a measurable boundary consistent with the scope of the standard,'' while the proposal would create an ''open ended boundary that would confuse compliance efforts.'' OSHA has considered the suggestion but does not find Boeing's argument persuasive. OSHA does not believe this adds additional clarity to employer on which employees should be trained. OSHA expects that once the employer is covered under the standard they are in the best position to determine who would be potentially exposed to beryllium. Additionally, this language is consistent with other substance specific standards, such as Benzene (29 CFR 1910.1028).

NGK also commented on the proposed trigger. Specifically, it suggested the training requirements should be consistent with the lead standard (29 CFR 1910.1025(l)(1)(ii)) in that the training should be done for those workers exposed above the action level (Document ID 1663, p. 4). OSHA declines to adopt this suggestion. As discussed in Section V, Health Effects, and Section VI, Risk Assessment, risk of material impairment to health remains at exposure levels below the action level. Because of this risk, OSHA concludes that it is necessary and appropriate to train all employees who may be exposed to airborne beryllium at any level. The Agency finds that all such employees will benefit from this training. Therefore, OSHA is continuing to trigger the training requirements proposed in paragraph (m)(4)(i) based on airborne exposure, or anticipated exposure, at any level. The final provisions are contained in paragraph (m)(4)(i) of the standards for general industry and shipyards and paragraph (m)(3)(i) of the standard for construction.

Proposed paragraph (m)(4)(i)(A) required employers to provide employees who are or can reasonably be expected to be exposed to airborne beryllium with information and training in accordance with the requirements of the HCS (29 CFR 1910.1200(h)), including specific information on beryllium as well as any other hazards addressed in the workplace hazard communication program.

OSHA did not receive any objections to or comments on this provision. After a review of the rulemaking record, the Agency continues to believe that the provision of information and training in accordance with the HCS will benefit employees. For example, under the HCS, employers must provide their employees with information such as the location and availability of the written hazard communication program, including lists of hazardous chemicals and safety data sheets, and the location of operations in their work areas where hazardous chemicals are present. The HCS also requires employers to train their employees on ways to detect the presence or release of hazardous chemicals in the work area, such as any monitoring conducted, the physical and health hazards of the chemicals in the work area, measures employees can take to protect themselves, and the details of the employer's hazard communication program (29 CFR 1910.1200(h)(3)). Therefore, OSHA has included proposed paragraph (m)(4)(i)(A) substantively unchanged from the proposal in paragraph (m)(4)(i)(A) of the final standards for general industry and shipyards and paragraph (m)(3)(i)(A) of the final standard for construction.

Proposed paragraphs (m)(4)(i)(B) and (C) specified when an employer's obligation to train covered employees should begin and how often training should occur. Proposed paragraph (m)(4)(i)(B) required initial training by the time of initial assignment, which means before the employee's first day of work in a job that could reasonably be expected to involve exposure to airborne beryllium. Under proposed paragraph (m)(4)(i)(C), employers were required to repeat training at least annually thereafter. USW supported the requirement of initial and annual training for workers who are or can be reasonably expected to be exposed to beryllium (Document ID 1681, p. 15).

After reviewing the record on this topic, OSHA has decided to retain proposed paragraphs (m)(4)(i)(B) and (m)(4)(i)(C) in paragraph (m)(4)(i)(B) and (C) of the final standards for general industry and shipyards and paragraph (m)(3)(i)(B) and (C) of the final standard for construction. OSHA finds that initial training and annual retraining are necessary due to the serious and debilitating health effects of beryllium exposure, and for reinforcement of employees' knowledge of those hazards. The initial training requirement is consistent with the HCS, which requires that employers provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment (29 CFR 1910.1200(h)(1)). In addition, while the triggers may be slightly different, the initial and annual training requirement are consistent with other OSHA standards such as those for Lead (29 CFR 1910.1025), Cadmium (29 CFR 1910.1027), Benzene (29 CFR 1910.1028), Coke Oven emissions (29 CFR 1910.1029), Cotton Dust (29 CFR 1910.1043), and 1,3-Butadiene (29 CFR 1910.1051).

Proposed paragraph (m)(4)(ii) required the employer to ensure that each employee who is or can reasonably be expected to be exposed to airborne beryllium can demonstrate knowledge of nine enumerated categories of information. ORCHSE and NGK objected to this proposed requirement. ORCHSE suggested that OSHA replace ''can demonstrate knowledge of'' with ''has been informed of'' in paragraph (m)(4)(ii). ORCHSE also argued that employers can control what information they provide, but cannot control what information the employee retains, and a literal interpretation of the requirement that employees must ''demonstrate knowledge of'' the nine enumerated categories of information will result in citations whenever ''any employee, at any moment, is unable to recite detail'' on those topics (Document ID 1691, Attachment 1, pp. 21–23). Similarly, NGK commented that the requirement that employers must ensure that employees who may be exposed to beryllium can demonstrate knowledge of enumerated subjects should be replaced with a requirement that employers ensure employee participation in a training program, consistent with the lead standard (29 CFR 1910.1025(l)(1)(ii)) (Document ID 1663, p. 4).

OSHA does not find these arguments persuasive. Because beryllium is a hazardous chemical with serious and debilitating health effects, it is imperative that employers can ensure that employees can demonstrate that they understand the material and have knowledge of the topics covered during the training sessions, as previously indicated. To adjust the text to read ''has been informed of'' or to require the employer to ensure employee participation in training will not ensure employee comprehension and consequently could lead to employees not understanding the health effects associated with beryllium exposure and safety concerns to protect themselves from exposure. This language would also be inconsistent with the HCS, which requires effective training which OSHA indicates must be in a manner which an employee comprehends.

The Agency understands that employers would like more clarity on how to determine whether training requirements are met. However, OSHA has decided that the training requirements under the final beryllium standards, like those in HCS, are best accomplished when they are performance-oriented. But, as in past

standards, the Agency does offer some suggestions.

First, although OSHA finds that the employer is in the best position to determine how the training can most effectively be accomplished, the Agency notes that hands-on training, videotapes, DVD or slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. Second, to ensure that employees comprehend the material presented during training, it is critical that trainees have the opportunity to ask questions and receive answers if they do not fully understand the material that is presented to them. When videotape presentations or computer-based programs are used, this requirement may be met by having a qualified trainer available to address questions after the presentation, or providing a telephone hotline so that trainees will have direct access to a qualified trainer. Although it is important that employees be able to ask questions, OSHA finds that the employer is in the best position to determine whether the instructor must be available for questions during training or if an instructor or trainer can answer questions after the training session. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program for each workplace.

Third, in addition to being performance-oriented, these training requirements are also results-oriented. As discussed in the respirable crystalline silica standard, there are a variety of methods employers can use to determine whether employees have the requisite knowledge. For example, employers may choose to facilitate discussions of the required training subjects or administer written tests or oral quizzes. Any of these methods could alert an employer to an employee knowledge gap.

Finally, OSHA has included a modification in the final standards that was prompted by ORCHSE and NGK's questions. In the final standards (paragraph (m)(4)(ii) of the standards for general industry and shipyards and paragraph (m)(3)(ii) of the standard for construction), OSHA requires that the employer must ensure that employees demonstrate understanding, in addition to knowledge. As discussed above this is consistent with the HCS and emphasizes that it is not enough for an employee to simply be provided with the information; the employer must also ensure that the employee understands the topics on which he or she is trained.

This change is consistent with Assistant Secretary David Michaels' memorandum to OSHA Regional Administrators (Document ID 1754, p. 2). The memorandum explains that because employees have varying educational levels, literacy, and language skills, training must be presented in a language, or languages, and at a level of understanding that accounts for these differences in order to ensure that employees understand the training. As stated by Assistant Secretary Michaels:

> [A]n employer must instruct its employees using both a language and vocabulary that the employees can understand. For example, if an employee does not speak or comprehend English, instruction must be provided in a language that the employee can understand. Similarly, if the employee's vocabulary is limited, the training must account for that limitation. By the same token, if employees are not literate, telling them to read training materials will not satisfy the employer's training obligation (Document ID 1754, p. 2).

This may mean, for example, providing materials, instruction, or assistance in Spanish rather than or in addition to English if some of the employees being trained are Spanish-speaking and do not understand English. However, the employer is not required to provide training in the employee's preferred language if the employee understands the language used for training.

Finally, Boeing suggested that OSHA add the text ''or equally as effective documentation'' to paragraph (m)(4)(ii)(B), so that the employer could satisfy its obligations by ensuring that employees who are or can reasonably be expected to be exposed to airborne beryllium could demonstrate knowledge of ''[t]he written exposure control plan, or equally as effective documentation, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature of operations that could result in employee exposure, especially employee exposure above the TWA PEL or STEL.'' They contend that this added language would allow employers ''to provide the required information through the use of existing processes instead of through the creation of a second redundant document'' (Document ID 1667, p. 7).

OSHA has considered Boeing's suggestion but does not find its arguments persuasive. Paragraph (m)(4)(ii)(B) of the final standards specifically requires the employer to ensure that employees can demonstrate understanding and knowledge of the topics covered in the written control plan, not from a similar document. The suggested language makes it unclear whether the employee would get the appropriate training needed and still gain the same knowledge and understanding required by the beryllium standard. OSHA, therefore, has decided to retain paragraph (m)(4)(ii)(B)'s requirements from the proposed rule in these final standards. That said, employers are free to incorporate their current exposure control program into the written control program required by paragraph (f)(1) if their program meets the requirements of that paragraph. If they do so, and train their employees on that program, paragraph (m)(4)(ii)(B) requires no ''second redundant document.''

Proposed paragraph (m)(4)(ii)(A)–(I) specified the contents of training for employees who are or can reasonably be expected to be exposed to airborne beryllium. The proposed list required employers to ensure that employees can demonstrate knowledge of: (1) The health hazards associated with exposure to soluble beryllium compounds, including the signs and symptoms of CBD; (2) the written exposure control plan, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature operations that could result in employee exposure, especially employee exposure above the TWA PEL or STEL; (3) the purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators; (4) applicable emergency procedures; (5) measures employees can take to protect themselves from exposure to beryllium and contact with soluble beryllium compounds, including personal hygiene practices; (6) the purpose and a description of the medical surveillance program required by paragraph (k) of this standard, including risks and benefits of each test to be offered; (7) the purpose and a description of the medical removal protection provided under paragraph (l) of this standard; (8) the contents of this standard; and (9) the employee's right of access to records under the Records Access Standard (29 CFR 1910.1020).

Stakeholders offered several comments on these proposed training topics. For example, ORCHSE commented that the employer should just ''provide information and training as specified in the HCS'' (Document 1691, Attachment 1, p. 23). OSHA has chosen not to adopt this suggestion because it finds that employees need training specific to beryllium and its hazards, not only the general training

required by the HCS on the hazards in the workplace. The Agency concludes that providing information and training on the topics proposed is essential to ensuring that employees are informed about the hazards attributed to beryllium exposures, the measures necessary to protect themselves, and the rights accorded to them under these standards.

Stakeholder comments support OSHA's finding that training will lead to better work practices and hazard avoidance. For example, in hearing testimony, Chris Trahan from North America's Building Trades Unions (NABTU) commented that in construction, she does not ''see a high level of awareness about hazards related to beryllium'' (Document ID 1756, pp. 207–08). NABTU also commented that it ''developed a survey to determine the level of awareness of beryllium hazards and knowledge of exposures among building trades trainers,'' and found widespread ignorance of beryllium health risks even among survey respondents responsible for delivering hazard awareness training (Document ID 1679 p. 5). Ashlee Fitch from the USW testified that in her experience in abrasive blasting, there was no training specific to what the material contained, and ''the health effects associated with . . . blasting media'' were not discussed (Document ID 1756, p. 247). Thus, OSHA concludes that mandating information and training on the topics specific to beryllium as outlined in proposed paragraph (m)(4)(ii) is particularly important.

In light of these comments, OSHA reaffirms its finding that all nine of the training topics listed in proposed paragraph (m)(4)(ii)(A)–(I) should be included in the final standards. The Agency has thus retained these topics in final paragraphs (m)(4)(ii)(A)–(I) of the standards for general industry and shipyards and paragraph (m)(3)(ii)(A)–(I) of the standard for construction, with minor alterations for consistency with triggers that were updated from the proposal to the final. For example, OSHA has changed the (m)(4)(ii)(A) from ''contact with soluble beryllium'' to ''contact with beryllium.''

OSHA is not mandating additional training for a competent person in paragraph (m) of the standards for construction. As discussed in more detail in the summary and explanation of *Written Exposure Control Plan,* the knowledge required by an individual implementing the written exposure control plan required by these standards already ensure a high level of competence. OSHA recognizes that there may be situations in which an employee needs additional training in order to ensure that he or she has the knowledge, skill, and ability to be a designated competent person, but because of unique scenarios in the construction and shipyard environments, those training requirements would vary widely. OSHA concludes, therefore, that it is the employer's responsibility to identify and provide any additional training that the competent person would need to implement the written exposure control plan.

Proposed paragraph (m)(4)(iii) required employers to provide additional training when workplace changes (such as modification of equipment, tasks, or procedures) result in new or increased employee exposure that exceeds or can reasonably be expected to exceed either the TWA PEL or the STEL. OSHA did not receive any comments on this provision, and retains it in the final to ensure that employees are aware of new or additional hazards. This training must be provided at the time of (or prior to) the new or increased exposure, even if a year has not passed since the previous training. New training would be required under the standard if the employer changes work production operations or personnel in a way that would require equipment to be operated differently to avoid exposures above the TWA PEL or STEL. Additional training would also be required if employers introduce new production or personal protective equipment to employees who do not yet know how to properly use the new equipment. Misuse of either the new production equipment or PPE could result in new exposures above the TWA PEL or STEL. Similarly, employers must provide additional training before employees repair or upgrade engineering controls if exposures during these activities will exceed or can reasonably be expected to exceed either the TWA PEL or the STEL. OSHA has concluded that the additional training requirement in this final rule is essential because it ensures that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

Proposed paragraph (m)(4)(iv) required the employer to make a copy of the standard and its appendices readily available at no cost to each employee and designated employee representative(s). OSHA did not receive any comments on this provision, and the Agency has retained the requirement in paragraph (m)(4)(iv) of the standards for general industry and shipyards and paragraph (m)(3)(iv) of the standard for construction. This is a common requirement in OSHA standards such as Chromium (VI) (29 CFR 1910.1026), Acrylonitrile (29 CFR 1910.1045), respirable crystalline silica (29 CFR 1910.1053), and Cotton Dust (29 CFR 1910.1043). The provision leaves employers free to determine the best way to make the standard available, which could include giving the employer a copy of the standard or placing a printed or electronic copy in a central location that the employees can easily access. In order to help ensure employees are protected against beryllium hazards, they need to be familiar with and have access to the beryllium standard applicable to their workplace (general industry, shipyard, or construction), and be aware of the employer's obligations to comply with it.

(n) Recordkeeping

Paragraph (n) of the final standards for general industry, construction, and shipyards sets forth the employer's obligation to comply with requirements to maintain records of air monitoring data, objective data, medical surveillance, and training. The recordkeeping requirements are in accordance with section 8(c) of the OSH Act (29 U.S.C. 657(c)), which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries and illnesses. The recordkeeping provisions are also consistent with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard at 29 CFR 1910.1020, which addresses access to employee exposure and medical records.

As discussed in more detail below, the recordkeeping requirements in the final standards are similar to those included in the proposal. In the proposed rule, OSHA identified recordkeeping requirements for exposure measurements, historical monitoring data, objective data, medical surveillance, and training, and required employers to comply with Record Access standard requirements regarding access to and transfer of these records. Ameren Corporation (Ameren) expressed support for these requirements (Document ID 1675, p. 7). All other comments regarding the recordkeeping requirements focused on specific areas of the recordkeeping requirements and are discussed in the appropriate subject section.

Proposed paragraph (n)(1)(i) required employers to maintain records of all

measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard. OSHA did not receive comments on this provision and has decided to retain it in the final rule, in part, because it will enable both employers and OSHA to ensure compliance with exposure assessment requirements under paragraph (d) of the standards. It will also allow employers to ascertain which of the final standards' provisions that are triggered at various exposure levels apply to their employees. Thus, OSHA is retaining the proposed provision with one minor modification. Specifically, the Agency has added the words ''make and'' prior to ''maintain'' in order to clarify that the employer's obligation is to create and preserve such records. This clarification has also been made for other records required by the final beryllium standards. The revised language is consistent with OSHA's Records Access standard, which refers to employee exposure and medical records that are made or maintained (29 CFR 1910.1020(b)(3)).

Proposed paragraph (n)(1)(ii) required that records of all measurements taken to monitor employee exposure include at least the following information: The date of measurement for each sample taken; the operation being monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) recommended that the recordkeeping provision should include the purpose and rationale for the sampling performed as this would show that the exposure monitoring requirements are being met (Document ID 1665, p. 2). After careful consideration, OSHA has decided not to require that records include the purpose and rationale for the sampling. The Agency points out that the purpose and rationale for the sampling performed are dictated by the exposure assessment provision in paragraph (d), which requires the employer to assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either a performance option or the scheduled monitoring option. The air monitoring requirements described in paragraph (d) and the air monitoring data retention described in this section (paragraph (n)) provide adequate information to show whether the exposure monitoring requirements are being met. Furthermore, paragraphs (n)(1)(ii)(A)–(F) of the standards are generally consistent with other OSHA standards, such as respirable crystalline silica (29 CFR 1910.1053), chromium (VI) (29 CFR 1910.1026), and methylene chloride (29 CFR 1910.1052).

OSHA received several comments regarding the requirement in paragraph (n)(1)(ii)(F) that the employer include employee social security numbers in exposure measurement records. The American Dental Association (ADA), the Boeing Company (Boeing), and ORCHSE Strategies (ORCHSE) cited employee privacy and identity theft concerns (Document ID 1597, p. 4 (pdf); 1667, pp. 7–8; 1691, Attachment 1, p. 19). Boeing and ORCHSE suggested the use of an identifier other than the social security number, such as an employee identification number or another unique personal identification number. The ADA recommended that employers with fewer than ten employees should not be required to include employee social security numbers in records required by the standard. It further stated that some state statutes ''impose data security and breach notification requirements on those who collect social security numbers,'' and in small businesses, ''the risk to employees of identity theft outweighs the difficulty of identifying employee records'' (Document ID 1597, p. 2–4 (pdf)).

OSHA has considered these comments and decided to retain the requirement for including the employee's social security number in the recordkeeping requirements of the rule. The requirement to use an employee's social security number is a long-standing OSHA practice, because a social security number is unique to an individual, is retained for a lifetime, and does not change when an employee changes employers. The social security number is therefore a useful tool for evaluating an individual's exposure over time, particularly where exposures are associated with chronic beryllium disease (CBD), which has a varying rate of progression during which time an employee may have several employers or had beryllium exposure sometime in the past.

OSHA recognizes the privacy concerns expressed by commenters regarding this requirement, and understands the need to balance that interest against the public health interest in requiring the social security identifier. Instances of identity theft and breaches of personal privacy are widely reported and concerning. However, OSHA has concluded that this rule should adhere to the past, consistent practice of requiring employee social security numbers on exposure records mandated by every OSHA substance-specific health standard, and that any change to the Agency's requirements for including employee social security numbers on exposure records should be comprehensive and apply to all OSHA standards, not just the standards for beryllium.

OSHA is proposing to delete the requirement that employers include employee social security numbers in records required by its substance-specific standards in the Agency's Standards Improvement Project—Phase IV (SIP–IV) proposed rule (81 FR 68504, 68526–68528 (10/4/16)). OSHA will revisit, if necessary, its decision to require employers to maintain employee social security numbers in beryllium records in light of the decision it makes in the SIP–IV rulemaking. In the meantime, OSHA has included the requirement to use and retain social security numbers in the final standards.

The ADA also urged OSHA to pursue Regulatory Alternative #1b, which would exempt, except for recordkeeping purposes, operations where the employer can show that employee exposures will not meet or exceed the action level or exceed the STEL. It further argued under this option that OSHA should limit employers' recordkeeping requirements to those records that show that employees' exposure will not meet or exceed the action level or exceed the STEL (Document ID 1597, p. 3 (pdf)). It maintained that this is reasonable because the ''employees are not at significant risk of exposure'' and ''the record retention period is onerous'' (Document ID 1597, p. 3 (pdf)).

OSHA disagrees with this suggestion for several reasons. First, the OSH Act states that standards adopted by OSHA must require employers maintain ''accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6.'' OSH Act § 8(c)(3). Thus, on its face, the Act requires records of all exposure measurements required by the final standards to be maintained, not just high ones. The OSH Act also requires that employees have access to exposure records, (id.), and requiring the employer to maintain those records helps to fulfill that right. Further, as discussed in Section V,

Health Effects, and Section VII, Significant Risk, employees who are exposed below the action level may still be at risk. Maintaining records of those exposures may assist in the diagnosis of employee disease long after the exposure occurs. It also allows employees to have confidence that their exposures are within the requirements of the final standards, and valuable insights about exposure control methods may be gained through the review of exposure records, even those that are below the action level. In addition, as the Supreme Court noted in the *Benzene* case, air monitoring and medical testing, when done for employees exposed below the PEL, ''keep a constant check on the validity of the assumptions made in developing'' the PEL, giving a basis to lower the PEL if necessary. *Benzene,* 448 U.S. at 657–58. Requiring the employers to maintain those records furthers that purpose. Other OSHA substance-specific rules also require employee exposure records to be maintained, regardless of exposure level, such as the standards addressing exposure to respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

Second, employee information and training requirements under paragraph (m) of the standards apply to each employee who is or can reasonably be expected to be exposed to airborne beryllium. As discussed in paragraph (m) of the Summary and Explanation in this preamble, OSHA finds that all employees who are or can be reasonably expected to be exposed in this manner will benefit from the specified forms of training. The creation and maintenance of training records will permit both OSHA and employers to ensure that the required training has occurred on schedule. Finally, OSHA notes that employers may reduce their recordkeeping burden in some cases by ensuring their employees are only exposed below the action level. For example, under paragraph (k), employers are required to offer medical surveillance those employees who meet certain exposure thresholds. By keeping exposures level below the action level, employers decrease the likelihood that their employees will fall into one of the enumerated groups. If employers do not have any employees covered by medical surveillance under paragraph (k), then they have no medical surveillance records to retain under these standards.

As to the expense and difficulty of maintaining the records required under these standards, OSHA recognizes that there will be time, effort, and expense involved in maintaining medical records. However, as stated earlier, OSHA expects that employers will have a system for maintaining these records, just as they do for their other business records. In addition, the Agency allows employers to use whatever method works best for them in meeting these requirements, paper or electronic (29 CFR 1910.1020(d)(2)).

In summary, paragraph (n)(1)(ii) in the final standards is substantively unchanged from the proposed rule. However, OSHA has made one editorial modification to paragraph (n)(1)(ii)(B), which is to change ''operation'' to ''task.'' Both ''task'' and ''operation'' are commonly used in describing work. However, OSHA uses the term ''task'' throughout the rule, and the Agency is using ''task'' in the recordkeeping provision for consistency and to avoid any potential misunderstanding that could result from using a different term. This editorial change neither increases nor decreases an employer's obligations as set forth in the proposed rule. The requirements of paragraph (n)(1)(ii) are generally consistent with those found in other OSHA standards, such as the standards for respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026).

Proposed paragraph (n)(1)(iii) required the employer to maintain exposure records in accordance with OSHA's Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)). The Agency did not receive comment on this provision. However, OSHA has changed the requirement that the employer ''maintain this record as required by'' OSHA's Records Access standard to ''ensure that exposure records are maintained and made available in accordance with'' that standard. OSHA believes that the language of the final standard more clearly conveys the Agency's intent that in addition to maintaining records, employers must make records available to employees and others as specified in the Records Access standard. As noted above, this clarifying change is editorial and neither increases nor decreases an employer's obligations as set forth in the proposed rule. This clarification has also been made for other records required by the final beryllium standards.

Proposed paragraph (n)(2) contained the requirement to retain records of any historical monitoring data used to satisfy the proposed standard's the initial monitoring requirements. As explained in the Summary and Explanation of paragraphs (b) and (d) in this preamble, the definition of the term ''objective data'' in the final rule includes all information that demonstrates airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. Historical data that reflects workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations would be considered objective data under the final rule. The requirement to keep records of objective data is addressed under a separate paragraph. Therefore, OSHA has chosen to delete the separate recordkeeping requirement for historical data.

Proposed paragraph (n)(3) contained the requirements to keep accurate records of objective data. Proposed paragraph (n)(3)(i) required employers to establish and maintain accurate records of the objective data relied upon to satisfy the requirement for initial monitoring in proposed paragraph (d)(2). Under proposed paragraph (n)(3)(ii), the record was required to contain at least the following information: The data relied upon; the beryllium-containing material in question; the source of the data; a description of the operation exempted from initial monitoring and how the data supported the exemption; and other information demonstrating that the data met the requirements for objective data in accordance with paragraph (d)(2)(ii).

OSHA did not receive comments regarding this provision, and the Agency finds that it should be included in the final rule. Since objective data may be used to exempt the employer from certain types of monitoring, as specified in paragraph (d), it is critical that the use of these types of data be carefully documented. Objective data are intended to provide the same degree of assurance that employee exposures have been correctly characterized as would exposure assessment. The specified content elements are required to ensure that the records are capable of demonstrating to OSHA a reasonable basis for the conclusions drawn by the employer from the objective data.

Therefore, OSHA has included proposed paragraph (n)(3) as paragraph (n)(2) in the final standards, with minor alterations. Specifically, in the final standards, OSHA has changed paragraphs (n)(2)(ii)(D) to require the record to contain ''[a] description of the process, task, or activity on which the objective data were based,'' and paragraph (n)(2)(ii)(E) to require the

record to contain ''[o]ther data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.'' These changes are editorial, and intended to clarify the maintenance and availability of objective data records. They are only intended to aid employers in determining the precise information to be retained. They do not affect the employer's obligations as set forth in the proposed rule.

Proposed paragraph (n)(3)(iii) required the employer to maintain a record of objective data relied upon as required by the Records Access standard, which specifies that exposure records must be maintained for 30 years (29 CFR 1910.1020(d)(1)(ii)). The Agency did not receive comment on this provision. Objective data may include employee exposure records that must be maintained, and therefore, the Agency has retained it in the final standards as paragraph (n)(2)(iii). OSHA notes that this final provision, like all of the final provisions in this paragraph related to the Records Access standard, includes the non-substantive change from the proposed requirement to maintain the record as required by the Records Access standard, to the requirement to maintain and make available the record in accordance with the Records Access standard. OSHA's reasons for this change are discussed above.

Paragraph (n)(3) of the final standards, like paragraph (n)(4) of the proposal, addresses medical surveillance records. Under proposed paragraph (n)(4)(i), employers had to establish and maintain medical surveillance records for each employee covered by the medical surveillance requirements in paragraph (k) of the proposed standard. Proposed paragraph (n)(4)(ii) listed the categories of information that an employer was required to record: The employee's name, social security number, and job classification; a copy of all licensed physicians' written medical opinions; and a copy of the information provided to the PLHCP as required by paragraph (k)(4) of the proposed standard.

The ADA and ORCHSE questioned the requirement that the employee's social security number be included in medical surveillance records (Document ID 1597, pp. 2–4 (pdf); 1691, Attachment 1, p. 19). As noted above in the discussion on exposure measurement records, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above, the Agency has decided to retain the requirement for use of social security numbers in medical records. OSHA is examining the requirements for social security numbers separately from this rulemaking.

Medical records document the results of medical surveillance and are especially important when an employee's medical condition places him or her at increased risk of health impairment from further exposure to beryllium in the workplace. Furthermore, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to beryllium exposure, evaluate compliance programs, and assess the efficacy of the standards. OSHA concludes that medical surveillance records are necessary and appropriate for protection of employee health, enforcement of the standards, and development of information regarding the causes and prevention of occupational illnesses. Therefore, OSHA has decided to retain proposed paragraph (n)(4)(ii)'s requirements regarding medical surveillance records in paragraph (n)(3)(ii) of the final standards. However, OSHA has changed the requirement in proposed paragraph (n)(4)(ii)(B) that the record include copies of all licensed physicians' written opinions to the requirement that the record include copies of all licensed physicians' written medical opinions for each employee in paragraph (n)(3)(ii)(B) of the final standards. These changes are editorial and intended to clarify that employees are entitled to their own written medical opinion, not all written opinions. This change neither increases nor decreases an employer's obligations as set forth in the proposed rule.

Proposed paragraph (n)(4)(iii) required the employer to maintain employee medical records for at least the duration of the employee's employment plus 30 years in accordance with OSHA's Records Access Standard at 29 CFR 1910.1020(d)(1)(i). The ADA objected to this provision, arguing that the proposed retention period is onerous (Document ID 1597, p. 3 (pdf)). OSHA has considered this comment and concluded that the best approach is to maintain consistency with 29 CFR 1910.1020 and its required retention periods of (1) 30 years for exposure records and objective data, and (2) the duration of employment plus 30 years for medical surveillance records. It is necessary to keep medical records for these extended time periods because of the varying rate of progression for CBD and the long latency period between exposure and development of lung cancer. OSHA recognizes that in some cases, the latency period for beryllium-related cancer may extend beyond 30 years. However, the Agency concludes that the retention periods specified in 29 CFR 1910.1020 represent a reasonable balance between the need to maintain records and the administrative burdens associated with maintaining those records for extended time periods. Because the 30-year, and the duration of employment plus 30-year, record retention requirements are currently included in 29 CFR 1910.1020, these time periods are consistent with longstanding Agency and employer practice. Other substance-specific rules are also subject to the retention requirements of 29 CFR 1910.1020, such as the standards addressing exposure to respirable crystalline silica (29 CFR 1910.1053), methylene chloride (29 CFR 1910.1052), and chromium (VI) (29 CFR 1910.1026). Thus, OSHA finds that the 30-year retention period is necessary and appropriate for exposure records, historical monitoring data, and objective data, and that the duration of employment plus 30-year retention period is necessary and appropriate for medical surveillance records.

Therefore, OSHA has decided to include the retention periods provided by the Records Access standard in paragraph (n)(3)(iii) of the final standards. For the reasons discussed above, OSHA has added ''and made available'' after ''maintained'' in paragraph (n)(3)(iii) of the standards. Under the final standards, the employer is responsible for the maintenance of records in his or her possession. The employer is also responsible for ensuring the retention of records in the possession of the licensed physician (*e.g.,* the written medical reports described in paragraph (n)(3) that are created pursuant to this rule's medical surveillance requirements). This responsibility, which derives from 29 CFR 1910.1020(b), means that employers must ensure that the licensed physician retains a copy of medical records for the employee's duration of employment plus 30 years. The employer can generally fulfill this obligation by including the retention requirement in its agreement with the licensed physician. The requirements are consistent with other OSHA health standards, such as Hexavalent Chromium (VI) (29 CFR 1910.1026), respirable crystalline silica (29 CFR 1910.1053), and Methylene Chloride (29 CFR 1910.1052).

Paragraph (n)(4) of the final standards, like proposed paragraph (n)(5), addresses training records. Proposed paragraph (n)(5)(i) required employers to prepare records of any training required by these standards. At the completion of training, the employer

was required to prepare a record that included the name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. This record maintenance requirement also applied to records of annual retraining or additional training as described in paragraph (m)(4).

The ADA and ORCHSE questioned the requirement that the employee's social security number be included in training records (Document ID 1597, p. 2–4 (pdf); 1691, Attachment 1, p. 19). As noted above in the discussions on exposure measurement and medical surveillance records, OSHA finds the privacy and security issues associated with the required use of social security numbers are of concern. However, for the same reasons discussed above, the Agency has decided to retain the requirement for use of social security numbers in training records. As stated above, OSHA is examining the requirements for social security numbers separately from this rulemaking. In the meantime, OSHA has retained the social security requirement in the final standards.

No other comments were received on this provision. Proposed paragraph (n)(5)(i) is now paragraph (n)(4)(i) in the final standards. Paragraph (n)(4)(i) in the final standards is substantively unchanged from the proposal.

Proposed paragraph (n)(5)(ii) required employers to retain training records, including records of annual retraining or additional training required under these standards, for a period of three years after the completion of the training. North America's Building Trades Unions (NABTU) commented that employers ''must maintain documentation of [any] training'' required for beryllium construction workers (Document ID 1679, p. 3). OSHA agrees. As noted above, OSHA finds that the creation and maintenance of training records will permit both OSHA and employers to ensure that the required training has occurred on schedule. Thus, the Agency has included this provision in the standard for construction, as well as the standards for general industry and shipyards. Proposed paragraph (n)(5)(ii) is now paragraph (n)(4)(ii) in the final standards, and is substantively unchanged from the proposal. The three-year time period is consistent with the Bloodborne Pathogens standard (29 CFR 1910.1030).

Paragraph (n)(5) of the final standards, like proposed paragraph (n)(6), addresses access to records. Proposed paragraph (n)(6) required employers to make all records mandated by these standards available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative as stipulated by OSHA's Records Access standard (29 CFR 1910.1020). OSHA did not receive comment on this provision, and includes it in the final standards to emphasize and ensure proper employee and government access to records.

Paragraph (n)(6) of the final standards, like proposed paragraph (n)(7), addresses transfer of records. Proposed paragraph (n)(7) required that employers comply with the Records Access standard regarding the transfer of records. The requirements for the transfer of records are explained in 29 CFR 1910.1020(h), which instructs employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business. OSHA did not receive comment on this provision, and includes it the final standards to help ensure consistent records access.

(o) Dates

Paragraph (o) of the standards for general industry, construction, and shipyards sets forth the effective date of the standards and the dates for compliance with their requirements. OSHA proposed that the final rule would become effective 60 days after its publication in the **Federal Register**, and that employer obligations to comply with most requirements of the final rule would begin 90 days after the effective date (150 days after publication of the final rule), while the requirements for establishing change rooms and implementing engineering controls would begin one year and two years after the effective date, respectively. Ameren, AFL–CIO, and United Steelworkers expressed support for the proposed effective and compliance dates (Document ID 1675, p. 7; 1681, Attachment 1, p. 15; 1689, p. 15).

OSHA sets the effective date to allow sufficient time for employers to obtain the standard and read and understand its requirements. Unchanged from the proposal, paragraph (o)(1) provides that the standards will become effective on March 10, 2017.

OSHA sets the compliance dates to allow sufficient time for employers to undertake the necessary planning and preparation for compliance with the various provisions of the standards. In addition to the default compliance date of 90 days that applied to most provisions, OSHA's proposal included extended compliance dates for the provisions that require the establishment of change rooms and the implementation of engineering controls in order to give affected employers sufficient time to design and construct change rooms where necessary, and to design, obtain, and install any required control equipment. In response to comments stating that more time is necessary to prepare for compliance, the compliance dates in the final rule have been extended from those proposed.

Paragraph (o)(2) of the standards establishes the dates for compliance with the requirements of the standard. Several employers and industry representatives commented that the proposal's default compliance date (90 days after the effective date) provided inadequate time to prepare for compliance. ORCHSE Strategies (ORCHSE) commented that an additional six months are needed ''to make necessary changes to facilities, broad-based exposure assessments, and delineate work and regulated areas'' (Document ID 1691, Attachment 1, p. 24). Also, the Boeing Company (Boeing) commented that the standard should require compliance two years after the effective date, explaining that ''it will take, for a company of our size, between 1 and 2 years to accurately and comprehensively determine what our exposures are, prior to developing and implementing an exposure plan'' (Document ID 1667, p. 8).

The Sampling and Analysis Subcommittee Task Group of the Beryllium Health and Safety Committee (BHSC Task Group) also commented on the amount of time needed to comply with the ''Accuracy of Measurement'' requirement in paragraph (d)(1)(v) of the proposal, which has been renamed ''Methods of sample analysis'' and moved to paragraph (d)(5) in the final standards (Document ID 1665, p. 3). Specifically, BHSC Task Group expressed concern that laboratories would need to adopt newer analytical methods not widely used by the majority of analytical laboratories to perform beryllium measurements to the level of accuracy specified by the standard. BHSC Task Group acknowledges that although the OSHA rule does not require it, a Department of Energy requirement for accreditation that exists in their Beryllium Worker Safety and Health Program would drive laboratories to obtain accreditation by an external accrediting body to use these newer methods, which can take well over 150 days. (Document ID 1665, p. 3–4). OSHA rejects the reasoning behind BHSC Task Group's concern on the amount of time needed to comply the accuracy of measurement

requirement, as the newer analytical methods for beryllium are available and, as pointed out by BHSC Task Group, OSHA does not require laboratories to be accredited in these methods to comply with the standards.

Nonetheless, OSHA recognizes the concerns expressed by Boeing, ORCHSE, and BHSC Task Group that employers may need additional time to assess exposures and undertake the necessary planning and preparation for compliance with the obligations of the standards, and has determined that some of those concerns are reasonable. OSHA has therefore extended the final standards' default compliance date, which applies to all provisions except for those with separate compliance dates under paragraphs (o)(2)(i) and (o)(2)(ii), to one year from the effective date.

Paragraph (o)(2)(i) of the standards provides the date for compliance with the requirement in paragraph (i) to establish change rooms, and in the general industry standard, to provide showers. OSHA proposed a compliance date of one year after the effective date for establishing change rooms, but commenters indicated that more time was needed to modify their facilities. Boeing requested that the compliance date for establishing change rooms begin three years after the effective date, stating that ''for large facilities, modifications such as showers, clothing storage and change rooms need a significant amount of time to be planned, designed, contracted, and constructed within operating factory sites'' (Document ID 1667, p. 8). ORCHSE also indicated that additional time is needed to ''make necessary changes to facilities'' (Document ID 1691, Attachment 1, p. 24).

OSHA expects that most employers will be able to establish change rooms and showers within a year of the effective date, but the Agency understands that some employers, both large and small, may need additional time to plan and construct these areas. OSHA is persuaded by the concerns expressed by the commenters that employers may need additional time to modify their facilities, and has extended the compliance date for the general industry standard's change rooms and showers requirements to two years after the effective date. Providing an extended compliance date for establishing change rooms and providing showers is consistent with the approach taken in OSHA's general industry standard for Cadmium (29 CFR 1910.1027(p)(2)(vi)(B)).

The construction and shipyard standards do not require employers to provide showers, but OSHA recognizes that construction and shipyard employers may also need additional time to plan and establish change rooms at construction sites and shipyard industry establishments. Change room facilities in these industries may be permanent or temporary, including mobile units that can be purchased or rented. OSHA has thus set the compliance date for the construction and shipyard standards' requirement to establish change rooms to two years after the effective date.

Paragraph (o)(2)(ii) of the standards provides the date for compliance with the requirements in paragraph (f) to implement engineering controls. OSHA proposed a compliance date of two years after the effective date for employers to comply with the engineering control requirements in paragraph (f). Boeing, however, commented that the compliance date for implementing engineering controls should be extended to four years after the effective date, explaining that ''for large companies, exposure assessments and feasibility studies would have to be completed on a vast scale, and then engineering controls may have to be installed,'' making four years ''a reasonable time frame for these compliance measures'' (Document ID 1667, pp. 8). The Non-Ferrous Founders' Society (NFFS) also commented that a two-year implementation period was insufficient because it takes 12 to 24 months to obtain an Environmental Protection Agency (EPA) permit for changes to ventilation systems, and foundries cannot begin work to modify ventilation systems until they obtain a permit (Document ID 1756, Tr. 61–62).

OSHA recognizes the concerns expressed by Boeing regarding the time needed to implement engineering controls, but does not agree that four years are needed to comply with the engineering control requirements. OSHA expects that many workplaces with beryllium will already have engineering controls in place for other hazardous materials that will need only modification or updating to comply with the final standards. For new installations, most types of engineering controls for working with materials such as beryllium are readily available.

Furthermore, because beryllium is regulated under EPA rules as a ''hazardous air pollutant'' with a relatively low volume threshold for a permit requirement, foundries that already exhaust beryllium in any quantity would likely already be subjected to the permitting requirements. Therefore, OSHA predicts that any changes to ventilation systems to comply with the final beryllium standards would generally only be subject to routine reporting requirements or permit modifications. Cases that are unusually problematic, however, can be addressed through OSHA's enforcement discretion if the employer can show that it has made good faith efforts to implement engineering controls, but has been unable to implement such controls due to the time needed for environmental permitting.

However, OSHA acknowledges that some general industry, construction and shipyard employers may need more than two years to comply with the engineering control obligations in paragraph (f), including the need to update any permits before modifying ventilation systems, and has extended the standards' compliance date for the engineering control requirements to three years from the effective date. OSHA has determined that setting a compliance date three years after the effective date will ensure that employers have sufficient time to complete the process of designing, obtaining, and installing the necessary control equipment.

OSHA's decision here to provide employers with an extended deadline for complying with engineering control requirements is consistent with what the Agency has done in health standards, including standards for respirable crystalline silica (29 CFR 1910.1053(l)), Chromium (VI) (29 CFR 1910.1026(n)(3), 29 CFR 1915.1026(l)(3), 29 CFR 1926.1126(l)(3)), and Cadmium (29 CFR 1910.1027(p)(2)(v)). Extending the compliance deadline for implementation of engineering controls will allow those firms that need extensive engineering controls time to adequately plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers. OSHA has also determined that the extension will have the ancillary benefit of limiting the economic impact of the rule by providing employers with additional time to plan for and absorb the costs associated with compliance. Based on its review of the rulemaking record, OSHA has concluded that employers will be able to implement engineering controls within the extended time frame that is established in the final rule.

(p) Appendix A to 29 CFR 1910.1024—Control Strategies To Minimize Beryllium Exposure

Appendix A to the final standard for general industry, 29 CFR 1910.1024, provides information to employers on

control options that employers could use to comply with paragraph (f)(2)(i) of the final rule, which requires employers to ensure that at least one of the types of controls listed in paragraph (f)(2)(i) is in place to reduce airborne exposure for each operation in a beryllium work area that releases airborne beryllium. Appendix A is for informational and guidance purposes only and none of the statements in Appendix A should be construed as imposing a mandatory requirement on employers that is not otherwise imposed by the standard. In addition, this appendix is not intended to detract from any obligation that the rule imposes.

The control strategies to minimize beryllium exposure were in Appendix B of the proposed rule, but proposed Appendix B has been redesignated as Appendix A in the final standard for general industry, following the deletion (discussed below) of proposed Appendix A. The information on control strategies presented in the appendix was derived from OSHA's analysis of the technological feasibility of the PELs, presented in Chapter IV of the Final Economic Analysis. The content of Appendix A of the final standard for general industry remains unchanged from that contained in Appendix B of the proposal.

The proposed rule also contained a non-mandatory appendix (designated in the proposal as Appendix A) that provided technical information on the BeLPT test. OSHA has determined that the information contained in proposed Appendix A is more suitable for separate guidance that will be issued in conjunction with the standards. OSHA will be able to more readily update this separate guidance to reflect technological advances and changes in recommendations from the medical community. Therefore, OSHA is not including proposed Appendix A in the final standards.

OSHA has also not included any appendices in the final standards for construction and shipyards since OSHA has identified only one principle operation (abrasive blasting) in these sectors involving worker exposure to beryllium.

List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Beryllium, Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

Authority and Signature

This document was prepared under the direction of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

The Agency issues the sections under the following authorities: 29 U.S.C. 653, 655, 657; 40 U.S.C. 3704; 33 U.S.C. 941; Secretary of Labor's Order 1–2012 (77 FR 3912 (1/25/2012)); and 29 CFR part 1911.

Signed at Washington, DC, on December 14, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons set forth in the preamble, Chapter XVII of Title 29, parts 1910, 1915, and 1926, of the Code of Federal Regulations is amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—[Amended]

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: 29 U.S.C. 653, 655, 657) Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 2. In § 1910.1000, paragraph (e):

■ a. Amend Table Z–1—Limits on Air Contaminants, by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote 8.

■ b. Amend Table Z–2 by revising the entry for ''Beryllium and beryllium compounds (Z37.29–1970)''; and adding footnote d.

The revisions read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm (a) [1]	mg/m³ (b) [1]	Skin designation
* * * *	*		*	*
Beryllium and beryllium compounds (as Be); see 1910.1024 [8]	7440–41–7			
* * * *	*		*	*

* * * * * * *

[8] *See* Table Z–2 for the exposure limits for any operations or sectors where the exposure limits in § 1910.1024 are stayed or otherwise not in effect.

TABLE Z–2

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling average concentration for an 8-hr shift	
			Concentration	Maximum duration
* * *	*	*	*	*
Beryllium and beryllium compounds (Z37.29–1970) [d]	2 μg/m³	5 μg/m³	25 μg/m³	30 minutes.

TABLE Z–2—Continued

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling average concentration for an 8-hr shift	
			Concentration	Maximum duration
* * *	*	*	*	*
* * *	*	*	*	*

[d] This standard applies to any operations or sectors for which the exposure limits in the beryllium standard, § 1910.1024, are stayed or is otherwise not in effect.

* * * * *

■ 3. Add § 1910.1024 to read as follows:

§ 1910.1024 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (§ 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (μg/m^3) calculated as an 8-hour time-weighted average (TWA).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee.

Beryllium lymphocyte proliferation test (BeLPT) means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt.

Beryllium work area means any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any uncontrolled release of airborne beryllium.

High-efficiency particulate air (HEPA) filter means a filter that is at least 99.97 percent efficient in removing particles 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this standard.

Regulated area means an area, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the time-weighted average (TWA) permissible exposure limit (PEL) or short term exposure limit (STEL).

This standard means this beryllium standard, 29 CFR 1910.1024.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m^3 calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m^3 as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne

exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of this paragraph (d)(3). In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory that can measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is measured or represented by the monitoring and each employee's representative(s).

(ii) When observation of monitoring requires entry into an area where the use of personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer and must ensure that each observer uses such clothing and equipment.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Beryllium work areas and regulated areas*—(1) *Establishment.* (i) The employer must establish and maintain a beryllium work area wherever the criteria for a ''beryllium work area'' set forth in paragraph (b) of this standard are met.

(ii) The employer must establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL.

(2) *Demarcation.* (i) The employer must identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area.

(ii) The employer must identify each regulated area in accordance with paragraph (m)(2) of this standard.

(3) *Access.* The employer must limit access to regulated areas to:

(i) Persons the employer authorizes or requires to be in a regulated area to perform work duties;

(ii) Persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring procedures under paragraph (d)(7) of this standard; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer must provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this standard; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination, including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas;

(E) Procedures for keeping surfaces as free as practicable of beryllium;

(F) Procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace;

(G) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(H) A list of personal protective clothing and equipment required by paragraph (h) of this standard; and

(I) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer must review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary, when:

(A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results, or can reasonably be expected to result, in new or additional airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (§ 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) For each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by paragraph (f)(2)(i) of this standard, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii) of this standard, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii) of this standard.

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (§ 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must provide at no cost, and ensure that each employee uses, appropriate personal protective clothing and equipment in accordance with the written exposure control plan required under paragraph (f)(1) of this standard and OSHA's Personal Protective Equipment standards (subpart I of this part):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal protective clothing or equipment from the workplace, except for employees authorized to do so for the purposes of laundering, cleaning, maintaining or disposing of beryllium-contaminated personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that

personal protective clothing and equipment are stored and transported in sealed bags or other closed containers that are impermeable and are labeled in accordance with paragraph (m)(3) of this standard and the HCS (§ 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee working in a beryllium work area, the employer must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1910.141) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees who work in a beryllium work area with a designated change room in accordance with this standard and the Sanitation standard (§ 1910.141) where employees are required to remove their personal clothing.

(3) *Showers.* (i) The employer must provide showers in accordance with the Sanitation standard (§ 1910.141) where:

(A) Airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and

(B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck.

(ii) Employers required to provide showers under paragraph (i)(3)(i) of this standard must ensure that each employee showers at the end of the work shift or work activity if:

(A) The employee reasonably could have had airborne exposure above the TWA PEL or STEL; and

(B) Beryllium could reasonably have contaminated the employee's hair or body parts other than hands, face, and neck.

(4) *Eating and drinking areas.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (§ 1910.141).

(5) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(j) *Housekeeping*—(1) *General.* (i) The employer must maintain all surfaces in beryllium work areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard; and

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.

(2) *Cleaning methods.* (i) The employer must ensure that surfaces in beryllium work areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

(iii) The employer must not allow the use of compressed air for cleaning beryllium-contaminated surfaces unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air.

(iv) Where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* The employer must ensure that:

(i) Materials designated for disposal that contain or are contaminated with beryllium are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard; and

(ii) Materials designated for recycling that contain or are contaminated with beryllium are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) of this standard recommends periodic medical surveillance.

(ii) The employer must ensure that all medical examinations and procedures required by this standard are performed by, or under the direction of, a licensed physician.

(2) *Frequency.* The employer must provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A), unless the employee has received a medical examination, provided in accordance

with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C).

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

(ii) The employer must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

(B) A physical examination with emphasis on the respiratory system;

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal protective clothing and equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l) of this standard.

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) A statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l) of this standard.

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of

this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv), and (v) of this standard and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraph (k)(6)(i), as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(4) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from a publicly or employer-funded compensation program, or receives income from another employer made possible by virtue of the employee's removal.

(m) *Communication of hazards*—(1) *General.* (i) Chemical manufacturers, importers, distributors, and employers must comply with all requirements of the HCS (§ 1910.1200) for beryllium.

(ii) In classifying the hazards of beryllium, at least the following hazards must be addressed: Cancer; lung effects (CBD and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

(iii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must ensure that each employee has access to labels on containers of beryllium and to safety data sheets, and is trained in accordance with the requirements of the HCS (§ 1910.1200) and paragraph (m)(4) of this standard.

(2) *Warning signs.* (i) *Posting.* The employer must provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area.

(ii) *Sign specification.* (A) The employer must ensure that the warning signs required by paragraph (m)(2)(i) of this standard are legible and readily visible.

(B) The employer must ensure each warning sign required by paragraph (m)(2)(i) of this standard bears the following legend:

DANGER
REGULATED AREA
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

(3) *Warning labels.* Consistent with the HCS (§ 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, at a minimum, include the following on the label:

DANGER
CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

(4) *Employee information and training.* (i) For each employee who has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (§ 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate

knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and contact with beryllium, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature of operations that could result in airborne exposure, especially airborne exposure above the TWA PEL or STEL;

(C) The purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators;

(D) Applicable emergency procedures;

(E) Measures employees can take to protect themselves from airborne exposure to and contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this standard including risks and benefits of each test to be offered;

(G) The purpose and a description of the medical removal protection provided under paragraph (l) of this standard;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (§ 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

(n) *Recordkeeping*—(1) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task that is being monitored;

(C) The sampling and analytical methods used and evidence of their accuracy;

(D) The number, duration, and results of samples taken;

(E) The type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and

(F) The name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer must ensure that exposure records are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain a record of the objective data relied upon.

(ii) This record must include at least the following information:

(A) The data relied upon;

(B) The beryllium-containing material in question;

(C) The source of the objective data;

(D) A description of the process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (§ 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must prepare a record that indicates the name, social security number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

(ii) This record must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance the Records Access standard (§ 1910.1020).

(6) *Transfer of records.* The employer must comply with the requirements involving transfer of records set forth in the Records Access standard (§ 1910.1020).

(o) *Dates*—(1) *Effective date.* This standard shall become effective March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms and showers required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

(p) *Appendix.* Appendix A—Control Strategies to Minimize Beryllium Exposure of this standard is non-mandatory.

Appendix A to § 1910.1024—Control Strategies To Minimize Beryllium Exposure (Non-Mandatory)

Paragraph (f)(2)(i) of this standard requires employers to use one or more of the control methods listed in paragraph (f)(2)(i) to minimize worker exposure in each operation in a beryllium work area, unless the operation is exempt under paragraph (f)(2)(ii). This appendix sets forth a non-exhaustive list of control options that employers could use to comply with paragraph (f)(2)(i) for a number of specific beryllium operations.

TABLE A.1—EXPOSURE CONTROL RECOMMENDATIONS

Operation	Minimal control strategy*	Application group
Beryllium Oxide Forming (*e.g.,* pressing, extruding).	For pressing operations: ..... (1) Install local exhaust ventilation (LEV) on oxide press tables, oxide feed drum breaks, press tumblers, powder rollers, and die set disassembly stations; (2) Enclose the oxide presses; and (3) Install mechanical ventilation (make-up air) in processing areas For extruding operations: (1) Install LEV on extruder powder loading hoods, oxide supply bottles, rod breaking operations, centerless grinders, rod laydown tables, dicing operations, surface grinders, discharge end of extrusion presses; (2) Enclose the centerless grinders; and (3) Install mechanical ventilation (make-up air) in processing areas.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites.
Chemical Processing Operations (*e.g.,* leaching, pickling, degreasing, etching, plating).	For medium and high gassing operations: ..... (1) Perform operation with a hood having a maximum of one open side; and (2) Design process so as to minimize spills; if accidental spills occur, perform immediate cleanup.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing and Extruding.
Finishing (*e.g.,* grinding, sanding, polishing, deburring).	(1) Perform portable finishing operations in a ventilated hood. The hood should include both downdraft and backdraft ventilation, and have at least two sides and a top. (2) Perform stationary finishing operations using a ventilated and enclosed hood at the point of operation. The grinding wheel of the stationary unit should be enclosed and ventilated.	Secondary Smelting; Fabrication of Beryllium Alloy Products; Dental Labs.
Furnace Operations (*e.g.,* Melting and Casting).	(1) Use LEV on furnaces, pelletizer; arc furnace ingot machine discharge; pellet sampling; arc furnace bins and conveyors; beryllium hydroxide drum dumper and dryer; furnace rebuilding; furnace tool holders; arc furnace tundish and tundish skimming, tundish preheat hood, and tundish cleaning hoods; dross handling equipment and drums; dross recycling; and tool repair station, charge make-up station, oxide screener, product sampling locations, drum changing stations, and drum cleaning stations (2) Use mechanical ventilation (make-up air) in furnace building	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Nonferrous Foundries; Secondary Smelting.
Machining	Use (1) LEV consistent with ACGIH® ventilation guidelines on deburring hoods, wet surface grinder enclosures, belt sanding hoods, and electrical discharge machines (for operations such as polishing, lapping, and buffing); (2) high velocity low volume hoods or ventilated enclosures on lathes, vertical mills, CNC mills, and tool grinding operations; (3) for beryllium oxide ceramics, LEV on lapping, dicing, and laser cutting; and (4) wet methods (*e.g.,* coolants).	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing, and Extruding; Precision Turned Products.
Mechanical Processing (*e.g.,* material handling (including scrap), sorting, crushing, screening, pulverizing, shredding, pouring, mixing, blending).	(1) Enclose and ventilate sources of emission; (2) Prohibit open handling of materials; and (3) Use mechanical ventilation (make-up air) in processing areas	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Aluminum and Copper Foundries; Secondary Smelting.
Metal Forming (*e.g.,* rolling, drawing, straightening, annealing, extruding).	(1) For rolling operations, install LEV on mill stands and reels such that a hood extends the length of the mill; (2) For point and chamfer operations, install LEV hoods at both ends of the rod; (3) For annealing operations, provide an inert atmosphere for annealing furnaces, and LEV hoods at entry and exit points; (4) For swaging operations, install LEV on the cutting head; (5) For drawing, straightening, and extruding operations, install LEV at entry and exit points; and (6) For all metal forming operations, install mechanical ventilation (make-up air) for processing areas.	Primary Beryllium Production; Copper Rolling, Drawing, and Extruding; Fabrication of Beryllium Alloy Products.
Welding	For fixed welding operations: ..... (1) Enclose work locations around the source of fume generation and use local exhaust ventilation; and (2) Install close capture hood enclosure designed so as to minimize fume emission from the enclosure welding operation. For manual operations: (1) Use portable local exhaust and general ventilation	Primary Beryllium Production; Fabrication of Beryllium Alloy Products; Welding.

*All LEV specifications should be in accordance with the ACGIH® Publication No. 2094, ''Industrial Ventilation—A Manual of Recommended Practice'' wherever applicable.

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 4. The authority citation for part 1915 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 5. In § 1915.1000 amend Table Z—Shipyards, by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote q.

The revisions read as follows:

* * * * *

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.[d]	ppm [a*]	mg/m³ [b*]	Skin designation
*	*	*	*	*
Beryllium and beryllium compounds (as Be); see 1915.1024 [(q)]	7440–41–7		0.002	
*	*	*	*	*

* The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * * * *

[q] This standard applies to any operations or sectors for which the beryllium standard, 1915.1024, is stayed or otherwise is not in effect.

* * * * *

■ 6. Add § 1915.1024 to read as follows:

§ 1915.1024 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in shipyards, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (μg/m³) calculated as an 8-hour time-weighted average (TWA).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee.

Beryllium lymphocyte proliferation test (BeLPT) means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any uncontrolled release of airborne beryllium.

High-efficiency particulate air (HEPA) filter means a filter that is at least 99.97 percent efficient in removing particles 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this standard.

Regulated area means an area, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's airborne exposure exceeds, or can reasonably be expected to exceed, either the time-weighted average (TWA) permissible exposure limit (PEL) or short term exposure limit (STEL).

This standard means this beryllium standard, 29 CFR 1915.1024.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m³ calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m³ as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of paragraph (d)(3) of this standard. In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory that can measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is measured or represented by the monitoring and each employee's representative(s).

(ii) When observation of monitoring requires entry into an area where the use of personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer and must ensure that each observer uses such clothing and equipment.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Regulated areas*—(1) *Establishment.* The employer must establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL.

(2) *Demarcation.* The employer must identify each regulated area in accordance with paragraph (m)(2) of this standard.

(3) *Access.* The employer must limit access to regulated areas to:

(i) Persons the employer authorizes or requires to be in a regulated area to perform work duties;

(ii) Persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring procedures under paragraph (d)(7) of this standard; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer must provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this standard; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination;

(E) Procedures for minimizing the migration of beryllium within or to locations outside the workplace;

(F) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(G) A list of personal protective clothing and equipment required by paragraph (h) of this standard; and

(H) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer must review and evaluate the effectiveness of each written exposure control plan at least annually and update it, as necessary, when:

(A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results, or can reasonably be expected to result, in new or additional airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) Where exposures are, or can reasonably be expected to be, at or above the action level, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by (f)(2)(i), the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii).

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must provide at no cost, and ensure that each employee uses, appropriate personal protective clothing and equipment in accordance with the written exposure control plan required under paragraph (f)(1) of this standard and OSHA's Personal Protective Equipment standards for shipyards (subpart I of this part):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal

protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal protective clothing or equipment from the workplace, except for employees authorized to do so for the purposes of laundering, cleaning, maintaining or disposing of beryllium-contaminated personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that personal protective clothing and equipment are stored and transported in sealed bags or other closed containers that are impermeable and are labeled in accordance with paragraph (m)(3) of this standard and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee required to use personal protective clothing or equipment by this standard, the employer must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1915.88) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees required to use personal protective clothing by this standard with a designated change room in accordance with the Sanitation standard (§ 1915.88) where employees are required to remove their personal clothing.

(3) *Eating and drinking areas.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (29 CFR 1915.88).

(4) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(j) *Housekeeping*—(1) *General.* (i) When cleaning beryllium-contaminated areas, the employer must follow the written exposure control plan required under paragraph (f)(1) of this standard; and

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1).

(2) *Cleaning methods.* (i) When cleaning beryllium-contaminated areas, the employer must ensure the use of HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

(iii) The employer must not allow the use of compressed air for cleaning in beryllium-contaminated areas unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air.

(iv) Where employees use dry sweeping, brushing, or compressed air to clean in beryllium-contaminated areas, the employer must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* When the employer transfers materials containing beryllium to another party for use or disposal, the employer must provide the recipient with a copy of the warning described in paragraph (m)(3) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance.

(ii) The employer must ensure that all medical examinations and procedures required by this standard are performed by, or under the direction of, a licensed physician.

(2) *Frequency.* The employer must provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A) of this standard, unless the employee has received a medical examination, provided in accordance with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C) of this standard.

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

(ii) The employer must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

(B) A physical examination with emphasis on the respiratory system;

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal protective clothing and equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) A statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraph (k)(5)(i), (ii), (iv), and (v) and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraphs (k)(6)(i), as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(4) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from a publicly or employer-funded compensation program, or receives income from another employer made possible by virtue of the employee's removal.

(m) *Communication of hazards*—(1) *General.* (i) Chemical manufacturers, importers, distributors, and employers must comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must ensure that each employee has access to labels on containers of beryllium and to safety data sheets, and is trained in accordance with the requirements of the HCS (29 CFR 1910.1200) and paragraph (m)(4) of this standard.

(2) *Warning signs.* (i) *Posting.* The employer must provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area.

(ii) *Sign specification.* (A) The employer must ensure that the warning signs required by paragraph (m)(2)(i) of this standard are legible and readily visible.

(B) The employer must ensure each warning sign required by paragraph (m)(2)(i) of this standard bears the following legend:

DANGER
REGULATED AREA
BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY
WEAR RESPIRATORY PROTECTION AND PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT IN THIS AREA

(3) *Warning labels.* Consistent with the HCS (29 CFR 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, at a minimum, include the following on the label:

DANGER
CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

(4) *Employee information and training.* (i) For each employee who has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and contact with beryllium, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the location(s) of any regulated areas, and the specific nature of operations that could result in airborne exposure, especially airborne exposure above the TWA PEL or STEL;

(C) The purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators;

(D) Applicable emergency procedures;

(E) Measures employees can take to protect themselves from airborne exposure to and contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this

standard including risks and benefits of each test to be offered;

(G) The purpose and a description of the medical removal protection provided under paragraph (l) of this standard;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (29 CFR 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

(n) *Recordkeeping*—(1) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task that is being monitored;

(C) The sampling and analytical methods used and evidence of their accuracy;

(D) The number, duration, and results of samples taken;

(E) The type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and

(F) The name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer must ensure that exposure records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain a record of the objective data relied upon.

(ii) This record must include at least the following information:

(A) The data relied upon;

(B) The beryllium-containing material in question;

(C) The source of the objective data;

(D) A description of the process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must prepare a record that indicates the name, social security number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

(ii) This record must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance the Records Access standard (29 CFR 1910.1020).

(6) *Transfer of records.* The employer must comply with the requirements involving transfer of records set forth in the Records Access standard (29 CFR 1910.1020).

(o) *Dates*—(1) *Effective date.* This standard shall become effective March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart D—Occupational Health and Environmental Controls

■ 7. The authority citation for subpart D of part 1926 is revised to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1926.61 also issued under 49 U.S.C. 5101 *et seq.*

Section 1926.62 also issued under 42 U.S.C. 4853.

Section 1926.65 also issued under 126 of Public Law 99–499, 100 Stat. 1613.

■ 8. In § 1926.55, amend appendix A by revising the entry for ''Beryllium and beryllium compounds (as Be)'' and adding footnote q.

The revisions read as follows:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

Appendix A to § 1926.55—1970 American Conference of Governmental Industrial Hygienists' Threshold Limit Values of Airborne Contaminants

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.[d]	ppm [a*]	mg/m [3b]	Skin designation
* * * *		*	*	*
Beryllium and beryllium compounds (as Be); see 1926.1124 [(q)]	7440–41–7		0.002	

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION—Continued

Substance	CAS No.[d]	ppm [a*]	mg/m 3[b]	Skin designation
* * * *	*	*	*	*

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * * * *

[q] This standard applies to any operations or sectors for which the beryllium standard, 1926.1124, is stayed or otherwise is not in effect.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 9. The authority for subpart Z of part 1926 is revised to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 10. Add § 1926.1124 to read as follows:

§ 1926.1124 Beryllium.

(a) *Scope and application.* (1) This standard applies to occupational exposure to beryllium in all forms, compounds, and mixtures in construction, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of this standard.

(2) This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This standard does not apply to materials containing less than 0.1% beryllium by weight where the employer has objective data demonstrating that employee exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions.

(b) *Definitions.* As used in this standard:

Action level means a concentration of airborne beryllium of 0.1 micrograms per cubic meter of air (μg/m³) calculated as an 8-hour time-weighted average (TWA).

Airborne exposure and *airborne exposure to beryllium* mean the exposure to airborne beryllium that would occur if the employee were not using a respirator.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee.

Beryllium lymphocyte proliferation test (BeLPT) means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt.

CBD diagnostic center means a medical diagnostic center that has an on-site pulmonary specialist and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). This evaluation must include pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The on-site pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic lung disease associated with airborne exposure to beryllium.

Competent person means an individual who is capable of identifying existing and foreseeable beryllium hazards in the workplace and who has authorization to take prompt corrective measures to eliminate or minimize them. The competent person must have the knowledge, ability, and authority necessary to fulfill the responsibilities set forth in paragraph (e) of this standard.

Confirmed positive means the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any uncontrolled release of airborne beryllium.

High-efficiency particulate air (HEPA) filter means a filter that is at least 99.97 percent efficient in removing particles 0.3 micrometers in diameter.

Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition of a substance, demonstrating airborne exposure to beryllium associated with a particular product or material or a specific process, task, or activity. The data must reflect workplace conditions closely resembling or with a higher airborne exposure potential than the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this standard.

This standard means this beryllium standard, 29 CFR 1926.1124.

(c) *Permissible Exposure Limits (PELs)*—(1) *Time-weighted average (TWA) PEL.* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 0.2 μg/m³ calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL).* The employer must ensure that no employee is exposed to an airborne concentration of beryllium in excess of 2.0 μg/m³ as determined over a sampling period of 15 minutes.

(d) *Exposure assessment*—(1) *General.* The employer must assess the airborne exposure of each employee who is or may reasonably be expected to be exposed to airborne beryllium in accordance with either the performance option in paragraph (d)(2) or the scheduled monitoring option in paragraph (d)(3) of this standard.

(2) *Performance option.* The employer must assess the 8-hour TWA exposure and the 15-minute short-term exposure for each employee on the basis of any

combination of air monitoring data and objective data sufficient to accurately characterize airborne exposure to beryllium.

(3) *Scheduled monitoring option.* (i) The employer must perform initial monitoring to assess the 8-hour TWA exposure for each employee on the basis of one or more personal breathing zone air samples that reflect the airborne exposure of employees on each shift, for each job classification, and in each work area.

(ii) The employer must perform initial monitoring to assess the short-term exposure from 15-minute personal breathing zone air samples measured in operations that are likely to produce airborne exposure above the STEL for each work shift, for each job classification, and in each work area.

(iii) Where several employees perform the same tasks on the same shift and in the same work area, the employer may sample a representative fraction of these employees in order to meet the requirements of paragraph (d)(3). In representative sampling, the employer must sample the employee(s) expected to have the highest airborne exposure to beryllium.

(iv) If initial monitoring indicates that airborne exposure is below the action level and at or below the STEL, the employer may discontinue monitoring for those employees whose airborne exposure is represented by such monitoring.

(v) Where the most recent exposure monitoring indicates that airborne exposure is at or above the action level but at or below the TWA PEL, the employer must repeat such monitoring within six months of the most recent monitoring.

(vi) Where the most recent exposure monitoring indicates that airborne exposure is above the TWA PEL, the employer must repeat such monitoring within three months of the most recent 8-hour TWA exposure monitoring.

(vii) Where the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the action level, the employer must repeat such monitoring within six months of the most recent monitoring until two consecutive measurements, taken 7 or more days apart, are below the action level, at which time the employer may discontinue 8-hour TWA exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(viii) Where the most recent exposure monitoring indicates that airborne exposure is above the STEL, the employer must repeat such monitoring within three months of the most recent short-term exposure monitoring until two consecutive measurements, taken 7 or more days apart, are below the STEL, at which time the employer may discontinue short-term exposure monitoring for those employees whose exposure is represented by such monitoring, except as otherwise provided in paragraph (d)(4) of this standard.

(4) *Reassessment of exposure.* The employer must reassess airborne exposure whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional airborne exposure at or above the action level or STEL, or when the employer has any reason to believe that new or additional airborne exposure at or above the action level or STEL has occurred.

(5) *Methods of sample analysis.* The employer must ensure that all air monitoring samples used to satisfy the monitoring requirements of paragraph (d) of this standard are evaluated by a laboratory that can measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this standard, the employer must notify each employee whose airborne exposure is represented by the assessment of the results of that assessment individually in writing or post the results in an appropriate location that is accessible to each of these employees.

(ii) Whenever an exposure assessment indicates that airborne exposure is above the TWA PEL or STEL, the employer must describe in the written notification the corrective action being taken to reduce airborne exposure to or below the exposure limit(s) exceeded where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(7) *Observation of monitoring.* (i) The employer must provide an opportunity to observe any exposure monitoring required by this standard to each employee whose airborne exposure is measured or represented by the monitoring and each employee's representative(s).

(ii) When observation of monitoring requires entry into an area where the use of personal protective clothing or equipment (which may include respirators) is required, the employer must provide each observer with appropriate personal protective clothing and equipment at no cost to the observer.

(iii) The employer must ensure that each observer follows all other applicable safety and health procedures.

(e) *Competent person.* Wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL, the employer must designate a competent person to

(1) Make frequent and regular inspections of job sites, materials, and equipment;

(2) Implement the written exposure control plan under paragraph (f) of this standard;

(3) Ensure that all employees use respiratory protection in accordance with paragraph (g) of this standard; and

(4) Ensure that all employees use personal protective clothing and equipment in accordance with paragraph (h) of this standard.

(f) *Methods of compliance*—(1) *Written exposure control plan.* (i) The employer must establish, implement, and maintain a written exposure control plan, which must contain:

(A) A list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium;

(B) A list of operations and job titles reasonably expected to involve airborne exposure at or above the action level;

(C) A list of operations and job titles reasonably expected to involve airborne exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination;

(E) Procedures for minimizing the migration of beryllium within or to locations outside the workplace;

(F) A list of engineering controls, work practices, and respiratory protection required by paragraph (f)(2) of this standard;

(G) A list of personal protective clothing and equipment required by paragraph (h) of this standard;

(H) Procedures for removing, laundering, storing, cleaning, repairing, and disposing of beryllium-contaminated personal protective clothing and equipment, including respirators; and

(I) Procedures used to restrict access to work areas when airborne exposures are, or can reasonably be expected to be, above the TWA PEL or STEL, to minimize the number of employees exposed to airborne beryllium and their level of exposure, including exposures generated by other employers or sole proprietors.

(ii) The employer must review and evaluate the effectiveness of each

written exposure control plan at least annually and update it, as necessary, when:

(A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results, or can reasonably be expected to result, in new or additional airborne exposure to beryllium;

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium; or

(C) The employer has any reason to believe that new or additional airborne exposure is occurring or will occur.

(iii) The employer must make a copy of the written exposure control plan accessible to each employee who is, or can reasonably be expected to be, exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) Where exposures are, or can reasonably be expected to be, at or above the action level, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(ii) An employer is exempt from using the controls listed in paragraph (f)(2)(i) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

(iii) If airborne exposure exceeds the TWA PEL or STEL after implementing the control(s) required by paragraph (f)(2)(i) of this standard, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the exposure limit(s) exceeded.

(iv) Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(iii), the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

(3) *Prohibition of rotation.* The employer must not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer must provide respiratory protection at no cost to the employee and ensure that each employee uses respiratory protection:

(i) During periods necessary to install or implement feasible engineering and work practice controls where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(ii) During operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL;

(iii) During operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce airborne exposure to or below the TWA PEL or STEL;

(iv) During emergencies; and

(v) When an employee who is eligible for medical removal under paragraph (l)(1) chooses to remain in a job with airborne exposure at or above the action level, as permitted by paragraph (l)(2)(ii) of this standard.

(2) *Respiratory protection program.* Where this standard requires an employer to provide respiratory protection, the selection and use of such respiratory protection must be in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) The employer must provide at no cost to the employee a powered air-purifying respirator (PAPR) instead of a negative pressure respirator when

(i) Respiratory protection is required by this standard;

(ii) An employee entitled to such respiratory protection requests a PAPR; and

(iii) The PAPR provides adequate protection to the employee in accordance with paragraph (g)(2) of this standard.

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer must provide at no cost, and ensure that each employee uses, appropriate personal protective clothing and equipment in accordance with the written exposure control plan required under paragraph (f)(1) of this standard and OSHA's Personal Protective and Life Saving Equipment standards for construction (29 CFR part 1926 Subpart E):

(i) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; or

(ii) Where there is a reasonable expectation of dermal contact with beryllium.

(2) *Removal and storage.* (i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

(ii) The employer must ensure that each employee removes beryllium-contaminated personal protective clothing and equipment as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iii) The employer must ensure that each employee stores and keeps beryllium-contaminated personal protective clothing and equipment separate from street clothing and that storage facilities prevent cross-contamination as specified in the written exposure control plan required by paragraph (f)(1) of this standard.

(iv) The employer must ensure that no employee removes beryllium-contaminated personal protective clothing or equipment from the workplace, except for employees authorized to do so for the purposes of laundering, cleaning, maintaining or disposing of beryllium-contaminated personal protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When personal protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer must ensure that personal protective clothing and equipment are stored and transported in sealed bags or other closed containers that are impermeable and are labeled in accordance with paragraph (m)(2) of this standard and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer must ensure that all reusable personal protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer must ensure that beryllium is not removed from personal protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee required to use personal protective clothing or equipment by this standard, the employer must:

(i) Provide readily accessible washing facilities in accordance with this standard and the Sanitation standard (§ 1926.51) to remove beryllium from the hands, face, and neck; and

(ii) Ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees required to use personal protective clothing by this standard with a designated change room in accordance with this standard and the Sanitation standard (§ 1926.51) where employees are required to remove their personal clothing.

(3) *Eating and drinking areas.* Wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (§ 1926.51).

(4) *Prohibited activities.* The employer must ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in work areas where there is a reasonable expectation of exposure above the TWA PEL or STEL.

(j) *Housekeeping*—(1) *General.* (i) When cleaning beryllium-contaminated areas, the employer must follow the written exposure control plan required under paragraph (f)(1) of this standard;

(ii) The employer must ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the written exposure control plan required under paragraph (f)(1) of this standard.

(2) *Cleaning methods.* (i) When cleaning beryllium-contaminated areas, the employer must ensure the use of HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning in beryllium-contaminated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

(iii) The employer must not allow the use of compressed air for cleaning in beryllium-contaminated areas unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air.

(iv) Where employees use dry sweeping, brushing, or compressed air to clean in beryllium-contaminated areas, the employer must provide, and ensure that each employee uses, respiratory protection and personal protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard.

(v) The employer must ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of airborne exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* When the employer transfers materials containing beryllium to another party for use or disposal, the employer must provide the recipient with a copy of the warning described in paragraph (m)(2) of this standard.

(k) *Medical surveillance*—(1) *General.* (i) The employer must make medical surveillance required by this paragraph available at no cost to the employee, and at a reasonable time and place, to each employee:

(A) Who is or is reasonably expected to be exposed at or above the action level for more than 30 days per year;

(B) Who shows signs or symptoms of CBD or other beryllium-related health effects;

(C) Who is exposed to beryllium during an emergency; or

(D) Whose most recent written medical opinion required by paragraph (k)(6) or (k)(7) recommends periodic medical surveillance.

(ii) The employer must ensure that all medical examinations and procedures required by this standard are performed by, or under the direction of, a licensed physician.

(2) *Frequency.* The employer must provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A), unless the employee has received a medical examination, provided in accordance with this standard, within the last two years; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C).

(ii) At least every two years thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A), (B), or (D) of this standard.

(iii) At the termination of employment for each employee who meets any of the criteria of paragraph (k)(1)(i) of this standard at the time the employee's employment terminates, unless an examination has been provided in accordance with this standard during the six months prior to the date of termination.

(3) *Contents of examination.* (i) The employer must ensure that the PLHCP conducting the examination advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination.

(ii) The employer must ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present airborne exposure to or dermal contact with beryllium, smoking history, and any history of respiratory system dysfunction;

(B) A physical examination with emphasis on the respiratory system;

(C) A physical examination for skin rashes;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1);

(E) A standardized BeLPT or equivalent test, upon the first examination and at least every two years thereafter, unless the employee is confirmed positive. If the results of the BeLPT are other than normal, a follow-up BeLPT must be offered within 30 days, unless the employee has been

confirmed positive. Samples must be analyzed in a laboratory certified under the College of American Pathologists/ Clinical Laboratory Improvement Amendments (CLIA) guidelines to perform the BeLPT.

(F) A low dose computed tomography (LDCT) scan, when recommended by the PLHCP after considering the employee's history of exposure to beryllium along with other risk factors, such as smoking history, family medical history, sex, age, and presence of existing lung disease; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP.* The employer must ensure that the examining PLHCP (and the agreed-upon CBD diagnostic center, if an evaluation is required under paragraph (k)(7) of this standard) has a copy of this standard and must provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium;

(ii) The employee's former and current levels of airborne exposure;

(iii) A description of any personal protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that personal protective clothing and equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining written consent from the employee.

(5) *Licensed physician's written medical report for the employee.* The employer must ensure that the employee receives a written medical report from the licensed physician within 45 days of the examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) and that the PLHCP explains the results of the examination to the employee. The written medical report must contain:

(i) A statement indicating the results of the medical examination, including the licensed physician's opinion as to whether the employee has

(A) Any detected medical condition, such as CBD or beryllium sensitization (*i.e.,* the employee is confirmed positive, as defined in paragraph (b) of this standard), that may place the employee at increased risk from further airborne exposure, and

(B) Any medical conditions related to airborne exposure that require further evaluation or treatment.

(ii) Any recommendations on:

(A) The employee's use of respirators, protective clothing, or equipment; or

(B) Limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, the written report must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD the written report must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(6) *Licensed physician's written medical opinion for the employer.* (i) The employer must obtain a written medical opinion from the licensed physician within 45 days of the medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard). The written medical opinion must contain only the following:

(A) The date of the examination;

(B) A statement that the examination has met the requirements of this standard;

(C) Any recommended limitations on the employee's use of respirators, protective clothing, or equipment; and

(D) A statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to airborne exposure that require further evaluation or treatment, and any special provisions for use of personal protective clothing or equipment;

(ii) If the employee provides written authorization, the written opinion must also contain any recommended limitations on the employee's airborne exposure to beryllium.

(iii) If the employee is confirmed positive or diagnosed with CBD or if the licensed physician otherwise deems it appropriate, and the employee provides written authorization, the written opinion must also contain a referral for an evaluation at a CBD diagnostic center.

(iv) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for continued periodic medical surveillance.

(v) If the employee is confirmed positive or diagnosed with CBD and the employee provides written authorization, the written opinion must also contain a recommendation for medical removal from airborne exposure to beryllium, as described in paragraph (l).

(vi) The employer must ensure that each employee receives a copy of the written medical opinion described in paragraph (k)(6) of this standard within 45 days of any medical examination (including any follow-up BeLPT required under paragraph (k)(3)(ii)(E) of this standard) performed for that employee.

(7) *CBD diagnostic center.* (i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The examination must be provided within 30 days of:

(A) The employer's receipt of a physician's written medical opinion to the employer that recommends referral to a CBD diagnostic center; or

(B) The employee presenting to the employer a physician's written medical report indicating that the employee has been confirmed positive or diagnosed with CBD, or recommending referral to a CBD diagnostic center.

(ii) The employer must ensure that the employee receives a written medical report from the CBD diagnostic center that contains all the information required in paragraphs (k)(5)(i), (ii), (iv), and (v) of this standard and that the PLHCP explains the results of the examination to the employee within 30 days of the examination.

(iii) The employer must obtain a written medical opinion from the CBD diagnostic center within 30 days of the medical examination. The written medical opinion must contain only the information in paragraph (k)(6)(i) of this standard, as applicable, unless the employee provides written authorization to release additional information. If the employee provides written authorization, the written opinion must also contain the information from paragraphs (k)(6)(ii), (iv), and (v), if applicable.

(iv) The employer must ensure that each employee receives a copy of the written medical opinion from the CBD diagnostic center described in paragraph (k)(7) of this standard within 30 days of any medical examination performed for that employee.

(v) After an employee has received the initial clinical evaluation at a CBD diagnostic center described in paragraph (k)(7)(i) of this standard, the employee may choose to have any subsequent

medical examinations for which the employee is eligible under paragraph (k) of this standard performed at a CBD diagnostic center mutually agreed upon by the employer and the employee, and the employer must provide such examinations at no cost to the employee.

(l) *Medical removal.* (1) An employee is eligible for medical removal, if the employee works in a job with airborne exposure at or above the action level and either:

(i) The employee provides the employer with:

(A) A written medical report indicating a confirmed positive finding or CBD diagnosis; or

(B) A written medical report recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(5)(v) or (k)(7)(ii) of this standard; or

(ii) The employer receives a written medical opinion recommending removal from airborne exposure to beryllium in accordance with paragraph (k)(6)(v) or (k)(7)(iii) of this standard.

(2) If an employee is eligible for medical removal, the employer must provide the employee with the employee's choice of:

(i) Removal as described in paragraph (l)(3) of this standard; or

(ii) Remaining in a job with airborne exposure at or above the action level, provided that the employer provides, and ensures that the employee uses, respiratory protection that complies with paragraph (g) of this standard whenever airborne exposures are at or above the action level.

(3) If the employee chooses removal:

(i) If a comparable job is available where airborne exposures to beryllium are below the action level, and the employee is qualified for that job or can be trained within one month, the employer must remove the employee to that job. The employer must maintain for six months from the time of removal the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(ii) If comparable work is not available, the employer must maintain the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal for six months or until such time that comparable work described in paragraph (l)(3)(i) becomes available, whichever comes first.

(4) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from a publicly or employer-funded compensation program, or receives income from another employer made possible by virtue of the employee's removal.

(m) *Communication of hazards*—(1) *General.* (i) Chemical manufacturers, importers, distributors, and employers must comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) Employers must include beryllium in the hazard communication program established to comply with the HCS. Employers must ensure that each employee has access to labels on containers of beryllium and to safety data sheets, and is trained in accordance with the requirements of the HCS (29 CFR 1910.1200) and paragraph (m)(4) of this standard.

(2) *Warning labels.* Consistent with the HCS (29 CFR 1910.1200), the employer must label each bag and container of clothing, equipment, and materials contaminated with beryllium, and must, at a minimum, include the following on the label:

DANGER
CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

(3) *Employee information and training.* (i) For each employee who has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium:

(A) The employer must provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer must provide initial training to each employee by the time of initial assignment; and

(C) The employer must repeat the training required under this standard annually for each employee.

(ii) The employer must ensure that each employee who is, or can reasonably be expected to be, exposed to airborne beryllium can demonstrate knowledge and understanding of the following:

(A) The health hazards associated with airborne exposure to and dermal contact with beryllium, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the specific nature of operations that could result in airborne exposure, especially airborne exposure above the TWA PEL or STEL;

(C) The purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators;

(D) Applicable emergency procedures;

(E) Measures employees can take to protect themselves from airborne exposure to and dermal contact with beryllium, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this standard including risks and benefits of each test to be offered;

(G) The purpose and a description of the medical removal protection provided under paragraph (l) of this standard;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (29 CFR 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased airborne exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer must provide additional training to those employees affected by the change in airborne exposure.

(iv) *Employee information.* The employer must make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

(n) *Recordkeeping*—(1) *Air monitoring data.* (i) The employer must make and maintain a record of all exposure measurements taken to assess airborne exposure as prescribed in paragraph (d) of this standard.

(ii) This record must include at least the following information:

(A) The date of measurement for each sample taken;

(B) The task that is being monitored;

(C) The sampling and analytical methods used and evidence of their accuracy;

(D) The number, duration, and results of samples taken;

(E) The type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and

(F) The name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer must ensure that exposure records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(2) *Objective data.* (i) Where an employer uses objective data to satisfy the exposure assessment requirements under paragraph (d)(2) of this standard, the employer must make and maintain

a record of the objective data relied upon.

(ii) This record must include at least the following information:

(A) The data relied upon;

(B) The beryllium-containing material in question;

(C) The source of the objective data;

(D) A description of the process, task, or activity on which the objective data were based; and

(E) Other data relevant to the process, task, activity, material, or airborne exposure on which the objective data were based.

(iii) The employer must ensure that objective data are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(3) *Medical surveillance.* (i) The employer must make and maintain a record for each employee covered by medical surveillance under paragraph (k) of this standard.

(ii) The record must include the following information about each employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written medical opinions for each employee; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

(iii) The employer must ensure that medical records are maintained and made available in accordance with the Records Access standard (29 CFR 1910.1020).

(4) *Training.* (i) At the completion of any training required by this standard, the employer must prepare a record that indicates the name, social security number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

(ii) This record must be maintained for three years after the completion of training.

(5) *Access to records.* Upon request, the employer must make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance the Records Access standard (29 CFR 1910.1020).

(6) *Transfer of records.* The employer must comply with the requirements involving transfer of records set forth in the Records Access standard (29 CFR 1910.1020).

(o) *Dates*—(1) *Effective date.* This standard shall become effective March 10, 2017.

(2) *Compliance dates.* All obligations of this standard commence and become enforceable on March 12, 2018, except:

(i) Change rooms required by paragraph (i) of this standard must be provided by March 11, 2019; and

(ii) Engineering controls required by paragraph (f) of this standard must be implemented by March 10, 2020.

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Part III

Environmental Protection Agency

40 CFR Part 300

Addition of a Subsurface Intrusion Component to the Hazard Ranking System; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2010–1086; FRL–9956–58–OLEM]

RIN 2050–AG67

Addition of a Subsurface Intrusion Component to the Hazard Ranking System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is adding a subsurface intrusion (SsI) component to the Hazard Ranking System (HRS), which is the principal mechanism that EPA uses to evaluate sites for placement on the National Priorities List (NPL). The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. Sites on the NPL are priorities for further investigation to determine if further response actions are warranted. The subsurface intrusion component (this addition) expands the number of available options for EPA and state and tribal organizations performing work on behalf of EPA to evaluate actual and potential threats to public health from releases of hazardous substances, pollutants, or contaminants. This addition enables EPA to directly consider human exposure to hazardous substances, pollutants, or contaminants that enter regularly occupied structures through subsurface intrusion in assessing a site's relative risk, and thus, enable sites with subsurface intrusion contamination to be evaluated for placement on the NPL.

DATES: This final rule is effective February 8, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–SFUND–2010–1086. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center Reading Room (see *https://www.epa.gov/dockets/epa-docket-center-reading-room* for more information).

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone: (703) 603–8852, email: *jeng.terry@epa.gov,* Site Assessment and Remedy Decisions Branch, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation (Mail Code 5204P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC metropolitan area.

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

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H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Executive Order 12580: Superfund Implementation
L. Congressional Review Act (CRA)

I. Statutory Authority for Regulatory Change

EPA has revised the HRS, the principal mechanism for placing sites on the NPL, to add a component for evaluating the threat or potential threat posed by subsurface intrusion to protect human health and the environment. Without an evaluation of threats posed by subsurface intrusion contamination, the HRS is not a complete assessment because it omits a known pathway of human exposure to contamination. The addition of subsurface intrusion to the HRS is compliant with Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 105(a)(8)(A), which requires EPA to prioritize sites based on ''the population at risk, the hazard potential of hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact [and] the potential for destruction of sensitive ecosystems. This addition to the HRS also improves the agency's ability to identify priority sites for further investigation and enhances EPA's ability, in dialogue with other federal agencies and the states and tribes, to determine the most appropriate state or federal authority to address sites. For information on alternatives to this rulemaking that were considered for addressing subsurface intrusion contamination, please see the

preamble to the proposed HRS SsI Addition [81 FR 10372, February 29, 2016].

Additionally, the Government Accountability Office (GAO) stated in its May 2010 report [1]:

> EPA may not be listing some sites that pose health risks that are serious enough that the sites should be considered for inclusion on the NPL. While EPA is assessing vapor intrusion contamination at listed NPL sites, EPA does not assess the relative risks posed by vapor intrusion when deciding which sites to include on the NPL. By not including these risks, states may be left to remediate those sites without federal assistance, and given states' constrained budgets, some states may not have the ability to clean up these sites on their own . . . However, if these sites are not assessed and, if needed, listed on the NPL, some seriously contaminated hazardous waste sites with unacceptable human exposure may not otherwise be cleaned up.

The authority for these technical modifications to the HRS is in section 105(a)(8)(A) of CERCLA enacted in 1980. Under CERCLA, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (40 CFR 300) must include criteria for determining priorities among releases or threatened releases for the purpose of taking remedial or removal actions. Section 105(a)(8)(A) of CERCLA required EPA to establish:

> [C]riteria for determining priorities among releases or threatened releases [of hazardous substances] throughout the United States for the purpose of taking remedial action and, to the extent practicable, taking into account the potential urgency of such action, for the purpose of taking removal action. Criteria and priorities . . . shall be based upon relative risk or danger to public health or welfare or the environment. . .taking into account to the extent possible the population at risk, the hazard potential of hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact [and] the potential for destruction of sensitive ecosystems. . . .

To meet this requirement and provide criteria to set priorities, EPA adopted the HRS as Appendix A to the NCP (47 FR 31180, July 16, 1982). The HRS was last revised on December 14, 1990 (55 FR 51532) to include the evaluation of additional threats to ensure a complete assessment of the relative risk that a site may pose to the public. Section 105(a)(8)(B) of CERCLA requires that the statutory criteria described in section 105(a)(8)(A) be used to prepare a list of national priorities among the known releases, or threatened releases throughout the United States. The NPL is Appendix B of the NCP (40 CFR 300, Appendix B).

In 1986, Congress passed the Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499), which added section 105(c)(1) to CERCLA, requiring EPA to amend the HRS to assure ''to the maximum extent feasible, that the hazard ranking system accurately assesses the relative degree of risk to human health and the environment posed by sites and facilities subject to review.'' In addition, CERCLA section 115 authorizes EPA to promulgate any regulations necessary to carry out the provisions of CERCLA.

Furthermore, the Congressional Conference Report on SARA included the absolute standard against which HRS revisions could be assessed:

> This standard is to be applied within the context of the purpose for the National Priorities List; *i.e.,* identifying for the States and the public those facilities and sites which appear to warrant remedial actions. * * * This standard does not, however, require the Hazard Ranking System to be equivalent to detailed risk assessments, quantitative or qualitative, such as might be performed as part of remedial actions. The standard requires the Hazard Ranking System to rank sites as accurately as the Agency believes is feasible using information from preliminary assessments and site inspections * * * Meeting this standard does not require long-term monitoring or an accurate determination of the full nature and extent of contamination at sites or the projected levels of exposure such as might be done during remedial investigations and feasibility studies. This provision is intended to ensure that the Hazard Ranking System performs with a degree of accuracy appropriate to its role in expeditiously identifying candidates for response actions. [H.R. Rep. No. 962, 99th Cong., 2nd Sess. at 199–200 [1986]]

When the HRS was last revised in 1990, the technology to detect and evaluate subsurface intrusion threats was not sufficiently developed. For example, there were no health-based benchmark concentration values for residences or standardized technologies for sampling indoor air, precision of analytical equipment prior to computerization was limited, and associations between contaminated ground water and soil vapors were not well understood. However, it is now possible for subsurface intrusion threats to be evaluated in a more comprehensive manner. Therefore, it is now appropriate, given the potential that subsurface intrusion presents for direct human contact, to add to the HRS the consideration of threats due to subsurface intrusion.

This final rule ensures the HRS does not omit a known pathway of human exposure to contamination due to subsurface intrusion of released hazardous substances and provides a mechanism for assessing subsurface intrusion threats and identifying sites for placement on the NPL. Furthermore, these sites are now eligible for Superfund-financed remedial actions.

II. Background

The HRS is a crucial part of the agency's program for determining which sites are a priority for further remedial investigation and possible cleanup under CERCLA. To understand the importance of this rulemaking it is necessary to understand the role of the HRS in identifying sites for the NPL, the role of the HRS in the overall site assessment and Superfund remedial process, and this final rule's impacts on current and future Superfund activities. In addition, it is also necessary to understand the impact of adding the SsI component to the HRS.

A. The Hazard Ranking System

The HRS is a scoring system used to assess the relative risk associated with actual or potential releases of hazardous substances from a site based on the information that can be collected in a preliminary assessment (PA) and site inspection (SI). The HRS is not a tool for conducting a quantitative risk assessment and was designed to be a measure of relative risk among sites rather than absolute site-specific risk. As required by CERCLA, EPA has designed the Superfund program to focus its resources on the priority sites. Consequently, the initial studies—the PA and SI—which are performed on a large number of sites, are relatively modest in scope and cost compared to the remedial investigations and feasibility studies subsequently performed on NPL sites.

Because of the need to expeditiously perform PAs and SIs, Congress placed certain constraints on the data requirements for an HRS evaluation. The required HRS data should be information that, for most sites, can be collected during a screening level site inspection or that are already available. Thus, the HRS does not rely on data that require extensive sampling or repeated sampling over extended periods of time. However, EPA allows for the expansion of the typical SI to allow for additional data collection for more complex sites that cannot be adequately characterized using standard SI methodologies. The HRS has also been designed so that it can be applied consistently to a wide variety of sites, enabling sites to be

[1] EPA's Estimated Costs to Remediate Existing Sites Exceed Current Funding Levels, and More Sites are Expected to Be Added to the National Priorities List, GAO Report to Congressional Requesters, GAO–10–380, May 2010.

ranked relative to each other with respect to actual or potential hazards.

Based on the state of the science, site specific data may be collected beyond that which is normally available after a typical site inspection. In these situations, the HRS in general, and the SsI component, can incorporate that data into the HRS evaluation. For example, the SsI component can use site-specific data as follows:

• Determination of the Hazardous Waste Quantity Factor Value—If the mass of all hazardous substances can be adequately determined (*i.e.,* is known or can be estimated with reasonable confidence), the HRS requires this estimate (identified as a Tier A estimate) be used to assign the hazardous waste quantity for all regularly occupied structures in an area of exposure (AOE) for which this information is available. See section 2.4.2 and 5.2.1.2.2 of the HRS.

• Determining the extent of an ASC—If sufficient data are available and state of the science shows there is no unacceptable risk due to subsurface intrusion into a regularly occupied structure located within an ASC, that structure or subunit can be excluded from the ASC. Therefore, such structures would not be included in the evaluation of the Hazardous Waste Quantity Factor or in the determination of other factors evaluated based on structures or subunits within an ASC. See section 5.2.0 of the HRS.

• Populations within the ASC—If sufficient structure-specific concentration data is available and state of the science shows there is no unacceptable risk of exposure to populations in a regularly occupied structure in an ASC, those populations are not included in the evaluation of the Targets Factor Category. See section 5.2.1.3 of the HRS.

EPA notes that if other site-specific information is available that clearly demonstrates that the site does not pose an unacceptable risk to human health via subsurface intrusion, there are points during the PA or SI process, where further evaluation of the site for the subsurface intrusion threat by the Superfund program can be terminated. Please see section B. of this preamble for further information on the Site Assessment process.

As EPA explained when it originally adopted the HRS, ''the HRS is a means for applying uniform technical judgment regarding the potential hazards presented by a facility relative to other facilities. It does not address the feasibility, desirability, or degree of cleanup required.'' (47 FR 31220, July 16, 1982).

The HRS uses a structured value analysis approach to scoring sites. This approach assigns values to factors related to or indicative of risk. The basic elements of the HRS are factors that are based on information that can be collected in a limited screening assessment. A scale of numerical rating values is provided for each factor and a value is assigned to each factor based on conditions at the site. Individual values are then weighted. The factors are grouped into three factor categories—observed release/route characteristics, waste characteristics, and targets—and are combined to obtain factor category scores. Each factor category has a maximum value, as does each of the component factors within the category. The relevant factor category scores are multiplied together within each pathway and normalized to obtain a pathway score. The pathway scores are combined using a root-mean-square approach to calculate the overall site score; that is, the final HRS score is the square root of the sum of the squares of the pathway scores divided by the square root of the number of HRS pathways. If all pathway scores are low, the HRS score will be low. However, the final score will be relatively high even if only one pathway score is high. EPA considers this an important requirement for the HRS scoring because some extremely dangerous sites pose threats through only one migration mode. For example, at a site, leaking drums of hazardous substances may be contaminating drinking water wells, thereby posing a significant threat via the groundwater migration pathway. But if the drums are buried deeply enough and the hazardous substances are not very volatile, the drums may not release any hazardous substances and not pose a threat to the air or to surface water.

EPA emphasizes that the HRS score is a number between 0 and 100, which reflects relative risk amongst candidate NPL sites. An HRS site score is not a measure of actual site-specific risk.

B. Site Assessment and the Superfund Remedial Process

EPA's Superfund remedial site assessment process evaluates sites to ascertain if further investigation is needed for determining whether an unacceptable risk is present.

The majority of sites evaluated through the EPA's site assessment program do not meet the criteria for possible placement on the NPL and are ''screened out'' of the Superfund Remedial process. (See Figure 1. Status of EPA's Site Assessments). Since EPA adopted the HRS, 52, 859 sites have been assessed under EPA's Superfund program. Of those sites, 1,782 were placed on the NPL, as of September 2016.

Site Assessment Strategy

The site assessment process is structured as a series of limited investigations which may include: (1) A Pre-CERCLA screening assessment; (2) a preliminary assessment; and (3) a site inspection or expanded site inspection (Figure 2. Site Assessment Process, below, illustrates this process). If a site progresses through the site assessment process for further investigation, the requirements for documenting risk become increasingly rigorous. The following includes a summary of the major phases of the site assessment process.

• A Pre-CERCLA Screening is an initial review of existing information on a possible Superfund site. If a release of a hazardous substance has occurred or if the potential of a hazardous substance to release exists the site may be eligible for further remedial evaluation under CERCLA authority. If further evaluation is warranted the site should be entered into the remedial assessment active site inventory for further assessment.

• The PA decision process parallels an HRS analysis, but makes environmental ''worst-case'' assumptions of possible significant risk regarding transport of contamination to receptors based on minimal available information and professional judgment.

• The SI collects information to confirm the accuracy of the PA assumptions. The information should be sufficient to support an HRS evaluation with minimal further investigation.

• If placement on the NPL is pursued, the information collected during the SI provides the basis for supporting the HRS scoring scenario.

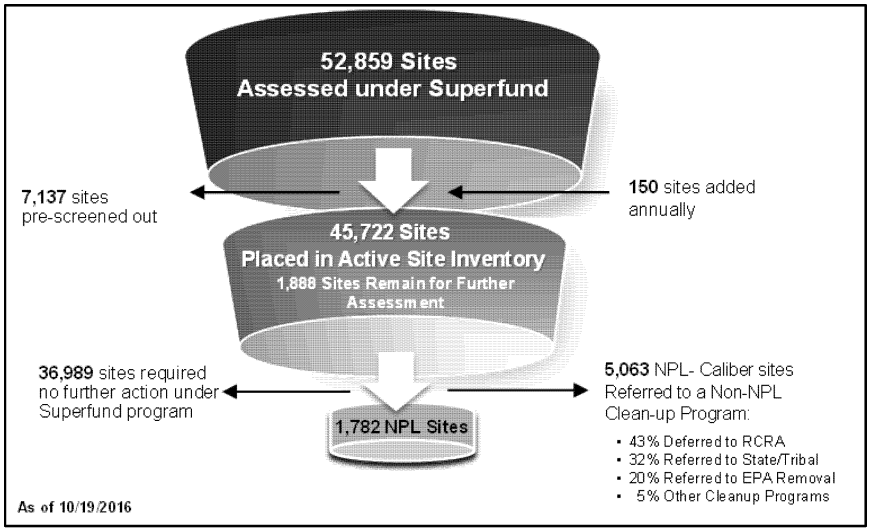


Figure 1. Status of EPA Site Assessments

The following discussion provides further information on each of these phases.

Pre-CERCLA Screening Assessment

A Pre-CERCLA Screening is used to establish whether:

- A release or potential release of a hazardous substance has occurred at a site;
- The site is eligible for further remedial assessment under CERCLA authority;
- The site needs further attention under Superfund or another cleanup program; and
- The site warrants entry into the federal Superfund program's active site inventory for further assessment or response.

Determining whether releases of hazardous substances, pollutants, or contaminants can be addressed by CERCLA requires the application of site-specific facts to CERCLA statutory requirements and EPA policy. The initial determination as to whether a site warrants further investigation is based on three site-specific facts including: (1) Evidence of an actual release or potential to release; (2) targets impacted by a release of contamination at the site; and (3) documentation that a target has been exposed to a hazardous substance released from the site. Examples of targets include populations, drinking water wells, drinking water surface intakes, municipal wells, fisheries and sensitive environments.

Preliminary Assessment

A PA uses readily available data to determine if there is evidence of a release that poses an unacceptable possible threat as specified in the NCP (40 CFR 300.420).

- The PA is a limited-scope investigation performed by States and/or EPA on every CERCLA site
- The PA may include the collection of readily available information and an on- or off-site reconnaissance may be conducted
- The PA distinguishes, based on already existing information, between sites that appear to pose little or no threat to human health and the environment and sites that require further investigation to determine if the threat to human health and the environment is unacceptable.

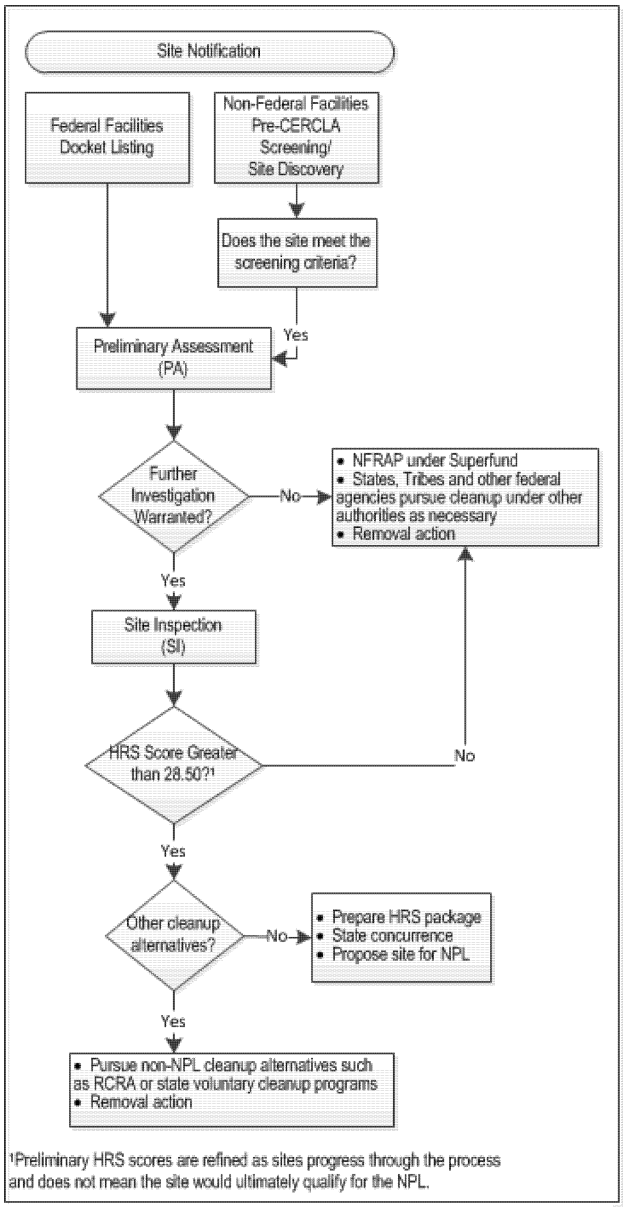


Figure 2. Site Assessment Process

If based on the results of a PA, EPA determines that a site warrants further screening under the CERCLA remedial program, the agency initiates a site inspection

Site Inspection

The purpose of the SI is to collect the data necessary to perform an HRS evaluation. An SI determines if a release of a hazardous substance poses an actual or potential threat to human health or the environment, to determine if there is an immediate threat to people or the environment in the area, and to collect sufficient data to enable the site to be scored using the HRS. EPA may expand the site inspection scope as needed. This expanded site inspection (ESI) collects additional data beyond what is collected in the standard site inspection to evaluate sites for HRS scoring. ESIs are reserved for more complex sites that cannot be adequately characterized using standard site inspection methods.

- SI investigators typically collect waste and environmental samples to determine the substances present at a site and whether they are being released to the environment, as well as other information to perform an HRS evaluation.
- EPA distinguishes, based on the information collected during the SI, between sites that appear to pose little or no threat to human health and the environment and sites that require further investigation to determine if the threat to human health and the environment exists.
- If the information indicates a threat, EPA determines the best approach for addressing the threat, which can be placement on the NPL or use of an alternative authority.

If at any time in this site assessment process, EPA determines that sufficient information indicates the site poses no unacceptable risk, or if it can be addressed under alternative authorities it can be removed from the process. Also, if an imminent or substantial endangerment to public health is identified, EPA can initiate CERCLA removal actions.

The NPL Rulemaking Process

The NPL is a list of national priorities for further investigation amongst the known or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), is required under section 105(a)(8)(B) of CERCLA, as amended. Section 105(a)(8)(B) defines the NPL as a list of ''releases'' and the highest priority ''facilities'' and requires that the NPL be revised at least annually. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance, however, as it does not assign liability to any party or to the owner of any specific property. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

For purposes of listing, the NPL includes two sections, one of sites that are generally evaluated and cleaned up by the EPA (the ''General Superfund section'') and one of sites that are owned or operated by other federal agencies (the ''Federal Facilities section''). With respect to the Federal Facilities sites, these sites are generally being addressed by other federal agencies. Under Executive Order 12580 (52 FR 2923, January 29, 1987) and CERCLA section 120, each federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody or control, although the EPA is responsible for preparing a Hazard Ranking System (''HRS'') score and determining whether the facility is placed on the NPL and having oversight authority at the sites for further actions.

NPL Site Selection Process

The NPL is required to be revised annually and it is intended primarily to guide EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. This selection process is illustrated in figure 3, below. Sites with HRS scores of 28.50 or greater are eligible for placement on the NPL. Only non-Federal Facility sites on the NPL are eligible for Superfund-financed remedial actions. Once a site is determined to be NPL-caliber and a decision has been made that the federal Superfund program should manage the site cleanup, EPA regions apply a strong initial presumption in favor of placement on the NPL.

Once the site is proposed for the NPL (*i.e.,* announced in the **Federal Register**), a 60-day comment period is initiated to allow the public to comment on the proposal. EPA responds to all public comments, and depending on the results of the public comment period, the site could be removed from consideration for placement of the NPL; re-proposed in the future due to public comments; or placed on the NPL. Once the site is placed on the NPL, the rulemaking can be challenged in court under the Administrative Procedure Act (APA). If no challenge is made or if the court finds the rulemaking consistent with APA requirements, it is then eligible for further investigation under the Superfund remedial program. (Figure 3. Process for Placing a Site on the NPL).

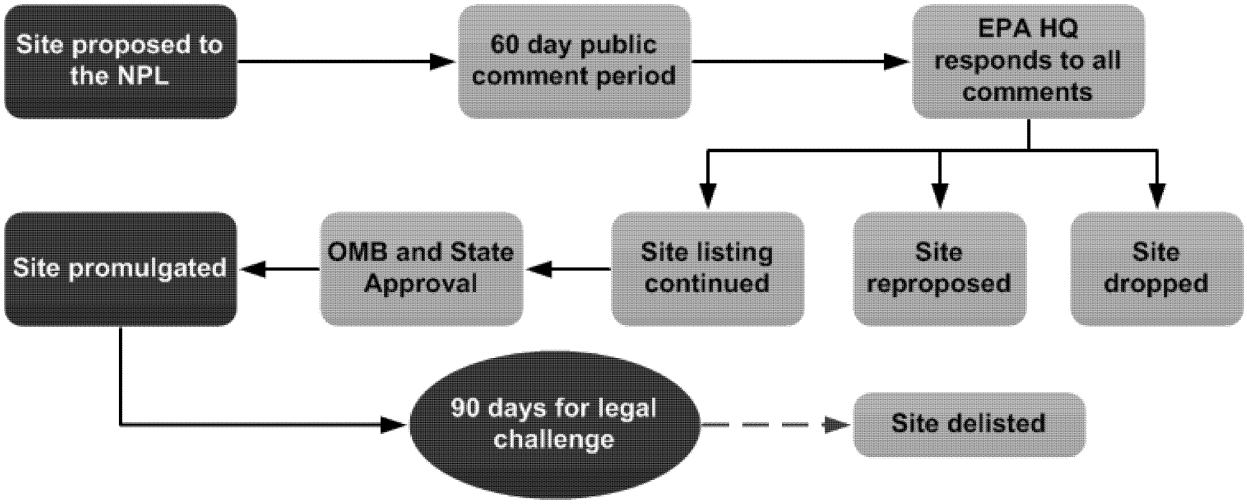


Figure 3. Process for Placing a Site on the NPL

C. Impact of the SsI Addition on Current Cleanup Programs, Resources and Cost

This SsI addition to the HRS will have the most significant impact on EPA's Superfund cleanup program. This regulatory change expands available options for EPA and organizations performing work on behalf of EPA (state and tribal partners) to evaluate actual and potential threats to public health and the environment from subsurface intrusion contamination. This modification to the HRS, by itself, only augments the criteria for applying the HRS. It has no effect on small businesses.

This final rule will not affect the status of sites currently on or proposed to the NPL. Sites that are currently on or proposed to the NPL have already been evaluated under another pathway (*i.e.,* ground water migration, air migration, surface water migration, or soil exposure) and have been shown to or are projected to qualify for placement on the NPL. The method selected for including the SsI evaluation in the HRS site score can only result in an increase in a site score, Therefore, all sites qualifying for the NPL based on its HRS site score prior to this final rule will continue to do so. It is consistent with section 105(c)(3) of CERCLA, as amended, that these sites will not be re-evaluated. This final rule will not disrupt EPA's placement of sites on the NPL.

The possible impact on federal agencies other than EPA performing Superfund actions will be less than that on private sites being addressed by EPA. Federal agencies currently address subsurface intrusion issues as part of their environmental programs and authorities. Executive Order 12580 delegates broad CERCLA authority to federal agencies for responding to actual and potential releases of hazardous substances where a release is either on, or the sole source of the release is from, any facility or vessel under the jurisdiction, custody, or control of the federal agency. Federal agencies are required to exercise this authority consistent with the requirements of CERCLA section 120, as amended, and implement regulations under the NCP, for both NPL and non-NPL sites. Therefore, federal agencies are in a position to proactively identify and respond to risks posed by subsurface intrusion of hazardous substances into regularly occupied structures for all populations who live and work in areas where the subsurface environment may create exposures. If it is determined that releases of hazardous substances pose immediate threats to public health and the environment, EPA fully expects that the appropriate federal agency will continue to undertake response actions to address such threats. Many federal agencies, including EPA, have developed or are developing new or updated agency-specific policy and guidance documents to address subsurface intrusion threats.

As a result of federal agency existing environmental programs and authorities, this rulemaking is not anticipated to have a significant impact to the resources and costs to federal cleanup programs.

Since EPA's overall appropriated Superfund budget as well EPA's cooperative agreement budget for performing site assessments will continue to remain relatively steady, EPA anticipates that this final rule will not result in additional site assessments nor the placement of more sites on the NPL during any particular interval, but rather a shift in the make-up of the type of sites included on the NPL. EPA will continue to review sites as part of Superfund remedial site assessment to determine whether sites are eligible for further remedial evaluation under CERCLA authorities and prioritize sites that pose the highest risk. This is not a change to how EPA currently evaluates and prioritizes sites for the NPL. Because the level of effort required to evaluate a site, regardless of pathway, varies on a site-by-site basis, depending on the size and extent of contamination at the site, it cannot be predicted with any certainly that there will be an increase in cost or level of effort for any particular site due to this rulemaking.

This rulemaking, which could lead to the inclusion of a site on the NPL that did not qualify for the NPL previously, does not itself impose any costs on outside parties; it does not establish that EPA will necessarily undertake response actions, nor does it require any action by a private party or determine liability for site response costs. Costs are limited to screening relevant sites for subsurface intrusion contamination during site inspections and the resulting HRS evaluation and documentation record preparation. Costs that arise from site remedial responses are the result of site-specific decisions made post-listing, not directly from the act of listing itself. These costs are a result of a release of hazardous substances and would not be incurred if hazardous substances had not been released.

Later Superfund-related decisions that consider information collected under the HRS SsI Addition could separately have specific economic costs and benefits (*e.g.,* remediation costs and reduced risk), but these impacts are contingent upon a series of separate and sequential actions after listing a site on the NPL. Therefore, addition of subsurface intrusion to the HRS is several regulatory steps removed from imposing costs on private entities.

This rulemaking does not impose any requirements on small entities, and therefore can be certified as no Significant Economic Impact on a Substantial Number of Small Entities (SISNOSE). With the exception of other federal agencies, site assessments are performed by EPA and on behalf of EPA by states and tribes in cooperative agreement partnerships with EPA. Under section 601 of the Regulatory Flexibility Act, federal agencies do not fit under the definition of small business, small entity, small organization or small governmental jurisdiction.

D. Impact of the Subsurface Intrusion Addition on the Hazard Ranking System

This final rule, with the addition of a subsurface intrusion component, does not change the purpose of the HRS, its fundamental structure or its application. It does not change the balance between the pathways or calculation of the overall HRS site score and the same cutoff score to qualify a site for the NPL is maintained. The current approach for scoring the ground water, surface water, and air migration pathways is not being altered by the addition of a subsurface intrusion component. EPA added the subsurface intrusion threat as a component to the present soil exposure pathway because its structure already focuses on populations actually or potentially coming into direct contact with hazardous substances. The re-structured pathway is called the ''Soil Exposure and Subsurface Intrusion'' pathway and now allows for the consideration of the threat posed by subsurface contaminant intrusion. The Soil Exposure and Subsurface Intrusion pathway retains the existing two soil exposure threats (resident population and nearby population) in the pathway as one component, with subsurface intrusion as the second component.

The narrow technical modifications resulting from this Final Rule reflect the agency's actions to encompass additional risks posed by releases of hazardous substances and to address the SARA statutory requirement that EPA amend the HRS to assure ''to the maximum extent feasible, that the HRS accurately assesses the relative degree of risk to human health and the environment posed by sites subject to review.'' Thus, the fundamental purpose and structure of the HRS approach has not changed with this amendment to the HRS to include the consideration of subsurface intrusion.

III. Overview of the Final Rule

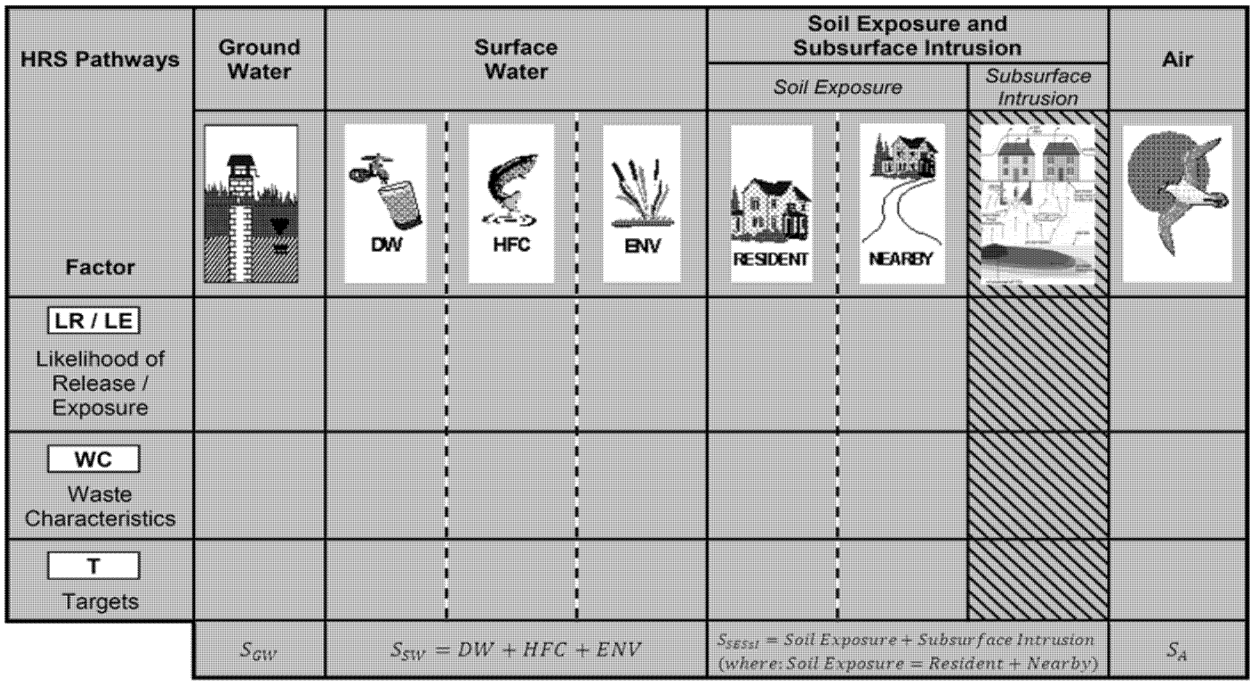
This final rule revises the 1990 HRS to include a component for evaluating the threats posed from subsurface intrusion. The following sections discuss the structure of the HRS, the subsurface intrusion component within the HRS, the major factors of the subsurface intrusion addition, and how the evaluation will be performed using a structure consistent with the other threats, components, and pathways in the HRS, but taking into account the unique parameters impacting the probability of exposure to subsurface intrusion. All sites that qualified for the NPL under the 1990 HRS, would still qualify for the NPL under this revised HRS. For a more comprehensive description and rationale of changes, see the February 29, 2016 Proposed Rule [81 FR 10372, February 29, 2016].

A. HRS Structure With the Subsurface Intrusion Component

EPA added the evaluation of the relative risk posed by subsurface intrusion of hazardous substances into regularly occupied structures by restructuring the soil exposure pathway from the 1990 HRS to include subsurface intrusion. The soil exposure pathway has been renamed the soil exposure and subsurface intrusion pathway to reflect both components of

the new pathway. No changes are included in the other three HRS pathways, with the exception of the use of a reference concentration instead of a reference dose to determine a hazardous substance's health-based benchmark in the air migration pathway. See Figure 4 for a depiction of how the promulgated addition fits into the HRS structure.

Figure 4. HRS Structure with Subsurface Intrusion Addition



S_{GW} = *Ground Water Migration Pathway Score*

S_{SW} = *Surface Water Migration Pathway Score*

S_{SESSI} = *Soil Exposure and Subsurface Intrusion Pathway Score*

S_A = *Air Migration Pathway Score*

As explained in the preamble to the proposed HRS SsI addition, the subsurface intrusion component is added as a new component of the soil exposure and subsurface intrusion pathway. The soil exposure pathway included in the 1990 HRS is retained as one component of the Soil Exposure and Subsurface Intrusion pathway. The scoring of the soil exposure component remains unaltered, but the score is assigned as the soil exposure component score, not the pathway score. (See section 5.1 of the HRS). As discussed in greater detail below, the SsI component has the same basic structure, scoring, and weighting as other parts of the HRS.

The score for the soil exposure and subsurface intrusion pathway is based on a combination of the two component scores—soil exposure and subsurface intrusion but the pathway score is capped at the same value as other HRS pathways. The soil exposure component score is added to the subsurface intrusion component score to determine the pathway score. The two component scores are additive to reflect that populations may be exposed via both routes: The soil exposure component reflects exposures to people when outside a structure and focuses on ingestion, and the subsurface intrusion component reflects exposures inside a structure and focuses on inhalation. Hence, the addition of the two component scores reflects the potential cumulative risk of multiple exposure routes and is not double counting the same relative risk.

A maximum pathway score is not contingent on scoring both the soil exposure and subsurface intrusion components. It is possible for a site to have only one component evaluated and still reach the maximum pathway score. Because the scoring of the soil exposure component is not being altered, this component would contribute the same score to the overall site score absent the addition of subsurface intrusion.

B. SsI Component Addition

The structure of the HRS is fundamentally the same for all individual pathways, components, and/or threats. The design of the HRS reflects a conceptual understanding of how hazardous substance releases from CERCLA sites can result in risks to public health and welfare and the environment. The risk scenario at these sites is a function of:

- The probability of exposure to (or releases to a medium in a migration pathway of) hazardous substances,
- The expected magnitude and duration of the releases or exposures,
- The toxicity or other potential adverse effects to a receptor associated with a target from the releases,

• For the three migration pathways, the probability that the release will reach a target and the expected change in the concentration of hazardous substances during the movement from the location of the contamination to the targets. For the exposure pathway, the probability a receptor will be exposed at the target location,

• The expected dose to the receptor, and

• The expected number and type of the receptors.

The above considerations are addressed in three factor categories: Likelihood of exposure (or release), waste characteristics, and targets.

The following subsections describe the structure of the subsurface intrusion component and how this structure is consistent conceptually with the existing structure of the other HRS pathways and components: (1) New definitions, (2) delineation of areas of subsurface intrusion, (3) likelihood of exposure, (4) waste characteristics, (5) targets, and (6) calculating and incorporating the subsurface intrusion component score into the HRS site score.

1. New Definitions—See Section 1.1 of the HRS [2]

EPA has added 15 new definitions to the HRS, section 1.1, along with updated nomenclature to existing definitions. EPA received no comments on the 14 proposed new definitions to the rule; therefore, EPA is finalizing the new definitions as proposed with the following change: The term surficial ground water has been changed to shallow ground water for clarity. In addition, EPA has added the term non-aqueous phase liquid (NAPL) to the definition section because EPA added consideration of NAPLs to the assignment of degradation factor values and the weighting of targets in the area of subsurface contamination (ASC).

2. Delineation of Areas of Subsurface Intrusion—See Section 5.2.0 of the HRS

EPA has included in the subsurface intrusion component evaluation two areas in which exposure due to subsurface intrusion contamination exists or is likely to exist: (1) Areas of observed exposure—areas in which contaminant intrusion into regularly occupied structures has been documented, and (2) areas of subsurface contamination—areas in which subsurface contamination underlying regularly occupied structures (such as in shallow ground water or soil vapor) has been documented, but at which either sampling of indoor air has not documented that subsurface contamination has entered a regularly occupied structure or no sampling of indoor air has been undertaken.

a. Area of Observed Exposure (AOE) (See Section 5.2.0 of the HRS)

An area (or areas) of observed exposure at a site is identified based on the location of regularly occupied structures with a documented significant increase in hazardous substance concentrations above background levels resulting at least in part from subsurface intrusion attributable to the site being evaluated. The area encompassed by such structures constitutes the area of observed exposure (AOE). Other regularly occupied structures within this encompassed area (or areas) are also inferred to be in the AOE unless available information indicates otherwise.

b. Area of Subsurface Contamination (ASC)—See Section 5.2.0 of the HRS

An area (or areas) of subsurface contamination is identified as an area outside that of the AOE, at which subsurface contamination has been documented at levels meeting observed release criteria (contamination at levels significantly above background and the significant increase can be attributed at least in part to the site). The contamination would be present in subslab or semi-enclosed or enclosed crawl space samples or in a subsurface sample. (See section 2.3 of the HRS for observed exposure criteria.) In addition, EPA is limiting the delineation of an ASC to be based on the location of subsurface contamination meeting the criteria for observed exposure or observed release and has a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol. The populations in an ASC are assigned a weighting value ranging from 0.1 to 0.9 depending on such factors as the distance of subsurface contamination to a regularly occupied structure's foundation, the sample media, and the presence of a non-aqueous phase liquid (NAPL).

3. Likelihood of Exposure—See Section 5.2.1.1 of the HRS

A key factor considered in the HRS relative risk ranking is whether any exposure to a hazardous substance via subsurface intrusion has occurred, or if not, whether there is a probability that exposure could occur in a regularly occupied structure. This is termed the likelihood of exposure for the subsurface intrusion component.

a. Observed Exposure—See Section 5.2.1.1.1 of the HRS

For HRS purposes, an observed exposure is established if it can be documented that a hazardous substance from the site being evaluated has moved through the subsurface and has entered at least one regularly occupied structure.

b. Potential for Exposure—See Section 5.2.1.1.2 of the HRS

When an observed exposure has not been established, the potential for exposure can be determined for any regularly occupied structure located in an ASC.

The evaluation of the potential for exposure for the subsurface intrusion component uses the same concept and framework used to estimate the potential to release in other pathways. This involves predicting the probability of exposure in an area of subsurface contamination based on structural containment features of the regularly occupied structure and a hazardous substance's physical and chemical properties and the physical subsurface properties that influence the probability that intrusion is occurring. These factor values include:

• Structure Containment
• Depth to Contamination
• Vertical Migration
• Vapor Migration Potential

Consistent with potential to release determinations in the HRS, the potential for exposure for this component is calculated by summing depth to contamination, vertical migration and vapor migration potential factor values and multiplying the sum by the containment factor value to determine a potential for exposure factor value.

c. Calculation of the Likelihood of Exposure Factor Category Value—See Section 5.2.1.1.3 of the HRS

As in all HRS pathways and components, the likelihood of exposure factor category value is assigned based on the higher of the observed exposure (or release) value or the potential for exposure (or release) value. The maximum value assigned for the likelihood of exposure factor category is 550 and is assigned if observed exposure is documented. If observed exposure is not documented, the value assigned when evaluating potential for exposure ranges between 0 and 500.

[2] *For references to a specific section of the HRS addition, please refer to the regulatory text of the rulemaking.*

4. Waste Characteristics—See Section 5.2.1.2 of the HRS

The waste characteristics factor category is based on factors that are related to the relative risk considerations included in the basic HRS structure. The factors considered in determining the waste characteristics factor category value are the toxicity of the hazardous substances, the ability of the hazardous substance to degrade, and an estimate of the quantity of the hazardous substances to which occupants could be exposed.

a. Toxicity/Degradation—See Section 5.2.1.2.1 of the HRS

The combined toxicity/degradation factor includes consideration of both the toxicity and the possibility for degradation of hazardous substances being evaluated for HRS purposes. The toxicity factor in the overall HRS structure reflects the toxicity of a hazardous substance associated with a source, release or exposure at a site, and is assigned the same factor value for all the pathways and components in the HRS. Any hazardous substance identified in an observed exposure within the AOE or meeting the observed release criteria in either the AOE or ASC will be assigned a toxicity factor value.

The degradation factor represents the possibility for a substance to degrade in the subsurface prior to intruding into a regularly occupied structure. The subsurface intrusion component evaluates degradation based on the substance being evaluated, the depth to contamination, and the presence of a NAPL. It also assumes the presence of biologically active soil unless information indicates otherwise. If it has been documented that a hazardous substance has been found to have entered a regularly occupied structure, regardless of the substance or the site conditions, the degradation value is assigned to reflect the likelihood that the substance is not significantly degrading in the subsurface. Additionally, any eligible hazardous substance present in the subsurface below an AOE or ASC as a NAPL at depth less than 30 feet is assigned a degradation value to reflect the likelihood that the substance will not significantly degrade in the subsurface environment.

The toxicity and degradation factors are multiplied together to assign a combined factor value. If multiple substances are present, the highest combined factor value is selected for use in determining the waste characteristics factor category value, as discussed below.

b. Hazardous Waste Quantity—See Section 5.2.1.2.2 of the HRS

The waste quantity factor value for this component reflects only the amount of hazardous substances that people are exposed to, that is, the amount in regularly occupied structures. EPA has retained a four-tiered hierarchical approach consistent with the HRS as well as minimum waste quantity factors. The estimation of waste quantity for the subsurface intrusion component considers the regularly occupied structures located within the AOE and ASC. For sites at which the component waste quantity (the sum waste quantities for all regularly occupied structures in the AOE and ASC) is below 10, a minimum factor of 10 would apply, the same as in other pathways and components. The minimum waste quantity factors are included because of insufficient information at many sites to adequately estimate waste quantity with confidence.

c. Calculation of the Waste Characteristics Factor Category Value—See Section 5.2.1.2.3 of the HRS

As in all HRS pathways and components, the waste characteristics category value is the product of the waste characteristics factor values (*e.g.,* toxicity/degradation factor value) for the SsI component and the hazardous waste quantity factor value, all of which are scaled so as to be weighted consistently in all pathways. Similar to the likelihood of exposure factor category, the waste characteristics factor category is subject to a maximum value to maintain the balance between factor categories. This approach is consistent with the 1990 HRS structure.

5. Targets—See Section 5.2.1.3 of the HRS

The targets factor is based upon estimates of the expected dose to each receptor associated with a target and the number and type of receptors present at each target. In assessing human risk, it is critical to understand the nature and extent of exposure to individuals, populations, and resources.

a. Identification of Eligible Targets—See Section 5.2.1.3 of the HRS

The soil exposure and subsurface intrusion pathway uses the same target categories used in the HRS soil exposure pathway, including exposed individual, resident populations, workers, and resources. However, unlike the HRS soil exposure pathway, workers are to be evaluated as exposed individuals and as part of the population within an area of subsurface contamination instead of being evaluated under a separate worker factor value.

b. Exposed Individual and Levels of Exposure—See Section 5.2.1.3.1 of the HRS

i. Identifying Levels of Exposure and Benchmarks for Subsurface Intrusion

In the SsI component, targets in the AOE are considered actually contaminated, whereas, those in the ASC are considered potentially contaminated. The targets in an AOE are further divided into Level I and II, based on whether the hazardous substance concentrations are at or above identified health-based benchmarks.

The targets within an ASC are categorized based on the type of sample (*e.g.,* gas, soil, water), the distance of the sample from the targets (*e.g.,* the depth of the sample below the structure), and whether a NAPL is present. Weighting factors ranging from 0.1 to 0.9 are then assigned accordingly.

ii. Exposed Individual—See Section 5.2.1.3.1 of the HRS

The evaluation of exposed individuals in the SsI component includes individuals living, attending school or day care, or working in a regularly occupied structure. Individuals in the eligible target population are expected to be exposed to the highest concentration of the hazardous substance in question for a significant time.

c. Population—See Section 5.2.1.3.2 of the HRS

The population factor for the SsI component includes all populations qualifying as exposed individuals, including residents, students, workers, and those attending day care. Workers are weighted slightly differently than other exposed individuals to reflect that a worker's exposure is limited to the time present in a workplace. The number of workers present in a structure or subunit is adjusted by an appropriate factor reflecting whether or not they are a full-time or part-time worker.

i. Weighting of Targets in the Area of Observed Exposure (AOE)—See Sections 5.2.1.3.2.1 and 5.2.1.3.2.2 of the HRS

Consistent with the weighting of populations throughout the HRS, the subsurface intrusion component will weight targets in an AOE subject to Level I contaminant concentrations by a factor of 10 and weight targets subject to Level II contaminant concentrations by a factor of 1. Eligible populations include individuals living, working, and

attending school or day care in regularly occupied structures.

Within the AOE, those populations in regularly occupied structures for which observed exposures have not been established but the structures are surrounded by regularly occupied structures in which observed exposures have been identified, are also considered as actually contaminated unless evidence indicates otherwise. Targets inferred to be exposed to this contamination will be weighted as Level II as there are no actual sample results to compare against benchmarks.

In the case of multi-story/multi-subunit structures, all regularly occupied subunits on a level with an observed exposure and all levels below are considered to be within an AOE, unless available information indicates otherwise. For multi-story/multi-subunit structures located within an AOE, but where an observed exposure has not been documented, only those regularly occupied spaces on the lowest level are considered to be within an AOE, unless available information indicates otherwise.

ii. Weighting of Targets in the Area of Subsurface Contamination (ASC)—See Section 5.2.1.3.2.3 of the HRS

Due to the variability in subsurface intrusion rates, the potential weighting factor values for targets within an ASC range from 0.1 to 0.9 and depend on where the subsurface contamination has been found and whether a NAPL is present.

Potential targets are weighted to reflect the distance to or the depth at which contamination is found and whether a NAPL is present. The weighting factors applied to populations being evaluated based on the presence of subsurface contamination containing a NAPL reflects greater subsurface source concentrations and an increased probability that contaminant intrusion into a regularly occupied structure from the subsurface will result in a concentration significantly above background levels for the site. In the case of multi-story/multi-subunit structures, all regularly occupied subunits on a level above one where an observed exposure has been documented or inferred, or where a gaseous indoor air sample meeting observed release criteria is present, are considered to be located within an ASC, unless available information indicates otherwise. For multi-story/multi-subunit structures located only within an ASC, only those regularly occupied subunits within the lowest level are considered in an HRS evaluation.

Eligible populations in an ASC include individuals living in, attending school or day care, and working in regularly occupied structures. However, the number of workers is adjusted to reflect that their exposure is limited to the time they are in a workplace.

d. Resources—See Section 5.2.1.3.3 of the HRS

Resources for this component include regularly occupied structures that are located within a defined AOE or ASC and in which populations may be exposed to contamination due to subsurface intrusion. Libraries, recreational facilities, and religious or tribal structures used by individuals may qualify as eligible resources.

e. Calculation of the Targets Factor Category Value—See Section 5.2.1.3.4 of the HRS

The Target Factor Category Value is the sum of all the Target Factor values.

6. Calculation and Incorporation of the SsI Component Score Into the HRS Site Score

The following subsections summarize the calculation of the subsurface intrusion component score, how the component score is used in the calculation of the soil exposure and subsurface intrusion pathway score, and how, in turn, the pathway score is subsequently incorporated into the HRS site score.

a. Calculation of the SsI Component Score—See Section 5.2.2 of the HRS

The SsI Component score is the product of the likelihood of exposure factor category value, the waste characteristics factor category value, and the targets factor category value; that value is divided by a weighting factor so that it has equal magnitude to other component scores (subject to a maximum value).

b. Incorporation of the SsI Component Score into the Soil Exposure and Subsurface Intrusion Pathway Score—See Section 5.3 of the HRS

The Soil Exposure and Subsurface Intrusion pathway score is a combination of the two component scores.

c. Incorporation of the Soil Exposure and Subsurface Intrusion Pathway Score Into a Site Score—See Section 2.1.1 of the HRS

EPA did not change the methodology used to assign an overall site score due to the addition of the subsurface intrusion component to the soil exposure pathway and renaming that pathway the soil exposure and subsurface intrusion pathway. The overall site score remains a function of four pathway scores and the same weighting is given to each pathway score as in the 1990 HRS.

C. Testing the SsI Component

The SsI component was tested extensively throughout the development of this rule, using multiple methods. The main goals of testing the component included:

- Ensuring the addition of the SsI component to the soil exposure pathway did not change relative contribution to the site score as the other HRS pathways and maintained the same relative risk of a site with a similar threshold for qualifying for the NPL.
- Ensuring the number of targets subject to actual contamination needed to achieve a site score sufficient for NPL proposal remained consistent across pathways.
- Ensuring that applying the SsI component as part of an HRS evaluation would not result in identification of sites with a low level of risk or would not identify sites with a high level of risk.

These goals were met by using conceptual simulations to project the effectiveness and appropriateness for factor values, by developing and testing numerous example site scenarios to refine the model and by applying the model to test sites to determine its efficacy. The following information provides details on the approaches used to test the SsI component.

1. Conceptual Site Model/Sensitivity Analysis

Sensitivity analyses were performed during development of the rule to test the SsI component and identify and assign the relative magnitude of the factors having the greatest impact on the HRS site score. The analyses illustrated the types of sites that would qualify for the NPL considering subsurface intrusion contamination, and sites that would qualify for the NPL considering the contribution of subsurface intrusion contamination to other pathways. The scenarios illustrate different site characteristics and different factor value weightings. An initial conceptual site scenario evaluation was developed with varying likelihood of intrusion levels, zone of contamination, waste characteristics and levels of contamination. The conceptual site scenario evaluation was varied to reflect possible ranges in the factors considered in the HRS evaluation.

The first phase of testing estimated site scores based on options considered

for identifying eligible targets and delineating target areas. The testing was conducted using factor values, factor category values, and scoring algorithms consistent with other parts of the HRS. This ensured relative risk was evaluated and consistently weighted among pathways. A second phase was conducted for identifying target areas delineated by AOEs and ASCs of various site scenarios to test the HRS addition and to illustrate the features of sites that would qualify for the NPL considering vapor intrusion contamination. To illustrate the subsurface intrusion component and contribution of weighting of factor values, three comprehensive site scoring scenarios were evaluated: A site would not qualify for placement on the NPL (score below 28.50), a site would marginally qualify for the NPL (score of or about 28.50), and a site would exceed the scoring criterion for the NPL (site score considerably above 28.50). Based on this final rule, the results revealed that sites without areas of observed exposures and a typical waste characteristic value would require a minimum of 685 receptors living, working or attending school or daycare above an area of subsurface contamination to receive a score of 28.50 based on shallow subsurface sampling. Sites with documented subsurface intrusion into an occupied structure, a typical waste characteristic value and indoor air samples below health-based benchmarks would require a minimum of 223 receptors to receive a score of 28.50. This illustrates that this final rule will not result in a large number of sites qualifying for the NPL as it is unlikely this number of receptors in an area of subsurface contamination will commonly occur. This is the similar number of receptors needed for a site to qualify for the NPL in other pathways.

2. Test Sites (Tier 1)

To support the final rulemaking, EPA conducted a screening-level assessment of sites with identified subsurface intrusion threats. As a first step in collecting the list of sites potentially affected by the final rule, EPA consulted with site assessment experts that work in Superfund to identify potential site candidates. EPA also reached out to state counterparts, in particular to state programs that were known to have taken a more thorough investigation of the subsurface intrusion pathway at sites. Through this process, EPA identified approximately 1,073 sites. These sites are not currently on the NPL, and all have a potential or identified SsI threat. Within the group of sites potentially affected by the HRS SsI Addition, EPA defined four categories:

1. Tier 4: Sites identified as having a suspected SsI threat based on EPA's Superfund database and Agency for Toxic Substances and Disease Registry keyword searches, as well as EPA or state self-identification, but for which no sampling data were obtained;
2. Tier 3: Sites identified as having characteristics or evidence that indicate SsI may have occurred or will occur;
3. Tier 2: Sites identified as having an SsI threat documented by subslab, crawl space, or indoor air samples, but insufficient HRS-required evaluation factors to qualify for the NPL; and
4. Tier 1: Sites identified as having an SsI threat with documented actual exposure of a sufficient number of targets with enough other HRS-required evaluation factors to suggest the site may qualify for the NPL.

EPA selected the Tier 1 sites for use in testing the SsI component evaluation process. The 11 Test Sites had documentation of indoor contamination due to subsurface intrusion based on actual sampling data and other typically HRS-required data. Of the 11 sites scored, 9 were projected to score 28.50 or higher using only the SsI component. 1 site was projected to score 28.50 or higher only by including both the scores from the SsI component evaluation and the ground water migration pathway evaluation in the site score. It was unknown whether these sites would qualify for the NPL when they were chosen as Test Sites, as the SsI scoring process had not been developed. The Test Site with a projected score below 28.50 did not qualify for the NPL even though the site was located in a mixed-used residential and industrial area, illustrating that not all sites in an urban area will qualify for the NPL.

That 10 of the 11 Test Sites have a projected HRS site score of 28.50 or greater using the SsI component is not an indication that the addition of the SsI component will result in a large number of SsI sites qualifying for the NPL; this would be a possible projection if the Test Sites were chosen randomly so as to represent a typical SsI site. The Test Sites were not randomly chosen, but instead were specifically chosen because they have a documented subsurface intrusion threats at the sites and sufficient available data to test all parts of the SsI component. The Test Sites all had areas of observed exposure; most had more than 38 structures at the site (some with hundreds of structures), and all but two Test Sites had at least 50 targets (more than half had over 100 targets). Each site was also associated with volatile hazardous substances that are considered hazardous to human health at low concentrations. Appendix B of the Technical Support Document (TSD) for this final rulemaking provides a summary of these scoring evaluations.

3. Pilot Study

The main purpose of the Pilot Study was to identify sites currently being evaluated for SsI by the EPA regions with a suspected subsurface intrusion threat and determine whether an SI would provide enough information to score a site under the new component. Additional goals of the Pilot Study were to gather data and determine if design of the SsI model is practical and gives expected results; identify a range for the cost of a projected SsI site assessment; and assist in developing future guidelines for SsI assessments. A total of 10 sites were identified across 5 of the 10 EPA Regions. The pilot studies were not intended to identify sites for placement on the NPL, and not all sites considered for the pilot studies achieved an HRS score greater than (or equal to) 28.50. However, collecting actual data for the purposes of generating an SsI component score, ensured the HRS was considering subsurface intrusion threats appropriately. Ultimately, the pilot studies were used to proof the concept and validate the SsI component in terms of the application of selected weighting factor values and the efficacy for accurately identifying sites with significant relative risk.

IV. Summary of Changes to the HRS

Comments on the Proposed Rule were received from 15 organizations/individuals. The commenters included state and federal agencies, industry associations, community groups, consultants, and private citizens. No major conceptual or structural changes were necessary based on comments received during the public comment period. While many of the comments focused on the structure of the SsI component, there was not sufficient rationale for making major changes to the basic structure of the SsI component. There were minor revisions made based on comments, which help refine the mechanics of assigning an HRS site score. As a result, the SsI component better reflects current science and better aligns with underlying concepts in the *OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Sources to Indoor Air* (VI Guide). These changes had no impact on the overall structure of the SsI component and do not impact the relative weighting among the HRS

pathways or the level of risk required to qualify for the NPL.

A. Changes Since Proposal

1. Consideration of Contaminated Ground Water Intrusion

Section 5.2 was revised to clarify that areas of subsurface contamination are only delineated based on the presence of hazardous substances meeting the criteria for observed exposure or observed release and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol. However, if samples indicate intrusion of liquids containing hazardous substances has occurred into regularly occupied structures, the samples of that liquid are still used in delineating an Area of Observed Exposure to reflect the threat to targets. These revisions were made to correct a seeming inconsistency in wording between the discussion in the preamble to the proposed rule and the proposed regulatory language.

2. Consideration of Non-Aqueous Phase Liquids (NAPLs) in Weighting of Targets in an ASC

Table 5–21, Weighting Factor Values for Populations within an Area of Subsurface Contamination, of the HRS was revised to include consideration of the presence of NAPLs identified in an area of subsurface contamination. These additions increase the weighting of the population in an area of subsurface contamination to the SsI component score. These revisions were in response to comments that the proposed addition did not reflect the magnitude of contaminant concentrations in the evaluation of targets in the area of subsurface contamination. While EPA considers it unlikely that the actual aerial distribution and magnitude of contaminant concentrations can be determined in an area of observed contamination during a site inspection, if NAPLs are identified as present, EPA agrees that there is a greater risk to receptors than if no NAPL is present.

3. Modifications to the Determination of Degradation Factor Values

Section 5.2.1.2.1.2 of the HRS was revised to make it easier for the reader to determine degradation factor values and to add consideration of the presence of NAPLs. Commenters asserted that the text was difficult to follow and that the presence of NAPLs was a major factor in the impact of degradation. A new table, Table 5–18 of the HRS, simplifying the assignment of degradation factor values based on the depth to contamination and a substance's half-life was inserted to replace proposed text. Additionally, if no half-life information is available for a hazardous substance and the substance is not already assigned a degradation factor value of 1, a value of 1 will be assigned. This modification further simplifies the degradation evaluation and is also protective of human health, for if no half-life information is available for a hazardous substance, EPA cannot assume that degradation will occur. In addition, parent-daughter relationships between substances are no longer considered in the assignment of the degradation factor value, in part to simplify the assignment and in part to reflect the variation in rates of degradation due to site-specific subsurface conditions. Even if degradation occurs, if a contaminant is at high enough concentration to exist as a NAPL at depths less than or equal to 30 feet, it is more likely to pose a threat to populations in overlying structure.

4. Modifications Made to Section 5.2.1.1.2.1, Structure Containment and Table 5–12

Section 5.2.1.1.2.1 and Table 5–12 of the HRS were revised in response to comments on the rationale for assigning containment values to individual structures. The assignment of a structure containment factor value assigned to structures in Table 5–12 with vapor mitigation systems or other response actions was revised. These revisions were made in response to a comment questioning why response actions taken by federal, state, and tribal authorities are treated differently than those taken by private entities in determining containment for a structure. The language regarding treatment of removals by federal, state, and tribal authorities has been removed from Table 5–12 and the corresponding containment value was assigned a 1. This change allows a consideration of public and private removal actions to be evaluated in a consistent manner.

Section 5.2.1.1.2.1 and Table 5–12 of the HRS was also revised to remove from the table the direction of the assignment of a structure containment value for a regularly occupied structure with unknown containment features. This direction, which assigns a value of ''greater than zero'' to this situation, was moved to the text in section 5.2.1.1.2.1 of the HRS. This revision was made in response to a comment questioning the rationale for the various containment values and was made to improve the continuity of the table, which directs the assignment of values when containment features of the structure are known. A structure with a containment factor value of greater than zero cannot be used in assigning a potential for exposure factor value. EPA considers it appropriate that the potential for exposure factor value should be based on actual field observations. However a structure with a structure containment value of greater than zero allows the structure to be evaluated for assigning waste characteristics values (*e.g.,* a hazardous waste quantity factor value) and for assigning target factor values. EPA considers the inclusion of structures with unknown containment features in the calculation of waste characteristics and targets values appropriate as it reflects that very few structures are built to be sufficiently air tight to prevent subsurface intrusion.

5. Consideration of Hydraulic Conductivity in Vertical Migration

Table 5–14 of the HRS was revised to allow assignment of an effective porosity/permeability factor value based on site-specific measurements of hydraulic conductivity, if known. This addition was made in response to a comment suggesting the rule be modified to allow use of site-specific information for this purpose when available.

6. Changes to Definitions

The term surficial ground water was re-named shallow ground water and was changed to be consistent with current EPA usage.

EPA has added the term non-aqueous phase liquid (NAPL) to the definition section. EPA added consideration of the identification of concentrations of hazardous substances high enough to indicate the presence of NAPLs in the subsurface during a site inspection to the assignment of degradation factor values and the weighting of targets in the ASC. The presence of NAPLs in the subsurface demonstrates the hazardous substances will be present at high concentrations for a significant time period at that location and the high concentration is not a transient situation.

B. Summary of Updates to the HRS (Sections 2, 5, 6, and 7)

1. Addition of an SsI Component to the HRS (Sections 2, 5, and 7)

a. The addition of a subsurface intrusion component is added to the 1990 Soil Exposure pathway as section 5.2 in Chapter 5 of the 2016 Revised HRS. The new pathway name is the soil exposure and subsurface intrusion pathway. The existing method for evaluating the soil exposure threat will remain unchanged.

b. Chapter 2: Evaluations Common to All Pathways is updated to reflect the

addition of the subsurface intrusion component to the renamed the soil exposure and subsurface intrusion pathway. The evaluations for the migration pathways and the soil exposure component remain unchanged. A parallel structure was added for the subsurface intrusion component.

c. Chapter 7: Sites Containing Radioactive Substances is updated to reflect how radioactive substances are evaluated using the added subsurface intrusion component.

2. Terminology Updates Affecting Specific Sections of the HRS (Sections 2, 5 & 6)

The following terms are updated to reflect current terminology and procedures used by EPA in performing risk assessments.

a. Ambient Water Quality Criteria: Ambient Water Quality Criteria (AWQC) are now identified also as National Recommended Water Quality Criteria (NRWQC). In addition, the acute AWQC are now identified as the Criterion Maximum Concentration (CMC) and the chronic criteria are referred to as the Criterion Continuous Concentration (CCC). (See section 1.1 of the HRS.) These criteria are used to determine the level of threat to environmental targets.

b. Reference Concentrations: For inhalation exposures, EPA is adopting the use of Reference Concentrations (RfCs) instead of Reference Doses (RfDs) when determining non-cancer-related risk levels. RfCs are used in determining the level of threat to human targets due to possible inhalation and when determining the toxicity of the substances.

c. Cancer Unit Risk: For inhalation exposures, EPA is adopting the use of Inhalation Unit Risk (IUR) instead of cancer slope factors in determining cancer-related risk levels. IURs are used in determining the level of threat to human targets due to possible inhalation and when determining the toxicity of the substances.

d. Weight-of-Evidence Groupings: The 2005 EPA weight-of-evidence groupings supporting the designation of a substance as a human carcinogen have been incorporated into the HRS algorithm for assigning the toxicity factor value. (The former EPA weight-of-evidence categories included as part of the 1990 HRS have been retained as EPA has not yet completed assigning all substances to the revised categories and are doing so at the time the EPA substance literature reviews are updated.)

V. Discussion of Major Comments

Comments on the Proposed Rule were received from 15 organizations/individuals. The commenters included state and federal agencies, industry associations, community groups, consultants, and private citizens. This section discusses the major issues raised by commenters, which are summarized, and EPA's summary of responses. In addition, EPA solicited and received input from commenters on three technical questions posed in the Preamble to the Proposed Rule.

A support document, Response to Comments on the 2016 Revisions to the Hazard Ranking System (HRS), that includes all issues raised during the public comment period, comments received on the questions posed in the preamble to the proposed rule and EPA's more comprehensive response to each issue, is available in the docket for this rulemaking.

A. Responses to Comments on EPA Questions Posed in the Proposed Rule

Question 1: Is there a way to determine the presence and extent of biologically active soil at a site during a limited site investigation? If so, what soil characteristics should EPA consider to determine whether biologically active soil is documented to be present?

EPA received multiple comments in response to this question. One commenter suggested that this activity is beyond the scope of the site assessment process, while another commenter suggested that EPA consider measuring specific compounds or other factors reflecting biological activity when conducting soil vapor analysis. A third commenter remarked that half-lives faster than 100 days are presumably due to aerobic biodegradation and that most vadose zone soils that are not grossly impacted are considered biologically active. A commenter also suggested using soil characteristics reflected in soil surveys to reflect the possibility that biologically active soil could be present. No commenter suggested practical methods to determine site-specific biological activity throughout a site or over time.

The HRS SsI addition was revised to clarify the assumption of the presence of biologically soil in evaluating the degradation factor unless evidence indicates otherwise (see section 5.2.1.2.1.2 of the HRS).

Question 2: How could EPA further take into account the difference in dilution and air exchange rates in large industrial buildings as compared to smaller residential and commercial structures when calculating the hazardous waste quantity for the HRS SsI Addition?

EPA received multiple comments in response to this question. One commenter suggested developing intrusion screening values based on exposure scenarios for ''most sensitive individual'' and ''industrial'' models. One commenter indicated that there is not a dependable way to account for the differences between large commercial/industrial structures and smaller residential/commercial structures. Another commenter noted that there are several parameters (*e.g.,* building energy efficiency) that would impact the differences in dilution and air exchange rates and which are generally unavailable during an initial assessment. A commenter discussed developing a sliding scale based on the size of the building and the building's general use to account for the differences in contaminant clearance rates.

EPA did not make any changes to the final rule based on the comments received as the type of information requested in these responses is generally not available during a typical site inspection. The HRS has also been designed so that it can be applied consistently to a wide variety of sites. The HRS is not a tool for conducting quantitative risk assessment and was designed to be a measure of relative risk among sites rather than absolute site-specific risk.

Question 3: The HRS SsI addition considers source strength in delineating ASCs and AOEs, in scoring in likelihood of exposure, in assigning waste quantity specifically when estimating hazardous constituent quantity and in weighting targets in an ASC. The HRS algorithm for all pathways incorporates the consideration of source strength in determining an HRS site score. Could EPA further take into account source strength in performing an HRS evaluation?

EPA received multiple comments in response to this question. One commenter suggested that EPA assign a higher score when the contaminant concentration is high (*e.g.,* when a non-aqueous phase liquid is present) to account for source strength. Comments were also received that reflected the difficulty of accessing large low concentration sources and how to account for that in considering source strength. Another commenter remarked that there may be a large ground water plume without a discrete source that would cause an increased risk of vapor intrusion; and that a large diffuse source is different from having a concentrated discrete source. One commenter

provided a copy of the proposed rule with their suggested edits reflecting the evaluation of source strength in assigning HRS specific factors.

The assignment of a degradation factor value (see section 5.2.1.2.1.2 of the HRS) and the weighting factors for targets in an area of subsurface contamination (see Table 5–21 of the HRS) were revised to include consideration of source strength; specifically in the situation where NAPLs are present.

B. Major Comment Theme Summaries and Responses

Statutory Authority and Rationale for the Proposed HRS Addition

Justification for Revising the HRS

EPA received comments suggesting that sufficient justification or rationale for the need to revise the HRS has not been provided and that a revision to the HRS is unnecessary because the 1990 HRS adequately evaluates the relative risk posed by a site and identifies those priority sites for further investigation.

The rationale for revising the HRS to add a subsurface intrusion component is EPA's statutory authority. Specifically, CERCLA 105(a)(8)(A), requires EPA to amend the HRS ''to assure to the maximum extent feasible, that the HRS accurately assess the relative degree of risk to human health and the environment posed by sites and facilities subject to review.'' Contamination due to subsurface intrusion is a known risk to human health and the ability to evaluate those risks is consistent with the CERCLA 105 mandate. The 1990 HRS did not evaluate the risk posed by subsurface intrusion when evaluating sites for the NPL. As part of the development of this rule, EPA identified high priority sites with significant contamination due to SsI that could not be evaluated using the 1990 HRS for possible placement on the NPL. With the addition of the SsI component to the HRS, sites can now be evaluated more comprehensively to consider the relative risk posed by a site.

Priority for Drinking Water Sites

EPA received comments suggesting that the proposed HRS SsI addition conflicts with CERCLA's statutory mandate regarding prioritizing drinking water sites.

The revision to the HRS to add a subsurface intrusion component is not in conflict with the CERCLA 105 mandate to prioritize drinking water sites. The priority given by EPA under CERCLA to sites with a high risk of populations exposed to hazardous substances in drinking water has not decreased with the addition of a subsurface intrusion component to the HRS. In fact, the score for some sites with contaminated drinking water supplies may increase because sites with contaminated drinking water may also be associated with subsurface intrusion contamination and the combination of the ground water migration pathway score and the SsI component score may increase the overall site score. Furthermore, EPA notes that drinking water is a priority identified by CERCLA, but it is not the only priority identified in CERCLA 105, which also mandates the prioritization of dangers of direct human contact, for which SsI is one example.

The addition of the SsI component does not change the priority given to drinking water sites. It does not change the scoring of contaminated drinking water supplies under the HRS, reduce in anyway the overall HRS score for any site based on drinking water contamination (or any other threat due to exposure to released hazardous substances in the HRS), or change the site score of 28.50 being the HRS score that qualifies sites for placement on the NPL. If a site qualifies for placement on the NPL based on its HRS score reflecting drinking water contamination prior to the addition of the SsI component, it will continue to do so. Adding an evaluation of the SsI component can only increase an overall site score. The algorithm used to combine pathways scores to obtain an overall site score results in an increase in the overall site score with the evaluation of additional pathways, components and threats scored. In fact, the SsI addition may raise the overall site score at some sites with ground water drinking water contamination from below the 28.50 cut-off score to above it. This may occur because, as stated above, a site's HRS score can increase with the scoring of additional threats. Sites with ground water contaminated by volatile substances and used for drinking water are also sites at which the ground water contamination may volatilize and intrude into overlying regularly occupied structures. Thus, a site at which ground water contamination has occurred but does not have an HRS score above 28.50 based only on the ground water threat, may have an overall HRS site score above 28.50 based on the combination of the scores for the contaminated drinking water and SsI threats.

Furthermore, EPA notes that CERCLA 118 refers to CERCLA sections104 and 108, which address activities that occur pre- or post-NPL-listing, and not to the section of CERCLA that addresses site ranking using the HRS, which is addressed in CERCLA section 105. CERCLA Section 105 and specifically 105(a)(8)(A) requires EPA to prioritize sites based on ''the population at risk, the hazard potential of hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact [and] the potential for destruction of sensitive ecosystems.'' Since subsurface intrusion contamination is a direct human contact threat, the addition of a subsurface intrusion component, which addresses this threat, is mandated by CERCLA.

Resource Impacts of the Proposed HRS Addition

Increased Cost and Level of Effort

EPA received comments suggesting that contrary to EPA's suggestion that the HRS SsI addition may not result in more site assessments per year and only minimal cost increases, commenters claimed that there will be substantial increases in cost and level of effort for states and federal agencies, due to the complexity in assessing subsurface intrusion sites.

EPA acknowledges that in some cases the scope of a typical site inspection (SI) may need to be expanded to collect the information necessary to evaluate the SsI threat present at a site. EPA also acknowledges that sites that did not qualify previously for the NPL, may now do so. The number of samples and level of effort required to evaluate a site using the 1990 HRS pathways or components already varies on a site-by-site basis depending on the size and extent of contamination at the site. Therefore, it cannot be predicted with certainty that there will be an overall increase in cost or level of effort for any particular site due to the HRS SsI addition. However, the overall budget for performing site assessments per year is not expected to change significantly. EPA's budget for site assessment is dependent on Congressional appropriation and EPA does not expect the rulemaking to impact the appropriation. EPA's budget for site assessment has remained relatively constant for the last several years. Hence, EPA expects that the allocation of available resources may be changed to reflect this rulemaking but will continue to be optimized by EPA, its state and tribal partners, and with other federal agencies to evaluate priority sites. However, the number of site assessments or NPL proposals conducted each year will not significantly increase.

Potential Limitations With Implementing the HRS SsI Addition

Scope of Site Inspection

EPA received comments stating that the type and amount of information available for collection during a time-limited site inspection would be insufficient to properly evaluate a site using the HRS SsI addition and would be beyond the scope of site evaluations typically conducted at the preliminary assessment or site inspection stage.

During development of the HRS SsI addition EPA considered the type of information that could be collected during a time-limited site inspection when selecting the factors to include in an evaluation of the subsurface intrusion component. The purpose of the site inspection (NCP 300.420(c)) is to determine if a release of a hazardous substance poses an actual or potential threat to human health or the environment, to determine if there is an immediate threat to people or the environment, and to collect sufficient data to enable the site to be scored using the HRS. EPA also notes that neither the NCP nor the HRS requires a certain number of samples be collected during an SI, because the number of samples required to evaluate a site varies on a site-by-site basis and the possible risk pathways being evaluated. However, to properly evaluate the subsurface intrusion component, additional information may be required beyond that collected during a typical current site inspection may be required; this is consistent with the need to collect data on the threat posed by a different pathway. In these instances, as stated in EPA's Guidance for Performing Site Inspections under CERCLA (September 1992), an expanded site inspection (ESI) may be required. The objective of the ESI is to collect data that was not collected during an initial site inspection. Furthermore, EPA found that information required for an SsI evaluation was available based on a pilot study which included several candidate NPL sites. The pilot study was performed in part to demonstrate the availability of the necessary data from screening level investigations. Therefore, EPA considers that the information required to properly evaluate the subsurface intrusion component can be obtained during the site assessment process.

Need for Guidance

EPA received comments questioning or requesting additional information or guidance regarding the type and amount of data to collect, data collection methods, and how to apply the subsurface intrusion component to a site. Commenters also suggested it was difficult to properly evaluate and comment on the proposed HRS SsI addition without a thorough understanding of how the SsI component would be implemented and that promulgation should be delayed until guidance is developed.

The HRS does not provide prescriptive methods for performing site investigations for any HRS pathway evaluation because the methods used during the collection and analysis of environmental samples depend on site conditions and could not be written to cover all possible situations and could also become outdated in the future. Additionally, it is outside the scope of the HRS to identify and describe methods for conducting a subsurface intrusion screening for HRS purposes. The sampling and data collection information in the EPA OSWER VI Guide, (particularly in section 6 of the guide) are an appropriate resource for gathering data for HRS purposes. For example, Section 6.4 of the guide identifies basic principles, methods and procedures for indoor air sampling. In addition, states, federal agencies, and private contractors have considerable experience in VI investigations and collecting VI-related data. Guidance on implementation of the proposed SsI addition is not necessary for evaluating the SsI component, which is a scoring mechanism not procedures for data collection. Any guidance developed will provide details on collecting data to support an HRS SsI evaluation. EPA also notes that to delay addressing sites that may pose a significant human health risk until all necessary guidance documents have been developed would not be consistent with EPA's mandate to protect human health. Therefore, EPA does not agree that promulgation of the HRS SsI addition needs to be delayed until guidance documents related to its implementation have been developed.

Roles of the HRS SsI Addition and the 2015 OSWER VI Guide

EPA received comments suggesting that the HRS SsI addition is not consistent with the VI Guide, published in June 2015 and will create confusion when evaluating sites for SsI.

The VI Guide and HRS SsI rule work in concert to establish national consistency in the evaluation of SsI threats. The HRS SsI addition and the OSWER VI Guide both address the threat posed by vapor intrusion and use the same principles, sampling procedures and concepts to characterize the threat posed by vapor intrusion as the sites. However, the HRS SsI addition and the OSWER VI Guide serve different purposes and support different phases of EPA's site remediation process with different data quality requirements and different enabling legislations.

The purpose of the OSWER VI Guide is to guide the investigation and assessment of the threat posed by vapor intrusion into structures from all sources under all Office of Land and Emergency Management (OLEM, formerly OSWER) programs, particularly actions taken under CERCLA and RCRA. This guidance is used to support decisions by EPA on whether vapor intrusion is posing an unacceptable risk to human health based on sufficient site specific data. It contains principles for making such a decision, as well as procedures and guidance for collecting the information necessary to make these decisions.

The HRS and the SsI addition is part of the NCP, (the regulations implementing CERCLA) required by CERCLA to identify priority sites for further investigation based on screening level information (Such sites are identified for the public by placing the sites on the NPL, a separate rulemaking process). This prioritization is based on the possible cumulative relative risk amongst all candidate sites posed by releases of hazardous substances to human health and the environment by either migration to receptors or by direct contact with the contamination, such as by subsurface intrusion. The HRS is only a method for assigning a relative score to candidate sites. It is not a method for determining site specific risk. The HRS SsI addition is not guidance. The HRS SsI addition does not address such subjects as data collection and sampling procedures: Many of the procedures and many of the guidelines in the OSWER VI Guide are also applicable for HRS purposes if they can be implemented as part of a screening level assessment.

Given that the purposes for the two documents are considerably different and based on different levels of information, it is not an issue that decision criteria are different in the two documents. It is certainly possible that, based on an HRS evaluation, EPA may determine a site warrants further investigation, and that after further investigation is performed EPA may decide no remediation is necessary. However until further information is collected during a remedial investigation, such an outcome cannot be predicted. Furthermore, such a situation is not an indication the results of the HRS evaluation was incorrect.

Application of HRS SsI Component

Inferring Contamination

EPA received comments suggesting that by inferring contamination between sampling locations, the extent of the risk is overstated. The commenters considered identifying targets as actually or potentially exposed based on inference to inflate the HRS site score. It was also suggested that this method conflicts with the other HRS pathways.

The HRS is not a quantitative risk assessment. Instead, the HRS SsI addition score reflects the possible threat posed by subsurface intrusion at one site relative to other sites. By inferring contamination in an AOE or an ASC between sampling locations, it is not assumed that all populations within the two areas are exposed to contamination from the subsurface. Inferring contamination also allows sites with large populations within the two areas to be ranked higher than sites with smaller populations. If the HRS scoring required sampling every structure a sufficient number of times to assure that all exposed targets were accounted for, the scope of the sampling effort would be beyond that of a screening tool and more consistent with the scope of a remedial investigation.

Inference of contamination between sampling locations is also assumed in other HRS pathways. The other pathways allow the inference of contamination based on the location of samples documenting the presence of contamination attributable to the site being investigated. For example, in the soil exposure component, inference of contamination is done by drawing AOC boundaries based on sample locations and inferring that those targets associated with the properties within the boundaries are actually exposed.

In the SsI component, unless site-specific information indicates otherwise, when delineating an AOE or an ASC, populations in occupied structures within an AOE are inferred to be actually exposed, and, populations in occupied structures within an ASC are inferred to likely be exposed to contamination.

Purpose of Hazardous Waste Quantity

Commenters noted that as explained in the TSD for the proposed HRS SsI Addition, the hazardous waste quantity factor serves as a surrogate for the contaminant dose that populations may be exposed to. Commenters asserted that the hazardous waste quantity factor is not adequately reflective of this dose to be used as a surrogate.

The commenters appear to be confusing consideration of waste quantity as a surrogate for dose in an HRS evaluation with the calculation of a site-specific risk level based on the ratio of waste quantity to receptors. EPA is not projecting a specific risk level based on the waste quantity alone when it performs an HRS evaluation. Other HRS factors such as the population associated with the structures, the probability of a release into the occupied structures, the possibility of degradation, and the toxicity of the substances are also considered,

The decision to include waste quantity as a surrogate for dose in all pathways and components in the HRS algorithm was made when the HRS was last revised in 1990 (see Section V.3 of the proposed 1988 HRS, 53 FR 51692, December 23, 1988; Section III.C of the 1990 HRS, 55 FR 51542, December 14, 1990). The decision was based on the concept that determining an accurate dose that receptors would be exposed to was beyond the scope of information available after a site inspection. It is not possible to accurately predict the hazardous substance concentration that receptors would be exposed to over a representative exposure period based on information collected during a site inspection due to the variability in exposure levels over time and space. Instead, hazardous waste quantity is used as a surrogate for dose in the sense that the quantity of the hazardous substances is at least qualitatively correlated to the magnitude of the exposure. If there is no waste quantity, there will be no exposure; as the waste quantity increases, the greater the possibility of exposure to hazardous substances that a receptor may come in contact with. EPA agrees this is not a perfect correlation, and has built into the HRS four order of magnitude ranges for assigning factor values that reflect the imperfection of this correlation.

In addition, the inclusion of hazardous waste quantity in the subsurface intrusion component is consistent with its inclusion in all the other existing HRS pathway evaluations and is consistent with the goal that the scoring of the new component not impact the balance built into overall HRS site scoring algorithm among the HRS pathways.

Furthermore, for determining waste quantity for the SsI component, EPA made a specific alteration to how waste quantity is calculated as compared to other HRS pathway. EPA decided to only include the amount of hazardous substance that actually enters into or that could enter into occupied structures, not the total amount in the release to the environment, based on the rationale that at least some of the original release in the subsurface would vent directly to the atmosphere. Therefore only the amount of hazardous substances that has entered into occupied structures or the amount located under structures is reflected in the estimate. This was achieved by not estimating the waste quantity based on the area or the volume of the contaminated media in the subsurface, but instead on the volume of the structures, or the basal area if the volume cannot be determined.

Finally, no comments were received that provided a viable alternative to the proposed method of estimating hazardous waste quantity. Commenters stated the amount of exposure was overestimated for large buildings because in general larger buildings have lower air exchange rates and suggested that this consideration be built into the estimation methods for all structures. However, the commenters did not present data to document this generality nor suggest how to determine the air exchange rate for all structures if it is not provided by the building owner. EPA notes that if air exchange rates are available, the present estimation method (which has not changed since proposal) allows for a hazardous waste quantity estimate using that information (see, HRS section 5.2.1.2.2 Tier B, hazardous wastestream quantity).

While some commenters suggested procedures for determining a more accurate hazardous waste quantity for specific situations they did not suggest how the hazardous waste quantity calculated for these situations could be relatively ranked against sites where equivalent information was not available. When developing a hazardous waste quantity factor in 1988, EPA performed studies that showed this level of information was not available at all sites, and was not likely to be collectible during a limited screening assessment. Therefore, EPA considers it inappropriate to incorporate the suggested procedures into the HRS.

In addition, EPA proposed the present hazardous waste quantity estimation process as part of the revision of the HRS in 1988. At that time EPA requested the Science Advisory Board's (SAB's) assistance on the use of concentration data in determining the hazardous waste quantity factor as part of the overall SAB peer review of the HRS changes. The current method for use of concentration data in determining the hazardous waste quantity factor is based on the SAB's recommendation.

Establishment of Attribution

Commenters noted that establishing that indoor air contamination is

attributable to subsurface intrusion will be very complex to demonstrate given all other possible origins of the indoor contamination (*e.g.,* outdoor air, consumer products).

The HRS SsI addition, just as in other HRS pathways and components, does not require absolute proof that the significant increase in indoor contaminant concentrations is due to subsurface intrusion. It only requires at least part of the significant increase be attributable to subsurface intrusion. EPA expects to use multiple lines-of-evidence in meeting the attribution requirement as discussed in various comments. The VI Guide outlines use of multiple lines-of-evidence and provides guidance on how to distinguish subsurface intrusion from other sources of vapor intrusion. As is done for other HRS pathways and components, the HRS standard for establishing attribution is to establish a reasoned explanation that is not shown to be incorrect during public review of placement of a proposed site on the NPL.

Establishing Observed Exposure

EPA received comments suggesting that the criteria for establishing background for the SsI component is too complex given the variability in sampling for SsI and that a significant difference between the background level and release concentration is not an adequate measure for establishing an observed exposure in a regularly occupied structure.

EPA agrees that establishing a background level for indoor air can be difficult. However, it does not mean that the HRS criteria for establishing actual exposure should not be used. Methods for establishing background levels are too site-specific to be discussed in the HRS regulation, which is a scoring methodology. Instead, as occurred after the 1990 HRS was promulgated, criteria for establishing background was refined based on actual experience gained as sites were being scored. EPA expects the same to occur for the HRS SsI component.

Comparison of background levels and indoor air concentrations are used only to establish that the contaminant level in a structure is elevated (*i.e.,* significantly different). This is only the first step in establishing observed exposure. The second step is to attribute at least a part of the significant increase to subsurface intrusion.

The argument that vapor intrusion rates are too variable to justify the use of the same procedure for establishing observed releases or exposures as in other parts of the HRS is invalid. Hazardous substance concentrations are unpredictably variable temporally and spatially for all HRS pathways and SsI variability is no different in that regard. For example, in the surface water migration pathway overland flow threat, the hazardous substance may only be entering surface water via runoff due to rain events. No runoff occurs if it is not raining. The amount entering surface water in this situation has been shown to vary with the length of time between rains, which impacts the amount of material deposited and available for entrainment into the runoff. Runoff also varies with the portion of each rain cycle whether the sample is collected at the beginning, middle or end of a rain event. At the beginning of a rain event all erodible materials are present and available. During the middle or during a high intensity period of rain, the force of the rain drops can dislodge and entrain hazardous substances at greater rates that during low intensity periods. At the end of a rain event, it may be that much of the hazardous substances have already been washed away. In continuous air releases, the contaminant concentration can vary by order of magnitudes with distance from the source, with wind direction and wind speed all of which can cause differences in concentrations spatially due to the three dimensionality of the atmosphere, and cannot be predicted or accounted for based on a screening assessment. Even in ground water contamination, the contaminant plume's concentration can vary spatially depending on the rate of ground water movement from the original spill concentrations. It is not possible to account for these factors that can drastically impact the contaminant concentration at a sampling location, based on screening level information.

For example, variation in the occurrence of releases is no greater in the SsI component than would be expected in point-source air releases or spills to surface water.

Degradation

Commenters suggested changes in how the degradation factor value for the subsurface intrusion component is assigned. Other comments dealt with conditions associated with assigning different degradation factor values based on the depth of biologically active soil and the half-lives of individual hazardous substances. In addition, commenters suggested moving the consideration of degradation from the waste characteristics factor category value calculations to the likelihood of exposure factor category value calculations.

After evaluation of the comments, EPA modified the assignment of the degradation factor to simplify the evaluation and to consider the presence of non-aqueous phase liquids (NAPLs); other changes suggested by commenters were not implemented. Some changes were not made because a sufficient rationale was not provided to justify a change. Regarding the placement of the degradation factor in the HRS equation, the consideration of an individual substance's characteristics in the waste characteristics factor category is consistent with other HRS pathways and components. Furthermore, whether the degradation factor is put in the likelihood of release or waste characteristic factor category, the impact of the factor on the score would be similar.

Targets

EPA received comments on the weightings assigned to targets in both the AOE and ASC. Commenters suggested that the weightings reflect the strength of the attribution argument that the significant increase in indoor air concentrations is due to subsurface intrusion and also reflect the concentration of the contaminants in the subsurface.

After consideration of these comments, EPA has changed the weightings of targets in the ASC to reflect the presence of NAPLs (*i.e.,* to reflect contaminant concentrations in the subsurface). EPA did not incorporate any changes into the weightings of targets based on the strength of attribution or concentration of contaminants in the subsurface. Regarding the strength of an attribution argument, the HRS does not recognize gradations of attribution in any other pathway or component and therefore for consistency, will not in this component. EPA notes that with the limited sampling that occurs during an SI, it is not reasonable to project the concentration of contaminants in the subsurface over time or distance.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. This action may raise novel

legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the EO. Any changes made in response to OMB recommendations have been documented in the docket.

EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, Addition of a Subsurface Intrusion (SsI) Component to the Hazard Ranking System (HRS): Regulatory Impact Analysis is available in the docket for this action.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2050–0095.

This regulatory change will only affect how EPA and organizations performing work on behalf of EPA (state or tribal partners) conduct site assessments and HRS scoring at sites where certain environmental conditions exist. This regulatory change will result in data collection at these types of sites to allow evaluation under the HRS. EPA expects that the total number of site assessments performed and the number of sites added to the NPL per year will not increase, but rather expects that there will be a realignment and reprioritization of its internal resources and state cooperative agreement funding.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This regulatory change enables the HRS evaluation to directly consider human exposure to hazardous substances that enter building structures through subsurface intrusion. This addition to the HRS would not impose direct impacts on any other entities. For additional discussion on this subject, see section 4.9 of the Regulatory Impact Analysis (see the docket for this action).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. EPA's evaluation of a site using the HRS does not impose any costs on a tribe (except those already in a cooperative agreement relationship with EPA). Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this action, EPA consulted with tribal officials through meetings and correspondence, including a letter sent to all federally recognized tribes asking for comment on the ''Notice of Opportunity for Public Input'' that was published in the **Federal Register** on January 31, 2011 (76 FR 5370), and public listening sessions regarding the decision to proceed with the development of this action. All tribal comments indicated support for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The site assessment activities affected by this rule are limited in scope and number and rely on existing energy distribution systems. Further, we have concluded that this rule would not significantly expand the energy demand for site assessments, and would not require an entity to conduct any action that would require significant energy use, that would significantly affect energy supply, distribution, or usage. Thus, Executive Order 13211 does not apply to this action.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on, low-income or indigenous populations. The results of this evaluation are contained in section 4.3 (and all subsections) of the Regulatory Impact Analysis for this rulemaking. A copy of the Addition of a Subsurface Intrusion (SsI) Component to the Hazard Ranking System (HRS): Regulatory Impact Analysis is available in the docket for this action.

K. Executive Order 12580—Superfund Implementation

Executive Order 12580, section 1(d), states that revisions to the NCP shall be made in consultation with members of the National Response Team (NRT) prior to publication for notice and comment. Revisions shall also be made in consultation with the Director of the Federal Emergency Management Agency (FEMA) and the Nuclear Regulatory Commission (NRC) to avoid inconsistent or duplicative requirements in the emergency planning responsibilities of those agencies. Executive Order 12580 delegates responsibility for revision of the NCP to EPA.

The agency has complied with Executive Order 12580 to the extent that it is related to the addition of a new component to the HRS, through consultation with members of the NRT.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping

requirements, Superfund, Water pollution control, Water supply.

Dated: December 7, 2016.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, Title 40, Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Amend Appendix A to Part 300:

■ a. In section 1.1 by:

■ i. Removing the definition heading ''Ambient Water Quality Criteria (AWQC) and adding ''Ambient Water Quality Criteria (AWQC)/National Recommended Water Quality Criteria'', in its place; and removing the text ''maximum acute or chronic toxicity'' and adding ''maximum acute (Criteria Maximum Concentration or CMC) or chronic (Criterion Continuous Concentration or CCC) toxicity.'' in its place;

■ ii. Adding in alphabetical order the definition ''Channelized flow'';

■ iii. Revising the definition ''Chronic toxicity'';

■ iv. Adding in alphabetical order the definition ''Crawl space'';

■ v. Revising the definitions ''Distance weight'' and ''Half-life'';

■ vi. Amending the definition ''HRS pathway'' by removing the word ''soil,'' and adding ''soil exposure and subsurface intrusion,'' in its place;

■ vii. Adding in alphabetical order the definitions ''Indoor air'', ''Inhalation Unit Risk (IUR)'', ''Non-Aqueous Phase Liquid (NAPL)'', ''Preferential subsurface intrusion pathways'', and ''Reference concentration (RfC)'';

■ viii. Revising the definition ''Reference dose (RfD)'';

■ ix. Adding in alphabetical order the definition ''Regularly occupied structures'';

■ x. Revising the definition ''Screening concentration'';

■ xi. Adding in alphabetical order the definition ''Shallow ground water'';

■ xii. Revising the definition ''Slope factor (also referred to as cancer potency factor)'';

■ xiii. Adding in alphabetical order the definitions ''Soil gas'', ''Soil porosity'', ''Subslab'', ''Subsurface intrusion'', ''Unit risk'', and ''Unsaturated zone''; and

■ xiv. Revising the definition ''Weight-of-evidence''.

■ b. Revising section 2.0;

■ c. Revising section 5.0;

■ d. In section 6.0 by revising Table 6–14; and

■ e. In section 7.0 by:

■ i. Revising Table 7–1;

■ ii. Under Table 7–1, the second undesignated paragraph, revising the third sentence;

■ iii. Revising sections 7.1, 7.1.1, and 7.1.2; 7.2.1; 7.2.3; 7.2.4; 7.2.5.1, 7.2.5.1.1 through 7.2.5.1.3; 7.2.5.2; 7.2.5.3; 7.3, 7.3.1, and 7.3.2; and

■ iv. Adding section 7.3.3.

The revisions and additions read as follows:

Appendix A to Part 300—Hazard Ranking System

* * * * *

1.1 Definitions

* * * * *

Channelized flow: Natural geological or manmade features such as karst, fractures, lava tubes, and utility conduits (*e.g.,* sewer lines), which allow ground water and/or soil gas to move through the subsurface environment more easily.

Chronic toxicity: Measure of toxicological responses that result from repeated exposure to a substance over an extended period of time (typically 3 months or longer). Such responses may persist beyond the exposure or may not appear until much later in time than the exposure. HRS measures of chronic toxicity include Reference Dose (RfD) and Reference Concentration (RfC) values.

* * * * *

Crawl space: The enclosed or semi-enclosed area between a regularly occupied structure's foundation (*e.g.,* pier and beam construction) and the ground surface. Crawl space samples are collected to determine the concentration of hazardous substances in the air beneath a regularly occupied structure.

* * * * *

Distance weight: Parameter in the HRS air migration pathway, ground water migration pathway, and the soil exposure component of the soil exposure and subsurface intrusion pathway that reduces the point value assigned to targets as their distance increases from the site. *[unitless].*

* * * * *

Half-life: Length of time required for an initial concentration of a substance to be halved as a result of loss through decay. The HRS considers five decay processes for assigning surface water persistence: Biodegradation, hydrolysis, photolysis, radioactive decay, and volatilization. The HRS considers two decay processes for assigning subsurface intrusion degradation: Biodegradation and hydrolysis.

* * * * *

Indoor air: The air present within a structure.

Inhalation Unit Risk (IUR): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent (*i.e.,* hazardous substance) at a concentration of 1μg/m^3 in air.

* * * * *

Non-Aqueous Phase Liquid (NAPL): Contaminants and substances that are water-immiscible liquids composed of constituents with varying degrees of water solubility.

* * * * *

Preferential subsurface intrusion pathways: Subsurface features such as animal burrows, cracks in walls, spaces around utility lines, or drains through which a hazardous substance moves more easily into a regularly occupied structure.

* * * * *

Reference concentration (RfC): An estimate of a continuous inhalation exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Reference dose (RfD): An estimate of a daily oral exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Regularly occupied structures: Structures with enclosed air space, where people either reside, attend school or day care, or work on a regular basis, or that were previously occupied but vacated due to a site-related hazardous substance(s). This also includes resource structures (*e.g.,* library, church, tribal structure).

* * * * *

Screening concentration: Media-specific benchmark concentration for a hazardous substance that is used in the HRS for comparison with the concentration of that hazardous substance in a sample from that media. The screening concentration for a specific hazardous substance corresponds to its reference concentration for inhalation exposures or reference dose for oral exposures, as appropriate, and, if the substance is a human carcinogen with either a weight-of-evidence classification of A, B, or C, or a weight-of-evidence classification of carcinogenic to humans, likely to be carcinogenic to humans or suggestive evidence of carcinogenic potential, to that concentration that corresponds to its 10^{-6} individual lifetime excess cancer risk for inhalation exposures or for oral exposures, as appropriate.

Shallow ground water: The uppermost saturated zone, typically unconfined.

* * * * *

Slope factor (also referred to as cancer potency factor): Estimate of the probability of response (for example, cancer) per unit intake of a substance over a lifetime. The slope factor is typically used to estimate upper-bound probability of an individual developing cancer as a result of exposure to a particular level of a human carcinogen with either a weight-of-evidence classification of A, B, or C, or a weight-of-evidence classification of carcinogenic to humans, likely to be carcinogenic to humans or having suggestive evidence of carcinogenic potential. [(mg/kg-day)$^{-1}$ for non-radioactive substances and (pCi)$^{-1}$ for radioactive substances].

Soil gas: The gaseous elements and compounds in the small spaces between particles of soil.

Soil porosity: The degree to which the total volume of soil is permeated with pores or cavities through which fluids (including air or gas) can move. It is typically calculated as the ratio of the pore spaces within the soil to the overall volume of the soil.

* * * * *

Subslab: The area immediately beneath a regularly occupied structure with a basement foundation or a slab-on-grade foundation. Subslab samples are collected to determine the concentration of hazardous substances in the soil gas beneath a home or building.

Subsurface intrusion: The migration of hazardous substances from the unsaturated zone and/or ground water into overlying structures.

* * * * *

Unit risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent (*i.e.,* hazardous substance) at a concentration of 1 μg/L in water, or 1 μg/m³ in air.

Unsaturated zone: The portion of subsurface between the land surface and the zone of saturation. It extends from the ground surface to the top of the shallowest ground water table (excluding localized or perched water).

* * * * *

Weight-of-evidence: EPA classification system for characterizing the evidence supporting the designation of a substance as a human carcinogen. The EPA weight-of-evidence, depending on the date EPA updated the profile, includes either the groupings:

- Group A: Human carcinogen—sufficient evidence of carcinogenicity in humans.
- Group B1: Probable human carcinogen—limited evidence of carcinogenicity in humans.
- Group B2: Probable human carcinogen—sufficient evidence of carcinogenicity in animals.
- Group C: Possible human carcinogen—limited evidence of carcinogenicity in animals.
- Group D: Not classifiable as to human carcinogenicity—applicable when there is no animal evidence, or when human or animal evidence is inadequate.
- Group E: Evidence of noncarcinogenicity for humans.

Or the descriptors:

- Carcinogenic to humans.
- Likely to be carcinogenic to humans.
- Suggestive evidence of carcinogenic potential.
- Inadequate information to assess carcinogenic potential.
- Not likely to be carcinogenic to humans.

2.0 Evaluations Common to Multiple Pathways

2.1 *Overview.* The HRS site score (S) is the result of an evaluation of four pathways:

- Ground Water Migration (S_{gw}).
- Surface Water Migration (S_{sw}).
- Soil Exposure and Subsurface Intrusion (S_{sessi}).
- Air Migration (S_a).

The ground water and air migration pathways use single threat evaluations, while the surface water migration and soil exposure and subsurface intrusion pathways use multiple threat evaluations. Three threats are evaluated for the surface water migration pathway: Drinking water, human food chain, and environmental. These threats are evaluated for two separate migration components—overland/flood migration and ground water to surface water migration. Two components are evaluated for the soil exposure and subsurface intrusion pathway: Soil exposure and subsurface intrusion. The soil exposure component evaluates two threats: Resident population and nearby population, and the subsurface intrusion component is a single threat evaluation.

The HRS is structured to provide a parallel evaluation for each of these pathways, components, and threats. This section focuses on these parallel evaluations, starting with the calculation of the HRS site score and the individual pathway scores.

2.1.1 *Calculation of HRS site score.* Scores are first calculated for the individual pathways as specified in sections 2 through 7 and then are combined for the site using the following root-mean-square equation to determine the overall HRS site score, which ranges from 0 to 100:

$$S = \sqrt{\frac{S_{gw}^2 + S_{sw}^2 + S_{sessi}^2 + S_a^2}{4}}$$

2.1.2 *Calculation of pathway score.* Table 2–1, which is based on the air migration pathway, illustrates the basic parameters used to calculate a pathway score. As Table 2–1 shows, each pathway (component or threat) score is the product of three ''factor categories'': Likelihood of release, waste characteristics, and targets. (The soil exposure and subsurface intrusion pathway uses likelihood of exposure rather than likelihood of release.) Each of the three factor categories contains a set of factors that are assigned numerical values and combined as specified in sections 2 through 7. The factor values are rounded to the nearest integer, except where otherwise noted.

2.1.3 *Common evaluations.* Evaluations common to all four HRS pathways include:

- Characterizing sources.
  - —Identifying sources (and, for the soil exposure and subsurface intrusion pathway, areas of observed contamination, areas of observed exposure and/or areas of subsurface contamination [see sections 5.1.0 and 5.2.0]).
  - —Identifying hazardous substances associated with each source (or area of observed contamination, or observed exposure, or subsurface contamination).
  - —Identifying hazardous substances available to a pathway.

TABLE 2–1—SAMPLE PATHWAY SCORESHEET

Factor category	Maximum value	Value assigned
Likelihood of Release		
1. Observed Release	550	
2. Potential to Release	500	
3. Likelihood of Release (higher of lines 1 and 2)	550	
Waste Characteristics		
4. Toxicity/Mobility	(a)	
5. Hazardous Waste Quantity	(a)	
6. Waste Characteristics	100	
Targets		
7. Nearest Individual		
7a. Level I	50	
7b. Level II	45	
7c. Potential Contamination	20	
7d. Nearest Individual (higher of lines 7a, 7b, or 7c)	50	
8. Population	(b)	
8a. Level I	(b)	
8b. Level II	(b)	

TABLE 2–1—SAMPLE PATHWAY SCORESHEET—Continued

Factor category	Maximum value	Value assigned
8c. Potential Contamination	(b)	
8d. Total Population (lines 8a+8b+8c)		
9. Resources	5	
10. Sensitive Environments	(b)	
10a. Actual Contamination	(b)	
10b. Potential Environments	(b)	
10c. Sensitive Environments (lines 10a+10b)	(b)	
11. Targets (lines 7d+8d+9+10c)	(b)	
12. Pathway Score is the product of Likelihood of Release, Waste Characteristics, and Targets, divided by 82,500. Pathway scores are limited to a maximum of 100 points.		

[a] Maximum value applies to waste characteristics category. The product of lines 4 and 5 is used in Table 2–7 to derive the value for the waste characteristics factor category.

[b] There is no limit to the human population or sensitive environments factor values. However, the pathway score based solely on sensitive environments is limited to a maximum of 60 points.

- Scoring likelihood of release (or likelihood of exposure) factor category.
  - —Scoring observed release (or observed exposure or observed contamination).
  - —Scoring potential to release when there is no observed release.
- Scoring waste characteristics factor category.
  - —Evaluating toxicity.
    - ▪ Combining toxicity with mobility, persistence, degradation and/or bioaccumulation (or ecosystem bioaccumulation) potential, as appropriate to the pathway (component or threat).
    - ▪ Evaluating hazardous waste quantity.
  - —Combining hazardous waste quantity with the other waste characteristics factors.
    - ▪ Determining waste characteristics factor category value.
- Scoring targets factor category.
  - —Determining level of contamination for targets.

These evaluations are essentially identical for the three migration pathways (ground water, surface water, and air). However, the evaluations differ in certain respects for the soil exposure and subsurface intrusion pathway.

Section 7 specifies modifications that apply to each pathway when evaluating sites containing radioactive substances.

Section 2 focuses on evaluations common at the pathway, component, and threat levels. Note that for the ground water and surface water migration pathways, separate scores are calculated for each aquifer (see section 3.0) and each watershed (see sections 4.1.1.3 and 4.2.1.5) when determining the pathway scores for a site. Although the evaluations in section 2 do not vary when different aquifers or watersheds are scored at a site, the specific factor values (for example, observed release, hazardous waste quantity, toxicity/mobility) that result from these evaluations can vary by aquifer and by watershed at the site. This can occur through differences both in the specific sources and targets eligible to be evaluated for each aquifer and watershed and in whether observed releases can be established for each aquifer and watershed. Such differences in scoring at the aquifer and watershed level are addressed in sections 3 and 4, not section 2.

2.2 *Characterize sources.* Source characterization includes identification of the following:

- Sources (and areas of observed contamination, areas of observed exposure, or areas of subsurface contamination) at the site.
- Hazardous substances associated with these sources (or areas of observed contamination, areas of observed exposure, or areas of subsurface contamination).
- Pathways potentially threatened by these hazardous substances.

Table 2–2 presents a sample worksheet for source characterization.

2.2.1 *Identify sources.* For the three migration pathways, identify the sources at the site that contain hazardous substances. Identify the migration pathway(s) to which each source applies. For the soil exposure and subsurface intrusion pathway, identify areas of observed contamination, areas of observed exposure, and/or areas of subsurface contamination at the site (see sections 5.1.0 and 5.2.0).

Table 2–2—Sample Source Characterization Worksheet

Source: ____

A. Source dimensions and hazardous waste quantity.

Hazardous constituent quantity: ____

Hazardous wastestream quantity: ____

Volume: ____

Area: ____

Area of observed contamination: ____

Area of observed exposure: ____

Area of subsurface contamination: ____

B. Hazardous substances associated with the source.

Hazardous substance	Available to pathway								
	Air		Ground Water (GW)	Surface Water (SW)		Soil Exposure/Subsurface Intrusion (SESSI)			
						Soil exposure		Subsurface Intrusion	
	Gas	Particulate		Overland/ flood	GW to SW	Resident	Nearby	Area of observed exposure	Area of subsurface contamination

2.2.2 *Identify hazardous substances associated with a source.* For each of the three migration pathways, consider those hazardous substances documented in a source (for example, by sampling, labels, manifests, oral or written statements) to be

associated with that source when evaluating each pathway. In some instances, a hazardous substance can be documented as being present at a site (for example, by labels, manifests, oral or written statements), but the specific source(s) containing that hazardous substance cannot be documented. For the three migration pathways, in those instances when the specific source(s) cannot be documented for a hazardous substance, consider the hazardous substance to be present in each source at the site, except sources for which definitive information indicates that the hazardous substance was not or could not be present.

For an area of observed contamination in the soil exposure component of the soil exposure and subsurface intrusion pathway, consider only those hazardous substances that meet the criteria for observed contamination for that area (see section 5.1.0) to be associated with that area when evaluating the pathway.

For an area of observed exposure or area of subsurface contamination (see section 5.2.0) in the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, consider only those hazardous substances that:

- Meet the criteria for observed exposure, or
- Meet the criteria for observed release in an area of subsurface contamination and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol, or
- Meet the criteria for an observed release in a structure within, or in a sample from below, an area of observed exposure and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol.

2.2.3 *Identify hazardous substances available to a pathway.* In evaluating each migration pathway, consider the following hazardous substances available to migrate from the sources at the site to the pathway:

- Ground water migration.
  —Hazardous substances that meet the criteria for an observed release (see section 2.3) to ground water.
  —All hazardous substances associated with a source with a ground water containment factor value greater than 0 (see section 3.1.2.1).
- Surface water migration—overland/flood component.
  —Hazardous substances that meet the criteria for an observed release to surface water in the watershed being evaluated.
  —All hazardous substances associated with a source with a surface water containment factor value greater than 0 for the watershed (see sections 4.1.2.1.2.1.1 and 4.1.2.1.2.2.1).
- Surface water migration—ground water to surface water component.
  —Hazardous substances that meet the criteria for an observed release to ground water.
  —All hazardous substances associated with a source with a ground water containment factor value greater than 0 (see sections 4.2.2.1.2 and 3.1.2.1).
- Air migration.
  —Hazardous substances that meet the criteria for an observed release to the atmosphere.
  —All gaseous hazardous substances associated with a source with a gas containment factor value greater than 0 (see section 6.1.2.1.1).
  —All particulate hazardous substances associated with a source with a particulate containment factor value greater than 0 (see section 6.1.2.2.1).
- For each migration pathway, in those instances when the specific source(s) containing the hazardous substance cannot be documented, consider that hazardous substance to be available to migrate to the pathway when it can be associated (see section 2.2.2) with at least one source having a containment factor value greater than 0 for that pathway.

In evaluating the soil exposure and subsurface intrusion pathway, consider the following hazardous substances available to the pathway:

- Soil exposure component—resident population threat.
  —All hazardous substances that meet the criteria for observed contamination at the site (see section 5.1.0).
- Soil exposure component—nearby population threat.
  —All hazardous substances that meet the criteria for observed contamination at areas with an attractiveness/accessibility factor value greater than 0 (see section 5.1.2.1.1).
- Subsurface intrusion component.
  —All hazardous substances that meet the criteria for observed exposure at the site (see section 5.2.0).
  —All hazardous substances with a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol that meet the criteria for an observed release in an area of subsurface contamination (see section 5.2.0).
  —All hazardous substances that meet the criteria for an observed release in a structure within, or in a sample from below, an area of observed exposure (see section 5.2.0).

2.3 *Likelihood of release.* Likelihood of release is a measure of the likelihood that a waste has been or will be released to the environment. The likelihood of release factor category is assigned the maximum value of 550 for a migration pathway whenever the criteria for an observed release are met for that pathway. If the criteria for an observed release are met, do not evaluate potential to release for that pathway. When the criteria for an observed release are not met, evaluate potential to release for that pathway, with a maximum value of 500. The evaluation of potential to release varies by migration pathway (see sections 3, 4 and 6).

Establish an observed release either by direct observation of the release of a hazardous substance into the media being evaluated (for example, surface water) or by chemical analysis of samples appropriate to the pathway being evaluated (see sections 3, 4 and 6). The minimum standard to establish an observed release by chemical analysis is analytical evidence of a hazardous substance in the media significantly above the background level. Further, some portion of the release must be attributable to the site. Use the criteria in Table 2–3 as the standard for determining analytical significance. (The criteria in Table 2–3 are also used in establishing observed contamination for the soil exposure component and for establishing areas of observed exposure and areas of subsurface contamination in the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, see section 5.1.0 and section 5.2.0). Separate criteria apply to radionuclides (see section 7.1.1).

TABLE 2–3—OBSERVED RELEASE CRITERIA FOR CHEMICAL ANALYSIS

Sample Measurement < Sample Quantitation Limit.[a]
No observed release is established.
Sample Measurement ≥ Sample Quantitation Limit.[a]
An observed release is established as follows:
• If the background concentration is not detected (or is less than the detection limit), an observed release is established when the sample measurement equals or exceeds the sample quantitation limit.[a]
• If the background concentration equals or exceeds the detection limit, an observed release is established when the sample measurement is 3 times or more above the background concentration.

[a] If the sample quantitation limit (SQL) cannot be established, determine if there is an observed release as follows:
—If the sample analysis was performed under the EPA Contract Laboratory Program, use the EPA contract-required quantitation limit (CRQL) in place of the SQL.
—If the sample analysis is not performed under the EPA Contract Laboratory Program, use the detection limit (DL) in place of the SQL.

2.4 *Waste characteristics.* The waste characteristics factor category includes the following factors: Hazardous waste quantity, toxicity, and as appropriate to the pathway or threat being evaluated, mobility, persistence, degradation, and/or

bioaccumulation (or ecosystem bioaccumulation) potential.

2.4.1 *Selection of substance potentially posing greatest hazard.* For all pathways (components and threats), select the hazardous substance potentially posing the greatest hazard for the pathway (component or threat) and use that substance in evaluating the waste characteristics category of the pathway (component or threat). For the three migration pathways (and threats), base the selection of this hazardous substance on the toxicity factor value for the substance, combined with its mobility, persistence, and/or bioaccumulation (or ecosystem bioaccumulation) potential factor values, as applicable to the migration pathway (or threat). For the soil exposure component of the soil exposure and subsurface intrusion pathway, base the selection on the toxicity factor alone. For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, base the selection on the toxicity factor value for the substance, combined with its degradation factor value. Evaluation of the toxicity factor is specified in section 2.4.1.1. Use and evaluation of the mobility, persistence, degradation, and/or bioaccumulation (or ecosystem bioaccumulation) potential factors vary by pathway (component or threat) and are specified under the appropriate pathway (component or threat) section. Section 2.4.1.2 identifies the specific factors that are combined with toxicity in evaluating each pathway (component or threat).

2.4.1.1 *Toxicity factor.* Evaluate toxicity for those hazardous substances at the site that are available to the pathway being scored. For all pathways and threats, except the surface water environmental threat, evaluate human toxicity as specified below. For the surface water environmental threat, evaluate ecosystem toxicity as specified in section 4.1.4.2.1.1.

Establish human toxicity factor values based on quantitative dose-response parameters for the following three types of toxicity:

- Cancer—Use slope factors (also referred to as cancer potency factors) combined with weight-of-evidence ratings for carcinogenicity for all exposure routes except inhalation. Use inhalation unit risk (IUR) for inhalation exposure. If an inhalation unit risk or a slope factor is not available for a substance, use its ED_{10} value to estimate a slope factor as follows:

$$\text{Slope factor} = \frac{1}{6\ (ED_{10})}$$

- Noncancer toxicological responses of chronic exposure—use reference dose (RfD) or reference concentration (RfC) values as applicable.
- Noncancer toxicological responses of acute exposure—use acute toxicity parameters, such as the LD_{50}.

Assign human toxicity factor values to a hazardous substance using Table 2–4, as follows:

- If RfD/RfC and slope factor/inhalation unit risk values are available for the hazardous substance, assign the substance a value from Table 2–4 for each. Select the higher of the two values assigned and use it as the overall toxicity factor value for the hazardous substance.
- If either an RfD/RfC or slope factor/inhalation unit risk value is available, but not both, assign the hazardous substance an overall toxicity factor value from Table 2–4 based solely on the available value (RfD/RfC or slope factor/inhalation unit risk).
- If neither an RfD/RfC nor slope factor/inhalation unit risk value is available, assign the hazardous substance an overall toxicity factor value from Table 2–4 based solely on acute toxicity. That is, consider acute toxicity in Table 2–4 only when both RfD/RfC and slope factor/IUR values are not available.
- If neither an RfD/RfC, nor slope factor/inhalation unit risk, nor acute toxicity value is available, assign the hazardous substance an overall toxicity factor value of 0 and use other hazardous substances for which information is available in evaluating the pathway.

TABLE 2–4—TOXICITY FACTOR EVALUATION

	Assigned value
Chronic Toxicity (Human)	
Reference dose (RfD) (mg/kg-day):	
RfD < 0.0005	10,000
0.0005 ≤ RfD < 0.005	1,000
0.005 ≤ RfD < 0.05	100
0.05 ≤ RfD < 0.5	10
0.5 ≤ RfD	1
RfD not available	0
Reference concentration (RfC) (mg/m^3):	
RfC < 0.0001	10,000
0.0001 ≤ RfC < 0.006	1,000
0.006 ≤ RfC < 0.2	100
0.2 ≤ RfC < 2.0	10
2.0 ≤ RfC	1
RfC not available	0

Carcinogenicity (human)			
A or Carcinogenic to humans	B or Likely to be carcinogenic to humans	C or Suggestive evidence of carcinogenic potential	Assigned value
Weight-of-evidence[a]/Slope factor (mg/kg-day)$^{-1}$			
0.5 ≤ SF[b]	5 ≤ SF	50 ≤ SF	10,000
0.05 ≤ SF < 0.5	0.5 ≤ SF < 5	5 ≤ SF < 50	1,000
SF < 0.05	0.05 ≤ SF < 0.5	0.5 ≤ SF < 5	100
	SF < 0.05	SF < 0.5	10
Slope factor not available	Slope factor not available	Slope factor not available	0
Weight-of-evidence[a]/Inhalation unit risk (μg/m^3)			
0.00004 ≤ IUR[c]	0.0004 ≤ IUR	0.004 ≤ IUR	10,000
0.00001 ≤ IUR < 0.00004	0.0001 ≤ IUR < 0.0004	0.001 ≤ IUR < 0.004	1,000
IUR < 0.00001	0.00001 ≤ IUR < 0.0001	0.0001 ≤ IUR < 0.001	100
	< 0.00001	IUR < 0.0001	10
Inhalation unit risk not available	Inhalation unit risk not available	Inhalation unit risk not available	0

[a] A, B, and C, as well as Carcinogenic to humans, Likely to be carcinogenic to humans, and Suggestive evidence of carcinogenic potential refer to weight-of-evidence categories. Assign substances with a weight-of-evidence category of D (inadequate evidence of carcinogenicity) or E (evidence of lack of carcinogenicity), as well as inadequate information to assess carcinogenic potential and not likely to be carcinogenic to humans a value of 0 for carcinogenicity.

[b] SF = Slope factor.

[c] IUR = Inhalation Unit Risk.

Acute Toxicity (human)				
Oral LD_{50} (mg/kg)	Dermal LD_{50} (mg/kg)	Dust or mist LC_{50} (mg/l)	Gas or vapor LC_{50} (ppm)	Assigned value
LD_{50} < 5	LD_{50} < 2	LC_{50} < 0.2	LC_{50} < 20	1,000

Acute Toxicity (human)				
Oral LD_{50} (mg/kg)	Dermal LD_{50} (mg/kg)	Dust or mist LC_{50} (mg/l)	Gas or vapor LC_{50} (ppm)	Assigned value
$5 \leq LD_{50} < 50$	$2 \leq LD_{50} < 20$	$0.2 \leq LC_{50} < 2$	$20 \leq LC_{50} < 200$	100
$50 \leq LD_{50} < 500$	$20 \leq LD_{50} < 200$	$2 \leq LC_{50} < 20$	$200 \leq LC_{50} < 2{,}000$	10
$500 \leq LD_{50}$	$200 \leq LD_{50}$	$20 \leq LC_{50}$	$2{,}000 \leq LC_{50}$	1
LD_{50} not available	LD_{50} not available	LC_{50} not available	LC_{50} not available	0

If a toxicity factor value of 0 is assigned to all hazardous substances available to a particular pathway (that is, insufficient toxicity data are available for evaluating all the substances), use a default value of 100 as the overall human toxicity factor value for all hazardous substances available to the pathway. For hazardous substances having usable toxicity data for multiple exposure routes (for example, inhalation and ingestion), consider all exposure routes and use the highest assigned value, regardless of exposure route, as the toxicity factor value. For HRS purposes, assign both asbestos and lead (and its compounds) a human toxicity factor value of 10,000.

Separate criteria apply for assigning factor values for human toxicity and ecosystem toxicity for radionuclides (see sections 7.2.1 and 7.2.2).

2.4.1.2 *Hazardous substance selection.* For each hazardous substance evaluated for a migration pathway (or threat), combine the human toxicity factor value (or ecosystem toxicity factor value) for the hazardous substance with a mobility, persistence, and/or bioaccumulation (or ecosystem bioaccumulation) potential factor value as follows:

- Ground water migration.
  —Determine a combined human toxicity/mobility factor value for the hazardous substance (see section 3.2.1).
- Surface water migration—overland/flood migration component.
  —Determine a combined human toxicity/persistence factor value for the hazardous substance for the drinking water threat (see section 4.1.2.2.1).
  —Determine a combined human toxicity/persistence/bioaccumulation factor value for the hazardous substance for the human food chain threat (see section 4.1.3.2.1).
  —Determine a combined ecosystem toxicity/persistence/bioaccumulation factor value for the hazardous substance for the environmental threat (see section 4.1.4.2.1).
- Surface water migration—ground water to surface water migration component.
  —Determine a combined human toxicity/mobility/persistence factor value for the hazardous substance for the drinking water threat (see section 4.2.2.2.1).
  —Determine a combined human toxicity/mobility/persistence/bioaccumulation factor value for the hazardous substance for the human food chain threat (see section 4.2.3.2.1).
  —Determine a combined ecosystem toxicity/mobility/persistence/bioaccumulation factor value for the hazardous substance for the environmental threat (see section 4.2.4.2.1).
- Air migration.
  —Determine a combined human toxicity/mobility factor value for the hazardous substance (see section 6.2.1).

Determine each combined factor value for a hazardous substance by multiplying the individual factor values appropriate to the pathway (or threat). For each migration pathway (or threat) being evaluated, select the hazardous substance with the highest combined factor value and use that substance in evaluating the waste characteristics factor category of the pathway (or threat).

For the soil exposure and subsurface intrusion pathway, determine toxicity and toxicity/degradation factor values as follows:

- Soil exposure and subsurface intrusion—soil exposure component.
  —Select the hazardous substance with the highest human toxicity factor value from among the substances that meet the criteria for observed contamination for the threat evaluated and use that substance in evaluating the waste characteristics factor category (see section 5.1.1.2.1).
- Soil exposure and subsurface intrusion—subsurface intrusion component.
  —Determine a combined human toxicity/degradation factor value for each hazardous substance being evaluated that:
    - Meets the criteria for observed exposure, or
    - Meets the criteria for observed release in an area of subsurface contamination and has a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol, or
    - Meets the criteria for an observed release in a structure within, or in a sample from below, an area of observed exposure and has a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol.
  —Select the hazardous substance with the highest combined factor value and use that substance in evaluating the waste characteristics factor category (see sections 5.2.1.2.1 and 5.2.1.2).

2.4.2 *Hazardous waste quantity.* Evaluate the hazardous waste quantity factor by first assigning each source (or area of observed contamination, area of observed exposure, or area of subsurface contamination) a source hazardous waste quantity value as specified below. Sum these values to obtain the hazardous waste quantity factor value for the pathway being evaluated.

In evaluating the hazardous waste quantity factor for the three migration pathways, allocate hazardous substances and hazardous wastestreams to specific sources in the manner specified in section 2.2.2, except: Consider hazardous substances and hazardous wastestreams that cannot be allocated to any specific source to constitute a separate ''unallocated source'' for purposes of evaluating only this factor for the three migration pathways. Do not, however, include a hazardous substance or hazardous wastestream in the unallocated source for a migration pathway if there is definitive information indicating that the substance or wastestream could only have been placed in sources with a containment factor value of 0 for that migration pathway.

In evaluating the hazardous waste quantity factor for the soil exposure component of the soil exposure and subsurface intrusion pathway, allocate to each area of observed contamination only those hazardous substances that meet the criteria for observed contamination for that area of observed contamination and only those hazardous wastestreams that contain hazardous substances that meet the criteria for observed contamination for that area of observed contamination. Do not consider other hazardous substances or hazardous wastestreams at the site in evaluating this factor for the soil exposure component of the soil exposure and subsurface intrusion pathway.

In evaluating the hazardous waste quantity factor for the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, allocate to each area of observed exposure or area of subsurface contamination only those hazardous substances and hazardous wastestreams that contain hazardous substances that:

- Meet the criteria for observed exposure, or
- Meet the criteria for observed release in an area of subsurface contamination and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol, or
- Meet the criteria for an observed release in a structure within, or in a sample from below, an area of observed exposure and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol.

Do not consider other hazardous substances or hazardous wastestreams at the site in evaluating this factor for the subsurface intrusion component of the soil exposure and subsurface intrusion pathway. When determining the hazardous waste quantity for multi-subunit structures, use the procedures identified in section 5.2.1.2.2.

2.4.2.1 *Source hazardous waste quantity.* For each of the three migration pathways, assign a source hazardous waste quantity

value to each source (including the unallocated source) having a containment factor value greater than 0 for the pathway being evaluated. Consider the unallocated source to have a containment factor value greater than 0 for each migration pathway.

For the soil exposure component of the soil exposure and subsurface intrusion pathway, assign a source hazardous waste quantity value to each area of observed contamination, as applicable to the threat being evaluated.

For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, assign a source hazardous waste quantity value to each regularly occupied structure within an area of observed exposure or an area of subsurface contamination that has a structure containment factor value greater than 0. If sufficient data is available and state of the science shows there is no unacceptable risk due to subsurface intrusion into a regularly occupied structure located within an area of subsurface contamination, that structure can be excluded from the area of subsurface contamination.

For determining all hazardous waste quantity calculations except for an unallocated source or an area of subsurface contamination, evaluate using the following four measures in the following hierarchy:

- Hazardous constituent quantity.
- Hazardous wastestream quantity.
- Volume.
- Area.

For the unallocated source, use only the first two measures. For an area of subsurface contamination, evaluate non-radioactive hazardous substances using only the last two measures and evaluate radioactive hazardous substances using hazardous wastestream quantity only. See also section 7.0 regarding the evaluation of radioactive substances.

Separate criteria apply for assigning a source hazardous waste quantity value for radionuclides (see section 7.2.5).

2.4.2.1.1 *Hazardous constituent quantity.* Evaluate hazardous constituent quantity for the source (or area of observed contamination) based solely on the mass of CERCLA hazardous substances (as defined in CERCLA section 101(14), as amended) allocated to the source (or area of observed contamination), except:

- For a hazardous waste listed pursuant to section 3001 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), 42 U.S.C. 6901 *et seq.,* determine its mass for the evaluation of this measure as follows:

—If the hazardous waste is listed solely for Hazard Code T (toxic waste), include only the mass of constituents in the hazardous waste that are CERCLA hazardous substances and not the mass of the entire hazardous waste.

—If the hazardous waste is listed for any other Hazard Code (including T plus any other Hazard Code), include the mass of the entire hazardous waste.

- For a RCRA hazardous waste that exhibits the characteristics identified under section 3001 of RCRA, as amended, determine its mass for the evaluation of this measure as follows:

—If the hazardous waste exhibits only the characteristic of toxicity (or only the characteristic of EP toxicity), include only the mass of constituents in the hazardous waste that are CERCLA hazardous substances and not the mass of the entire hazardous waste.

—If the hazardous waste exhibits any other characteristic identified under section 3001 (including any other characteristic plus the characteristic of toxicity [or the characteristic of EP toxicity]), include the mass of the entire hazardous waste.

Based on this mass, designated as C, assign a value for hazardous constituent quantity as follows:

- For the migration pathways, assign the source a value for hazardous constituent quantity using the Tier A equation of Table 2–5.
- For the soil exposure and subsurface intrusion pathway—soil exposure component, assign the area of observed contamination a value using the Tier A equation of Table 5–2 (section 5.1.1.2.2).
- For the soil exposure and subsurface intrusion pathway—subsurface intrusion component, assign the area of observed exposure a value using the Tier A equation of Table 5–19 (section 5.2.1.2.2).

If the hazardous constituent quantity for the source (or area of observed contamination or area of observed exposure) is adequately determined (that is, the total mass of all CERCLA hazardous substances in the source and releases from the source [or in the area of observed contamination or area of observed exposure] is known or is estimated with reasonable confidence), do not evaluate the other three measures discussed below. Instead assign these other three measures a value of 0 for the source (or area of observed contamination or area of observed exposure) and proceed to section 2.4.2.1.5.

If the hazardous constituent quantity is not adequately determined, assign the source (or area of observed contamination or area of observed exposure) a value for hazardous constituent quantity based on the available data and proceed to section 2.4.2.1.2.

TABLE 2–5—HAZARDOUS WASTE QUANTITY EVALUATION EQUATIONS

Tier	Measure	Units	Equation for assigning value [a]
A	Hazardous constituent quantity (C)	lb	C
B [b]	Hazardous wastestream quantity (W)	lb	W/5,000
C [b]	Volume (V)		
	Landfill	yd^3	V/2,500
	Surface impoundment	yd^3	V/2.5
	Surface impoundment (buried/backfilled)	yd^3	V/2.5
	Drums [c]	gallon	V/2.5
	Tanks and containers other than drums	yd^3	V/2.5
	Contaminated soil	yd^3	V/2,500
	Pile	yd^3	V/2.5
	Other	yd^3	V/2.5
D [b]	Area (A).		
	Landfill	ft^2	A/3,400
	Surface impoundment	ft^2	A/13
	Surface impoundment (buried/backfilled)	ft^2	A/13
	Land treatment	ft^2	A/270
	Pile [d]	ft^2	A/13
	Contaminated soil	ft^2	A/34,000

[a] Do not round to nearest integer.
[b] Convert volume to mass when necessary: 1 ton = 2,000 pounds = 1 cubic yard = 4 drums = 200 gallons.
[c] If actual volume of drums is unavailable, assume 1 drum = 50 gallons.
[d] Use land surface area under pile, not surface area of pile.

2.4.2.1.2 *Hazardous wastestream quantity.* Evaluate hazardous wastestream quantity for the source (or area of observed contamination or area of observed exposure) based on the mass of hazardous wastestreams plus the mass of any additional CERCLA pollutants and contaminants (as defined in CERCLA section 101[33], as amended) that are allocated to the source (or area of

observed contamination or area of observed exposure). For a wastestream that consists solely of a hazardous waste listed pursuant to section 3001 of RCRA, as amended or that consists solely of a RCRA hazardous waste that exhibits the characteristics identified under section 3001 of RCRA, as amended, include the mass of that entire hazardous waste in the evaluation of this measure.

Based on this mass, designated as W, assign a value for hazardous wastestream quantity as follows:

• For the migration pathways, assign the source a value for hazardous wastestream quantity using the Tier B equation of Table 2–5.

• For the soil exposure and subsurface intrusion pathway—soil exposure component, assign the area of observed contamination a value using the Tier B equation of Table 5–2 (section 5.1.1.2.2).

• For the soil exposure and subsurface intrusion pathway—subsurface intrusion component, assign the area of observed exposure a value using the Tier B equation of Table 5–19 (section 5.2.1.2.2).

Do not evaluate the volume and area measures described below if the source is the unallocated source or if the following condition applies:

• The hazardous wastestream quantity for the source (or area of observed contamination or area of observed exposure) is adequately determined—that is, total mass of all hazardous wastestreams and CERCLA pollutants and contaminants for the source and releases from the source (or for the area of observed contamination) is known or is estimated with reasonable confidence.

If the source is the unallocated source or if this condition applies, assign the volume and area measures a value of 0 for the source (or area of observed contamination) and proceed to section 2.4.2.1.5. Otherwise, assign the source (or area of observed contamination) a value for hazardous wastestream quantity based on the available data and proceed to section 2.4.2.1.3.

2.4.2.1.3 *Volume.* Evaluate the volume measure using the volume of the source (or the volume of the area of observed contamination, area of observed exposure, or area of subsurface contamination). For the soil exposure and subsurface intrusion pathway, restrict the use of the volume measure to those areas of observed contamination, areas of observed exposure, or areas of subsurface contamination as specified in sections 5.1.1.2.2 and 5.2.1.2.2.

Based on the volume, designated as V, assign a value to the volume measure as follows:

• For the migration pathways, assign the source a value for volume using the appropriate Tier C equation of Table 2–5.

• For the soil exposure and subsurface intrusion pathway—soil exposure component, assign the area of observed contamination a value for volume using the appropriate Tier C equation of Table 5–2 (section 5.1.1.2.2).

• For the soil exposure and subsurface intrusion pathway—subsurface intrusion component, assign the value based on the volume of the regularly occupied structures within the area of observed exposure or area of subsurface contamination using the Tier C equation of Table 5–19 (section 5.2.1.2.2).

If the volume of the source (or volume of the area of observed contamination, area of observed exposure, or area of subsurface contamination, if applicable) can be determined, do not evaluate the area measure. Instead, assign the area measure a value of 0 and proceed to section 2.4.2.1.5. If the volume cannot be determined (or is not applicable for the soil exposure and subsurface intrusion pathway), assign the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination) a value of 0 for the volume measure and proceed to section 2.4.2.1.4.

2.4.2.1.4 *Area.* Evaluate the area measure using the area of the source (or the area of the area of observed contamination, area of observed exposure, or area of subsurface contamination). Based on this area, designated as A, assign a value to the area measure as follows:

• For the migration pathways, assign the source a value for area using the appropriate Tier D equation of Table 2–5.

• For the soil exposure and subsurface intrusion pathway—soil exposure component, assign the area of observed contamination a value for area using the appropriate Tier D equation of Table 5–2 (section 5.1.1.2.2).

• For the soil exposure and subsurface intrusion pathway—subsurface intrusion component, assign a value based on the area of regularly occupied structures within the area of observed exposure or area of subsurface contamination using the Tier D equation of Table 5–19 (section 5.2.1.2.2).

2.4.2.1.5 *Calculation of source hazardous waste quantity value.* Select the highest of the values assigned to the source (or areas of observed contamination, areas of observed exposure, or areas of subsurface contamination) for the hazardous constituent quantity, hazardous wastestream quantity, volume, and area measures. Assign this value as the source hazardous waste quantity value. Do not round to the nearest integer.

2.4.2.2 *Calculation of hazardous waste quantity factor value.* Sum the source hazardous waste quantity values assigned to all sources (including the unallocated source) or areas of observed contamination, areas of observed exposure, or areas of subsurface contamination for the pathway being evaluated and round this sum to the nearest integer, except: If the sum is greater than 0, but less than 1, round it to 1. Based on this value, select a hazardous waste quantity factor value for the pathway from Table 2–6.

TABLE 2–6—HAZARDOUS WASTE QUANTITY FACTOR VALUES

Hazardous waste quantity value	Assigned value
0	0
1 [a] to 100	[b] 1
Greater than 100 to 10,000	100
Greater than 10,000 to 1,000,000	10,000
Greater than 1,000,000	1,000,000

[a] If the hazardous waste quantity value is greater than 0, but less than 1, round it to 1 as specified in text.

[b] For the pathway, if hazardous constituent quantity is not adequately determined, assign a value as specified in the text; do not assign the value of 1.

For a migration pathway, if the hazardous constituent quantity is adequately determined (see section 2.4.2.1.1) for all sources (or all portions of sources and releases remaining after a removal action), assign the value from Table 2–6 as the hazardous waste quantity factor value for the pathway. If the hazardous constituent quantity is not adequately determined for one or more sources (or one or more portions of sources or releases remaining after a removal action) assign a factor value as follows:

• If any target for that migration pathway is subject to Level I or Level II concentrations (see section 2.5), assign either the value from Table 2–6 or a value of 100, whichever is greater, as the hazardous waste quantity factor value for that pathway.

• If none of the targets for that pathway is subject to Level I or Level II concentrations, assign a factor value as follows:

—If there has been no removal action, assign either the value from Table 2–6 or a value of 10, whichever is greater, as the hazardous waste quantity factor value for that pathway.

—If there has been a removal action:

▪ Determine values from Table 2–6 with and without consideration of the removal action.

▪ If the value that would be assigned from Table 2–6 without consideration of the removal action would be 100 or greater, assign either the value from Table 2–6 with consideration of the removal action or a value of 100, whichever is greater, as the hazardous waste quantity factor value for the pathway.

▪ If the value that would be assigned from Table 2–6 without consideration of the removal action would be less than 100, assign a value of 10 as the hazardous waste quantity factor value for the pathway.

For the soil exposure component of the soil exposure and subsurface intrusion pathway, if the hazardous constituent quantity is adequately determined for all areas of observed contamination, assign the value from Table 2–6 as the hazardous waste quantity factor value. If the hazardous constituent quantity is not adequately determined for one or more areas of observed contamination, assign either the value from Table 2–6 or a value of 10, whichever is greater, as the hazardous waste quantity factor value.

For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, if the hazardous constituent

quantity is adequately determined for all areas of observed exposure, assign the value from Table 2–6 as the hazardous waste quantity factor value. If the hazardous constituent quantity is not adequately determined for one or more areas of observed exposure, assign either the value from Table 2–6 or assign a factor value as follows:

• If any target for the subsurface intrusion component is subject to Level I or Level II concentrations (see section 2.5), assign either the value from Table 2–6 or a value of 100, whichever is greater, as the hazardous waste quantity factor value for this component.

• If none of the targets for the subsurface intrusion component is subject to Level I or Level II concentrations and if there has been a removal or other temporary response action that does not permanently interrupt target exposure form subsurface intrusion, assign a factor value as follows:

—Determine the values from Table 2–6 with and without consideration of the removal or other temporary response action.

—If the value that would be assigned from Table 2–6 without consideration of the removal or other temporary response action would be 100 or greater, assign either the value from Table 2–6 with consideration of the removal action or a value of 100, whichever is greater, as the hazardous waste quantity factor value for the component.

—If the value that would be assigned from Table 2–6 without consideration of the removal or other temporary response action would be less than 100, assign a value of 10 as the hazardous waste quantity factor value for the component.

• Otherwise, if none of the targets for the subsurface intrusion component is subject to Level I or Level II concentrations and there has not been a removal action, assign a value from Table 2–6 or a value of 10, whichever is greater.

2.4.3 *Waste characteristics factor category value.* Determine the waste characteristics factor category value as specified in section 2.4.3.1 for all pathways and threats, except the surface water-human food chain threat and the surface water-environmental threat. Determine the waste characteristics factor category value for these latter two threats as specified in section 2.4.3.2.

2.4.3.1 *Factor category value.* For the pathway (component or threat) being evaluated, multiply the toxicity or combined factor value, as appropriate, from section 2.4.1.2 and the hazardous waste quantity factor value from section 2.4.2.2, subject to a maximum product of $1x10^8$. Based on this waste characteristics product, assign a waste characteristics factor category value to the pathway (component or threat) from Table 2–7.

TABLE 2–7—WASTE CHARACTERISTICS FACTOR CATEGORY VALUES

Waste characteristics product	Assigned value
0	0
Greater than 0 to less than 10	1
10 to less than $1x10^2$	2
$1x10^2$ to less than $1x10^3$	3
$1x10^3$ to less than $1x10^4$	6
$1x10^4$ to less than $1x10^5$	10
$1x10^5$ to less than $1x10^6$	18
$1x10^6$ to less than $1x10^7$	32
$1x10^7$ to less than $1x10^8$	56
$1x10^8$ to less than $1x10^9$	100
$1x10^9$ to less than $1x10^{10}$	180
$1x10^{10}$ to less than $1x10^{11}$	320
$1x10^{11}$ to less than $1x10^{12}$	560
$1x10^{12}$	1,000

2.4.3.2 *Factor category value, considering bioaccumulation potential.* For the surface water-human food chain threat and the surface water-environmental threat, multiply the toxicity or combined factor value, as appropriate, from section 2.4.1.2 and the hazardous waste quantity factor value from section 2.4.2.2, subject to:

• A maximum product of $1x10^{12}$, *and*

• A maximum product exclusive of the bioaccumulation (or ecosystem bioaccumulation) potential factor of $1x10^8$.

Based on the total waste characteristics product, assign a waste characteristics factor category value to these threats from Table 2–7.

2.5 *Targets.* The types of targets evaluated include the following:

• Individual (factor name varies by pathway, component, and threat).

• Human population.

• Resources (these vary by pathway, component, and threat).

• Sensitive environments (included for the surface water migration pathway, air migration pathway, and soil exposure component of the soil exposure and subsurface intrusion pathway).

The factor values that may be assigned to each type of target have the same range for each pathway for which that type of target is evaluated. The factor value for most types of targets depends on whether the target is subject to actual or potential contamination for the pathway and whether the actual contamination is Level I or Level II:

• Actual contamination: Target is associated either with a sampling location that meets the criteria for an observed release (or observed contamination or observed exposure) for the pathway or with an observed release based on direct observation for the pathway (additional criteria apply for establishing actual contamination for the human food chain threat in the surface water migration pathway, see sections 4.1.3.3 and 4.2.3.3). Sections 3 through 6 specify how to determine the targets associated with a sampling location or with an observed release based on direct observation. Determine whether the actual contamination is Level I or Level II as follows:

—Level I:

▪ Media-specific concentrations for the target meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway and are at or above media-specific benchmark values. These benchmark values (see section 2.5.2) include both screening concentrations and concentrations specified in regulatory limits (such as Maximum Contaminant Level (MCL) values), or

▪ For the human food chain threat in the surface water migration pathway, concentrations in tissue samples from aquatic human food chain organisms are at or above benchmark values. Such tissue samples may be used in addition to media-specific concentrations only as specified in sections 4.1.3.3 and 4.2.3.3.

—Level II:

▪ Media-specific concentrations for the target meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway, but are less than media-specific benchmarks. If none of the hazardous substances eligible to be evaluated for the sampling location has an applicable benchmark, assign Level II to the actual contamination at the sampling location, or

▪ For observed releases or observed exposures based on direct observation, assign Level II to targets as specified in sections 3, 4, 5, and 6, or

▪ For the human food chain threat in the surface water migration pathway, concentrations in tissue samples from aquatic human food chain organisms, when applicable, are below benchmark values.

—If a target is subject to both Level I and Level II concentrations for a pathway (component or threat), evaluate the target using Level I concentrations for that pathway (component or threat).

• Potential contamination: Target is subject to a potential release (that is, target is not associated with actual contamination for that pathway or threat).

Assign a factor value for individual risk as follows (select the highest value that applies to the pathway, component or threat):

• 50 points if any individual is exposed to Level I concentrations.

• 45 points if any individual is exposed to Level II concentrations.

• Maximum of 20 points if any individual is subject to potential contamination. The value assigned is 20 unless reduced by a distance or dilution weight appropriate to the pathway. Assign factor values for population and sensitive environments as follows:

• Sum Level I targets and multiply by 10. (Level I is not used for sensitive environments in the soil exposure component of the soil exposure and subsurface intrusion and air migration pathways.)

• Sum Level II targets.

• Multiply potential targets in all but the soil exposure and subsurface intrusion pathway by distance or dilution weights appropriate to the pathway, sum, and divide by 10. Distance or dilution weighting accounts for diminishing exposure with increasing distance or dilution within the different pathways. For targets within an area

of subsurface contamination in the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, multiply by a weighting factor as directed in section 5.2.1.3.2.3.

• Sum the values for the three levels.

In addition, resource value points are assigned within all pathways for welfare-related impacts (for example, impacts to agricultural land), but do not depend on whether there is actual or potential contamination.

2.5.1 *Determination of level of actual contamination at a sampling location.* Determine whether Level I concentrations or Level II concentrations apply at a sampling location (and thus to the associated targets) as follows:

• Select the benchmarks applicable to the pathway (component or threat) being evaluated.

• Compare the concentrations of hazardous substances in the sample (or comparable samples) to their benchmark concentrations for the pathway (component or threat), as specified in section 2.5.2.

• Determine which level applies based on this comparison.

• If none of the hazardous substances eligible to be evaluated for the sampling location has an applicable benchmark, assign Level II to the actual contamination at that sampling location for the pathway (component or threat).

In making the comparison, consider only those samples, and only those hazardous substances in the sample, that meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway, except: Tissue samples from aquatic human food chain organisms may also be used as specified in sections 4.1.3.3 and 4.2.3.3 of the surface water-human food chain threat. If any hazardous substance is present in more than one comparable sample for the sampling location, use the highest concentration of that hazardous substance from any of the comparable samples in making the comparisons.

Treat sets of samples that are not comparable separately and make a separate comparison for each such set.

2.5.2 *Comparison to benchmarks.* Use the following media-specific benchmarks for making the comparisons for the indicated pathway (or threat):

• Maximum Contaminant Level Goals (MCLGs)—ground water migration pathway and drinking water threat in surface water migration pathway. Use only MCLG values greater than 0.

• Maximum Contaminant Levels (MCLs)—ground water migration pathway and drinking water threat in surface water migration pathway.

• Food and Drug Administration Action Level (FDAAL) for fish or shellfish—human food chain threat in surface water migration pathway.

• EPA Ambient Water Quality Criteria (AWQC/National Recommended Water Quality Criteria) for protection of aquatic life—environmental threat in surface water migration pathway.

• EPA Ambient Aquatic Life Advisory Concentrations (AALAC)—environmental threat in surface water migration pathway.

• National Ambient Air Quality Standards (NAAQS)—air migration pathway.

• National Emission Standards for Hazardous Air Pollutants (NESHAPs)—air migration pathway. Use only those NESHAPs promulgated in ambient concentration units.

• Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk for inhalation exposures (air migration pathway or subsurface intrusion component of the soil exposure and subsurface intrusion pathway) or for oral exposures (ground water migration pathway; drinking water and human food chain threats in surface water migration pathway; and soil exposure and subsurface intrusion pathway).

• Screening concentration for noncancer toxicological responses corresponding to the RfC for inhalation exposures (air migration pathway and subsurface intrusion component of the soil exposure and subsurface intrusion pathway) or RfD for oral exposures (ground water migration pathway; drinking water and human food chain threats in surface water migration pathway; and soil exposure and subsurface intrusion pathway).

Select the benchmark(s) applicable to the pathway (component or threat) being evaluated as specified in sections 3 through 6. Compare the concentration of each hazardous substance from the sampling location to its benchmark concentration(s) for that pathway (component or threat). Use only those samples and only those hazardous substances in the sample that meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway, except: Tissue samples from aquatic human food chain organisms may be used as specified in sections 4.1.3.3 and 4.2.3.3. If the concentration of any applicable hazardous substance from any sample equals or exceeds its benchmark concentration, consider the sampling location to be subject to Level I concentrations for that pathway (or threat). If more than one benchmark applies to the hazardous substance, assign Level I if the concentration of the hazardous substance equals or exceeds the lowest applicable benchmark concentration.

If no hazardous substance individually equals or exceeds its benchmark concentration, but more than one hazardous substance either meets the criteria for an observed release (or observed contamination or observed exposure) for the sample (or comparable samples) or is eligible to be evaluated for a tissue sample (see sections 4.1.3.3 and 4.2.3.3), calculate the indices I and J specified below based on these hazardous substances.

For those hazardous substances that are carcinogens (that is, those having either a carcinogen weight-of-evidence classification of A, B, or C or a weight-of-evidence classification of carcinogenic to humans, likely to be carcinogenic to humans, or suggestive evidence of carcinogenic potential), calculate an index I for the sample location as follows:

$$I = \sum_{i=1}^{n} \frac{C_i}{SC_i}$$

Where:

C_i = Concentration of hazardous substance i in sample (or highest concentration of hazardous substance i from among comparable samples).

SC_i = Screening concentration for cancer corresponding to that concentration that corresponds to its 10^{-6} individual cancer risk for applicable exposure (inhalation or oral) for hazardous substance i.

n = Number of applicable hazardous substances in sample (or comparable samples) that are carcinogens and for which an SC_i is available.

For those hazardous substances for which an RfD or RfC is available, calculate an index J for the sample location as follows:

$$I = \sum_{j=1}^{m} \frac{C_j}{CR_j}$$

Where:

C_j = Concentration of hazardous substance j in sample (or highest concentration of hazardous substance j from among comparable samples).

CR_j = Screening concentration for noncancer toxicological responses corresponding to RfD or RfC for applicable exposure (inhalation or oral) for hazardous substance j.

m = Number of applicable hazardous substances in sample (or comparable samples) for which a CR_j is available.

If either I or J equals or exceeds 1, consider the sampling location to be subject to Level I concentrations for that pathway (component or threat). If both I and J are less than 1, consider the sampling location to be subject to Level II concentrations for that pathway (component or threat). If, for the sampling location, there are sets of samples that are not comparable, calculate I and J separately for each such set, and use the highest calculated values of I and J to assign Level I and Level II.

See sections 7.3.1 and 7.3.2 for criteria for determining the level of contamination for radioactive substances.

* * * * *

5.0 Soil Exposure and Subsurface Intrusion Pathway

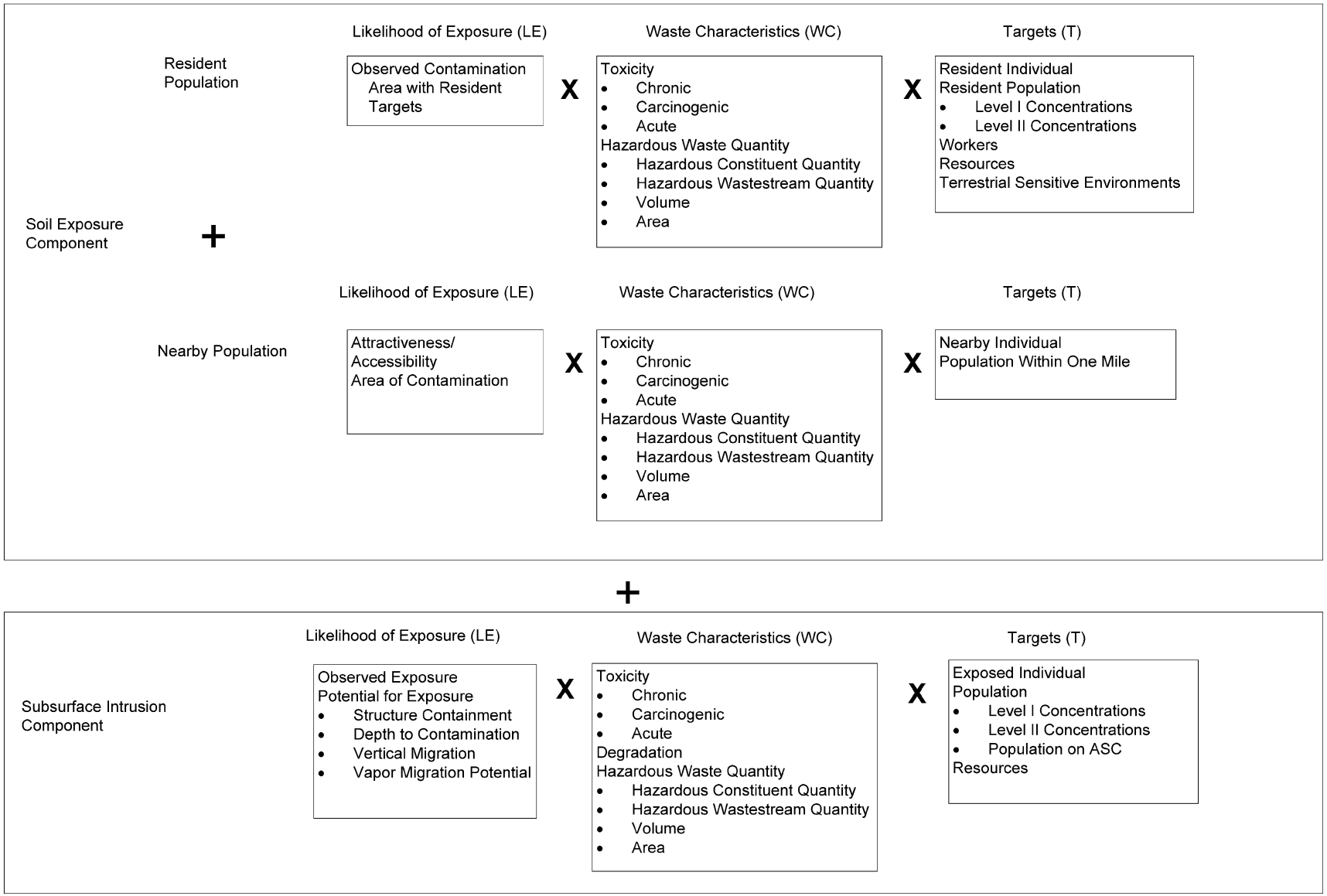
5.0.1 *Exposure components.* Evaluate the soil exposure and subsurface intrusion pathway based on two exposure components:

• Soil exposure component (see section 5.1).

• Subsurface intrusion component (see section 5.2).

Score one or both components considering their relative importance. If only one component is scored, assign its score as the soil exposure and subsurface intrusion pathway score. If both components are scored, sum the two scores and assign it as the soil exposure and subsurface intrusion pathway score, subject to a maximum of 100.

Figure 5-1 Overview of the Soil Exposure and Subsurface Intrusion Pathway



5.1 *Soil exposure component.* Evaluate the soil exposure component based on two threats: Resident population threat and nearby population threat. Evaluate both threats based on three factor categories: Likelihood of exposure, waste characteristics,

and targets. Figure 5–1 indicates the factors included within each factor category for each type of threat.

Determine the soil exposure component score (S_{se}) in terms of the factor category values as follows:

$$S_{se} = \frac{\sum_{i=1}^{2}(LE_i)(WC_i)(T_i)}{SF}$$

Where:

LE_i = Likelihood of exposure factor category value for threat i (that is, resident population threat or nearby population threat).

WC_i = Waste characteristics factor category value for threat i.

T_i = Targets factor category value for threat i.

SF = Scaling factor.

Table 5–1 outlines the specific calculation procedure.

TABLE 5–1—SOIL EXPOSURE COMPONENT SCORESHEET

Factor categories and factors	Maximum value	Value assigned
Resident Population Threat		
Likelihood of Exposure:		
1. Likelihood of Exposure	550	
Waste Characteristics:		
2. Toxicity	([a])	
3. Hazardous Waste Quantity	([a])	
4. Waste Characteristics	100	
Targets:		
5. Resident Individual	50	
6. Resident Population:.		
6a. Level I Concentrations	([b])	
6b. Level II Concentrations	([b])	
6c. Resident Population (lines 6a + 6b)	([b])	
7. Workers	15	
8. Resources	5	
9. Terrestrial Sensitive Environments	([c])	
10. Targets (lines 5 + 6c + 7 + 8 + 9)	([b])	
Resident Population Threat Score:		
11. Resident Population Threat (lines 1 × 4 × 10)	([b])	
Nearby Population Threat		
Likelihood of Exposure:		
12. Attractiveness/Accessibility	100	
13. Area of Contamination	100	
14. Likelihood of Exposure	500	
Waste Characteristics:		
15. Toxicity	([a])	
16. Hazardous Waste Quantity	([a])	
17. Waste Characteristics	100	
Targets:		
18. Nearby Individual	1	
19. Population Within 1 Mile	([b])	
20. Targets (lines 18 + 19)	([b])	
Nearby Population Threat Score:		
21. Nearby Population Threat (lines 14 × 17 × 20)	([b])	
Soil Exposure Component Score:		
22. Soil Exposure Component Score[d] (S_{se}), (lines [11 + 21]/82,500, subject to a maximum of 100)	100	

[a] Maximum value applies to waste characteristics category.
[b] Maximum value not applicable.
[c] No specific maximum value applies to factor. However, pathway score based solely on terrestrial sensitive environments is limited to maximum of 60.
[d] Do not round to nearest integer.

5.1.0 *General considerations.* Evaluate the soil exposure component based on areas of observed contamination:

- Consider observed contamination to be present at sampling locations where analytic evidence indicates that:
  - —A hazardous substance attributable to the site is present at a concentration significantly above background levels for the site (see Table 2–3 in section 2.3 for the criteria for determining analytical significance), *and*
  - —This hazardous substance, if not present at the surface, is covered by 2 feet or less of cover material (for example, soil).
- Establish areas of observed contamination based on sampling locations at which there is observed contamination as follows:
  - —For all sources except contaminated soil, if observed contamination from the site is present at any sampling location within the source, consider that entire source to be an area of observed contamination.
  - —For contaminated soil, consider both the sampling location(s) with observed contamination from the site and the area lying between such locations to be an area of observed contamination, unless available information indicates otherwise.
- If an area of observed contamination (or portion of such an area) is covered by a permanent, or otherwise maintained, essentially impenetrable material (for example, asphalt) that is not more than 2 feet thick, exclude that area (or portion of the area) in evaluating the soil exposure component.
- For an area of observed contamination, consider only those hazardous substances that meet the criteria for observed contamination for that area to be associated with that area in evaluating the soil exposure component (see section 2.2.2).

If there is observed contamination, assign scores for the resident population threat and the nearby population threat, as specified in sections 5.1.1 and 5.1.2. If there is no observed contamination, assign the soil exposure component of the soil exposure and subsurface intrusion pathway a score of 0.

5.1.1 *Resident population threat.* Evaluate the resident population threat only if there is an area of observed contamination in one or more of the following locations:

- Within the property boundary of a residence, school, or day care center *and* within 200 feet of the respective residence, school, or day care center, or
- Within a workplace property boundary *and* within 200 feet of a workplace area, or
- Within the boundaries of a resource specified in section 5.1.1.3.4, or
- Within the boundaries of a terrestrial sensitive environment specified in section 5.1.1.3.5.

If not, assign the resident population threat a value of 0, enter this value in Table 5–1, and proceed to the nearby population threat (section 5.1.2).

5.1.1.1 *Likelihood of exposure.* Assign a value of 550 to the likelihood of exposure factor category for the resident population threat if there is an area of observed contamination in one or more locations listed in section 5.1.1. Enter this value in Table 5–1.

5.1.1.2 *Waste characteristics.* Evaluate waste characteristics based on two factors: toxicity and hazardous waste quantity. Evaluate only those hazardous substances that meet the criteria for observed contamination at the site (see section 5.1.0).

5.1.1.2.1 *Toxicity.* Assign a toxicity factor value to each hazardous substance as specified in section 2.4.1.1. Use the hazardous substance with the highest toxicity factor value to assign the value to the toxicity factor for the resident population threat. Enter this value in Table 5–1.

5.1.1.2.2 *Hazardous waste quantity.* Assign a hazardous waste quantity factor value as specified in section 2.4.2. In estimating the hazardous waste quantity, use Table 5–2 and:

- Consider only the first 2 feet of depth of an area of observed contamination, except as specified for the volume measure.
- Use the volume measure (see section 2.4.2.1.3) only for those types of areas of observed contamination listed in Tier C of Table 5–2. In evaluating the volume measure for these listed areas of observed contamination, use the full volume, not just the volume within the top 2 feet.
- Use the area measure (see section 2.4.2.1.4), not the volume measure, for all other types of areas of observed contamination, even if their volume is known.

Enter the value assigned in Table 5–1.

TABLE 5–2—HAZARDOUS WASTE QUANTITY EVALUATION EQUATIONS FOR SOIL EXPOSURE COMPONENT

Tier	Measure	Units	Equation for assigning value [a]
A	Hazardous Constituent Quantity (C)	lb	C.
B [b]	Hazardous Wastestream Quantity (W)	lb	W/5,000.
C [b]	Volume (V).		
	Surface Impoundment [c]	yd^3	V/2.5.
	Drums [d]	gallon	V/500.
	Tanks and Containers Other Than Drums	yd^3	V/2.5.
D [b]	Area (A).		
	Landfill	ft^2	A/34,000.
	Surface Impoundment	ft^2	A/13.
	Surface Impoundment (Buried/backfilled)	ft^2	A/13.
	Land treatment	ft^2	A/270.
	Pile [e]	ft^2	A/34.
	Contaminated Soil	ft^2	A/34,000.

[a] Do not round nearest integer.
[b] Convert volume to mass when necessary: 1 ton = 2,000 pounds = 1 cubic yard = 4 drums = 200 gallons.
[c] Use volume measure only for surface impoundments containing hazardous substances present as liquids. Use area measures in Tier D for dry surface impoundments and for buried/backfilled surface impoundments.
[d] If actual volume of drums is unavailable, assume 1 drum = 50 gallons.
[e] Use land surface area under pile, not surface area of pile.

5.1.1.2.3 *Calculation of waste characteristics factor category value.* Multiply the toxicity and hazardous waste quantity factor values, subject to a maximum product of 1×10^8. Based on this product, assign a value from Table 2–7 (section 2.4.3.1) to the waste characteristics factor category. Enter this value in Table 5–1.

5.1.1.3 *Targets.* Evaluate the targets factor category for the resident population threat based on five factors: Resident individual, resident population, workers, resources, and terrestrial sensitive environments.

In evaluating the targets factor category for the resident population threat, count only the following as targets:

- Resident individual—a person living or attending school or day care on a property with an area of observed contamination *and* whose residence, school, or day care center, respectively, is on or within 200 feet of the area of observed contamination.
- Worker—a person working on a property with an area of observed contamination *and* whose workplace area is on or within 200 feet of the area of observed contamination.
- Resources located on an area of observed contamination, as specified in section 5.1.1.
- Terrestrial sensitive environments located on an area of observed contamination, as specified in section 5.1.1.

5.1.1.3.1 *Resident individual.* Evaluate this factor based on whether there is a resident individual, as specified in section 5.1.1.3, who is subject to Level I or Level II concentrations.

First, determine those areas of observed contamination subject to Level I concentrations and those subject to Level II concentrations as specified in sections 2.5.1 and 2.5.2. Use the health-based benchmarks from Table 5–3 in determining the level of contamination. Then assign a value to the resident individual factor as follows:

- Assign a value of 50 if there is at least one resident individual for one or more areas subject to Level I concentrations.
- Assign a value of 45 if there is no such resident individuals, but there is at least one resident individual for one or more areas subject to Level II concentrations.
- Assign a value of 0 if there is no resident individual.

Enter the value assigned in Table 5–1.

5.1.1.3.2 *Resident population.* Evaluate resident population based on two factors: Level I concentrations and Level II concentrations. Determine which factor applies as specified in sections 2.5.1 and 2.5.2, using the health-based benchmarks from Table 5–3. Evaluate populations subject to Level I concentrations as specified in section 5.1.1.3.2.1 and populations subject to Level II concentrations as specified in section 5.1.1.3.2.2.

TABLE 5–3—HEALTH-BASED BENCHMARKS FOR HAZARDOUS SUBSTANCES IN SOILS

Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk for oral exposures.
Screening concentration for noncancer toxicological responses corresponding to the Reference Dose (RfD) for oral exposures.

Count only those persons meeting the criteria for resident individual as specified in section 5.1.1.3. In estimating the number of people living on property with an area of observed contamination, when the estimate is based on the number of residences, multiply each residence by the average number of persons per residence for the county in which the residence is located.

5.1.1.3.2.1 *Level I concentrations.* Sum the number of resident individuals subject to Level I concentrations and multiply this sum by 10. Assign the resulting product as the value for this factor. Enter this value in Table 5–1.

5.1.1.3.2.2 *Level II concentrations.* Sum the number of resident individuals subject to Level II concentrations. Do not include those people already counted under the Level I concentrations factor. Assign this sum as the value for this factor. Enter this value in Table 5–1.

5.1.1.3.2.3 *Calculation of resident population factor value.* Sum the factor values for Level I concentrations and Level II concentrations. Assign this sum as the resident population factor value. Enter this value in Table 5–1.

5.1.1.3.3 *Workers.* Evaluate this factor based on the number of workers that meet the section 5.1.1.3 criteria. Assign a value for these workers using Table 5–4. Enter this value in Table 5–1.

TABLE 5–4—FACTOR VALUES FOR WORKERS

Number of workers	Assigned value
0	0
1 to 100	5
101 to 1,000	10
Greater than 1,000	15

5.1.1.3.4 *Resources.* Evaluate the resources factor as follows:

- Assign a value of 5 to the resources factor if one or more of the following is present on an area of observed contamination at the site:
  —Commercial agriculture.
  —Commercial silviculture.
  —Commercial livestock production or commercial livestock grazing.
- Assign a value of 0 if none of the above are present.

Enter the value assigned in Table 5–1.

5.1.1.3.5 *Terrestrial sensitive environments.* Assign value(s) from Table 5–5 to each terrestrial sensitive environment that meets the eligibility criteria of section 5.1.1.3.

Calculate a value (ES) for terrestrial sensitive environments as follows:

$$ES = \sum_{i=1}^{n} S_i$$

Where:

S_i = Value(s) assigned from Table 5–5 to terrestrial sensitive environment i.

n = Number of terrestrial sensitive environments meeting section 5.1.1.3 criteria.

Because the pathway score based solely on terrestrial sensitive environments is limited to a maximum of 60, determine the value for the terrestrial sensitive environments factor as follows:

TABLE 5–5—TERRESTRIAL SENSITIVE ENVIRONMENTS RATING VALUES

Terrestrial sensitive environments	Assigned value
Terrestrial critical habitat [a] for Federal designated endangered or threatened species	100
National Park	
Designated Federal Wilderness Area	
National Monument.	
Terrestrial habitat known to be used by Federal designated or proposed threatened or endangered species	75
National Preserve (terrestrial)	
National or State Terrestrial Wildlife Refuge	
Federal land designated for protection of natural ecosystems	
Administratively proposed Federal Wilderness Area	
Terrestrial areas utilized for breeding by large or dense aggregations of animals [b].	
Terrestrial habitat known to be used by State designated endangered or threatened species	50
Terrestrial habitat known to be used by species under review as to its Federal designated endangered or threatened status	
State lands designated for wildlife or game management	25
State designated Natural Areas	
Particular areas, relatively small in size, important to maintenance of unique biotic communities.	

[a] Critical habitat as defined in 50 CFR 424.02.
[b] Limit to vertebrate species.

- Multiply the values assigned to the resident population threat for likelihood of exposure (LE), waste characteristics (WC), and ES. Divide the product by 82,500.
  —If the result is 60 or less, assign the value ES as the terrestrial sensitive environments factor value.
  —If the result exceeds 60, calculate a value EC as follows:

$$EC = \frac{(60)(82{,}500)}{(LE)(WC)}$$

Assign the value EC as the terrestrial sensitive environments factor value. Do not round this value to the nearest integer.

Enter the value assigned for the terrestrial sensitive environments factor in Table 5–1.

5.1.1.3.6 *Calculation of resident population targets factor category value.* Sum the values for the resident individual, resident population, workers, resources, and terrestrial sensitive environments factors. Do not round to the nearest integer. Assign this sum as the targets factor category value for the resident population threat. Enter this value in Table 5–1.

5.1.1.4 *Calculation of resident population threat score.* Multiply the values for likelihood of exposure, waste characteristics, and targets for the resident population threat, and round the product to the nearest integer. Assign this product as the resident population threat score. Enter this score in Table 5–1.

5.1.2 *Nearby population threat.* Include in the nearby population only those individuals who live or attend school within a 1-mile travel distance of an area of observed contamination at the site and who do not meet the criteria for resident individual as specified in section 5.1.1.3.

Do not consider areas of observed contamination that have an attractiveness/accessibility factor value of 0 (see section

5.1.2.1.1) in evaluating the nearby population threat.

5.1.2.1 *Likelihood of exposure.* Evaluate two factors for the likelihood of exposure factor category for the nearby population threat: attractiveness/accessibility and area of contamination.

5.1.2.1.1 *Attractiveness/accessibility.* Assign a value for attractiveness/accessibility from Table 5–6 to each area of observed contamination, excluding any land used for residences. Select the highest value assigned to the areas evaluated and use it as the value for the attractiveness/accessibility factor. Enter this value in Table 5–1.

5.1.2.1.2 *Area of contamination.* Evaluate area of contamination based on the total area of the areas of observed contamination at the site. Count only the area(s) that meet the criteria in section 5.1.0 and that receive an attractiveness/accessibility value greater than 0. Assign a value to this factor from Table 5–7. Enter this value in Table 5–1.

TABLE 5–6—ATTRACTIVENESS/ACCESSIBILITY VALUES

Area of observed contamination	Assigned value
Designated recreational area	100
Regularly used for public recreation (for example, fishing, hiking, softball)	75
Accessible and unique recreational area (for example, vacant lots in urban area)	75
Moderately accessible (may have some access improvements, for example, gravel road), with some public recreation use	50
Slightly accessible (for example, extremely rural area with no road improvement), with some public recreation use	25
Accessible, with no public recreation use	10
Surrounded by maintained fence or combination of maintained fence and natural barriers	5
Physically inaccessible to public, with no evidence of public recreation use	0

TABLE 5–7—AREA OF CONTAMINATION FACTOR VALUES

Total area of the areas of observed contamination (square feet)	Assigned value
Less than or equal to 5,000	5
Greater than 5,000 to 125,000	20
Greater than 125,000 to 250,000	40
Greater than 250,000 to 375,000	60
Greater than 375,000 to 500,000	80
Greater than 500,000	100

5.1.2.1.3 *Likelihood of exposure factor category value.* Assign a value from Table 5–8 to the likelihood of exposure factor category, based on the values assigned to the attractiveness/accessibility and area of contamination factors. Enter this value in Table 5–1.

TABLE 5–8—NEARBY POPULATION LIKELIHOOD OF EXPOSURE FACTOR VALUES

Area of contamination factor value	Attractiveness/accessibility factor value						
	100	75	50	25	10	5	0
100	500	500	375	250	125	50	0
80	500	375	250	125	50	25	0
60	375	250	125	50	25	5	0
40	250	125	50	25	5	5	0
20	125	50	25	5	5	5	0
5	50	25	5	5	5	5	0

5.1.2.2 *Waste characteristics.* Evaluate waste characteristics based on two factors: toxicity and hazardous waste quantity. Evaluate only those hazardous substances that meet the criteria for observed contamination (see section 5.1.0) at areas that can be assigned an attractiveness/accessibility factor value greater than 0.

5.1.2.2.1 *Toxicity.* Assign a toxicity factor value as specified in section 2.4.1.1 to each hazardous substance meeting the criteria in section 5.1.2.2. Use the hazardous substance with the highest toxicity factor value to assign the value to the toxicity factor for the nearby population threat. Enter this value in Table 5–1.

5.1.2.2.2 *Hazardous waste quantity.* Assign a value to the hazardous waste quantity factor as specified in section 5.1.1.2.2, except: consider only those areas of observed contamination that can be assigned an attractiveness/accessibility factor value greater than 0. Enter the value assigned in Table 5–1.

5.1.2.2.3 *Calculation of waste characteristics factor category value.* Multiply the toxicity and hazardous waste quantity factor values, subject to a maximum product of 1×10^8. Based on this product, assign a value from Table 2–7 (section 2.4.3.1) to the waste characteristics factor category. Enter this value in Table 5–1.

5.1.2.3 *Targets.* Evaluate the targets factory category for the nearby population threat based on two factors: nearby individual and population within a 1-mile travel distance from the site.

5.1.2.3.1 *Nearby individual.* If one or more persons meet the section 5.1.1.3 criteria for a resident individual, assign this factor a value of 0. Enter this value in Table 5–1.

If no person meets the criteria for a resident individual, determine the shortest travel distance from the site to any residence or school. In determining the travel distance, measure the shortest overland distance an individual would travel from a residence or school to the nearest area of observed contamination for the site with an attractiveness/accessibility factor value greater than 0. If there are no natural barriers to travel, measure the travel distance as the shortest straight-line distance from the residence or school to the area of observed contamination. If natural barriers exist (for example, a river), measure the travel distance as the shortest straight-line distance from the residence or school to the nearest crossing point and from there as the shortest straight-

line distance to the area of observed contamination. Based on the shortest travel distance, assign a value from Table 5–9 to the nearest individual factor. Enter this value in Table 5–1.

TABLE 5–9—NEARBY INDIVIDUAL FACTOR VALUES

Travel distance for nearby individual (miles)	Assigned value
Greater than 0 to ¼	[a] 1
Greater than ¼ to 1	0

[a] Assign a value of 0 if one or more persons meet the section 5.1.1.3 criteria for resident individual.

5.1.2.3.2 *Population within 1 mile.* Determine the population within each travel distance category of Table 5–10. Count residents and students who attend school within this travel distance. Do not include those people already counted in the resident population threat. Determine travel distances as specified in section 5.1.2.3.1.

In estimating residential population, when the estimate is based on the number of residences, multiply each residence by the average number of persons per residence for the county in which the residence is located.

Based on the number of people included within a travel distance category, assign a distance-weighted population value for that travel distance from Table 5–10.

Calculate the value for the population within 1 mile factor (PN) as follows:

$$PN = \frac{1}{10}\sum_{i=1}^{3} W_i$$

Where:

W_i=Distance-weighted population value from Table 5–10 for travel distance category i.

If PN is less than 1, do not round it to the nearest integer; if PN is 1 or more, round to the nearest integer. Enter this value in Table 5–1.

5.1.2.3.3 *Calculation of nearby population targets factor category value.* Sum the values for the nearby individual factor and the population within 1 mile factor. Do not round this sum to the nearest integer. Assign this sum as the targets factor category value for the nearby population threat. Enter this value in Table 5–1.

TABLE 5–10—DISTANCE WEIGHTED POPULATION VALUES FOR NEARBY POPULATION THREAT [a]

Travel distance category (miles)	Number of people within the travel distance category											
	0	1 to 10	11 to 30	31 to 100	101 to 300	301 to 1,000	1,001 to 3,000	3,001 to 10,000	10,001 to 30,000	30,001 to 100,000	100,001 to 300,000	300,001 to 1,000,000
Greater than 0 to ¼	0	0.1	0.4	1.0	4	13	41	130	408	1,303	4,081	13,034
Greater than ¼ to ½	0	0.05	0.2	0.7	2	7	20	65	204	652	2,041	6,517
Greater than ½ to 1	0	0.02	0.1	0.3	1	3	10	33	102	326	1,020	3,258

[a] Round the number of people present within a travel distance category to nearest integer. Do not round the assigned distance-weighted population value to nearest integer.

5.1.2.4 *Calculation of nearby population threat score.* Multiply the values for likelihood of exposure, waste characteristics, and targets for the nearby population threat, and round the product to the nearest integer. Assign this product as the nearby population threat score. Enter this score in Table 5–1.

5.1.3 *Calculation of soil exposure component score.* Sum the resident population threat score and the nearby population threat score, and divide the sum by 82,500. Assign the resulting value, subject to a maximum of 100, as the soil exposure component score (S_{se}). Enter this score in Table 5–1.

5.2 *Subsurface intrusion component.* Evaluate the subsurface intrusion component based on three factor categories: likelihood of exposure, waste characteristics, and targets. Figure 5–1 indicates the factors included within each factor category for the subsurface intrusion component.

Determine the component score (S_{ssi}) in terms of the factor category values as follows:

$$S_{ssi} = \frac{(LE)(WC)(T)}{SF}$$

Where:

LE=Likelihood of exposure factor category value.

WC=Waste characteristics factor category value.

T=Targets factor category value.

SF=Scaling factor.

Table 5–11 outlines the specific calculation procedure.

TABLE 5–11—SUBSURFACE INTRUSION COMPONENT SCORESHEET

Factor categories and factors	Maximum value	Value assigned
Subsurface Intrusion Component:		
Likelihood of Exposure:		
1. Observed Exposure	550	
2. Potential for Exposure.		
2a. Structure Containment	10	
2b. Depth to contamination	10	
2c. Vertical Migration	15	
2d. Vapor Migration Potential	25	
3. Potential for Exposure (lines 2a * (2b + 2c + 2d), subject to a maximum of 500)	500	
4. Likelihood of Exposure (higher of lines 1 or 3)	550	
Waste Characteristics:		
5. Toxicity/Degradation	([a])	
6. Hazardous Waste Quantity	([a])	
7. Waste Characteristics (subject to a maximum of 100)	100	
Targets:		
8. Exposed Individual	50	
9. Population:.		
9a. Level I Concentrations	([b])	
9b. Level II Concentrations	([b])	
9c. Population within an Area of Subsurface Contamination	([b])	
9d. Total Population (lines 9a + 9b + 9c)	([b])	

TABLE 5–11—SUBSURFACE INTRUSION COMPONENT SCORESHEET—Continued

Factor categories and factors	Maximum value	Value assigned
10. Resources	5	
11. Targets (lines 8 + 9d + 10)	([b])	
Subsurface Intrusion Component Score:		
12. Subsurface Intrusion Component (lines 4 × 7 × 11)/82,500 [c] (subject to a maximum of 100)	100	
Soil Exposure and Subsurface Intrusion Pathway Score:		
13. Soil Exposure Component + Subsurface Intrusion Component (subject to a maximum of 100)	100	

[a] Maximum value applies to waste characteristics category.
[b] Maximum value not applicable.
[c] Do not round to the nearest integer.

5.2.0 *General considerations.* The subsurface intrusion component evaluates the threats from hazardous substances that have or could intrude into regularly occupied structures from the subsurface. Evaluate the subsurface intrusion component based on the actual or potential intrusion of hazardous substances into all regularly occupied structures that have structure containment values greater than zero and meet the criteria identified in the section below as being either in an area of observed exposure or in an area of subsurface contamination. These structures may or may not have subunits. Subunits are partitioned areas within a structure with separate heating, ventilating, and air conditioning (HVAC) systems or distinctly different air exchange rates. Subunits include regularly occupied partitioned tenant spaces such as office suites, apartments, condos, common or shared areas, and portions of residential, commercial or industrial structures with separate heating, ventilating, and air conditioning (HVAC) systems.

In evaluating the subsurface intrusion component, consider the following:

• Area(s) of observed exposure: An area of observed exposure is delineated by regularly occupied structures with documented contamination meeting observed exposure criteria; an area of observed exposure includes regularly occupied structures with samples meeting observed exposure criteria or inferred to be within an area of observed exposure based on samples meeting observed exposure criteria (see section 5.2.1.1.1 *Observed exposure*). Establish areas of observed exposure as follows:

—For regularly occupied structures that have no subunits, consider both the regularly occupied structures containing sampling location(s) meeting observed exposure criteria for the site and the regularly occupied structure(s) in the area lying between such locations to be an area of observed exposure (*i.e.,* inferred to be in an area of observed exposure), unless available information indicates otherwise.

—In multi-story, multi-subunit, regularly occupied structures, consider all subunits on a level with sampling locations meeting observed exposure criteria from the site and all levels below, if any, to be within an area of observed exposure, unless available information indicates otherwise.

—In multi-tenant structures, that do not have a documented observed exposure, but are located in an area lying between locations where observed exposures have been documented, consider only those regularly occupied subunits, if any, on the lowest level of the structure, to be within an area of observed exposure (*i.e.,* inferred to be in an area of observed exposure, unless available information indicates otherwise.

• Area(s) of subsurface contamination: An area of subsurface contamination is delineated by sampling locations meeting observed release criteria for subsurface intrusion, excluding areas of observed exposure (see Table 2–3 in section 2.3). The area within an area of subsurface contamination includes potentially exposed populations. If the significant increase in hazardous substance levels cannot be attributed at least in part to the site, and cannot be attributed to other sites, attribution can be established based on the presence of hazardous substances in the area of subsurface contamination. Establish areas of subsurface contamination as follows:

—Exclude those areas that contain structures meeting the criteria defined as an area of observed exposure.

—Consider both the sampling location(s) with subsurface contamination meeting observed release criteria from the site and the area lying between such locations to be an area of subsurface contamination (*i.e.,* inferred to be in an area of subsurface contamination). If sufficient data is available and state of the science shows there is no unacceptable risk due to subsurface intrusion into a regularly occupied structure located within an area of subsurface contamination, that structure can be excluded from the area of subsurface contamination.

Evaluate an area of subsurface contamination based on hazardous substances that:

▪ Meet the criteria for observed exposure of a chemical that has a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol, or

▪ Meet the criteria for observed release in an area of subsurface contamination and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol, or

▪ Meet the criteria for an observed release in a structure within, or in a sample from below, an area of observed exposure and have a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol.

—Evaluate all structures with no subunits that have containment factor values greater than zero, and not documented to meet observed exposure criteria to be in an area of subsurface contamination if they are lying between locations of subsurface intrusion samples meeting observed release criteria.

—Evaluate multi-subunit structures as follows:

▪ If an observed exposure has been documented based on a gaseous indoor air sample, consider all regularly occupied subunit(s), if any, on the level immediately above the level where an observed exposure has been documented (or has been inferred to be within an area of observed exposure), to be within an area of subsurface contamination. If sufficient data is available and state of the science shows there is no unacceptable risk due to subsurface intrusion on the level immediately above the level where an observed exposure has been documented (or has been inferred to be within an area of observed exposure) that level can be excluded from the area of subsurface contamination.

▪ If observed release criteria have been met based on a gaseous indoor air sample collected from a level not regularly occupied, consider all regularly occupied subunit(s), if any, on the level immediately above the level where the observed release criteria has been documented, to be within an area of subsurface contamination. If sufficient data is available and state of the science shows there is no unacceptable risk due to subsurface intrusion on the level immediately above the level where the observed release criteria has been documented that level can be excluded from the area of subsurface contamination.

▪ If any regularly occupied multi-subunit structure is inferred to be in an area of subsurface contamination, consider only those regularly occupied subunit(s), if any, on the lowest level, to be within an area of subsurface contamination. If sufficient data is available and state of the science shows there is no unacceptable risk due to subsurface intrusion on the lowest level, that structure can be excluded from the area of subsurface contamination.

See Section 7.0 for establishing an area of subsurface contamination based on the

presence of radioactive hazardous substances.

If there is no area of observed exposure and no area of subsurface contamination, assign a score of 0 for the subsurface intrusion component.

5.2.1 *Subsurface intrusion component.* Evaluate this component only if there is an area of observed exposure or area of subsurface contamination:

• Within or underlying a residence, school, day care center, workplace, or

• Within or underlying a resource specified in section 5.2.1.3.3.

5.2.1.1 *Likelihood of exposure.* Assign a value of 550 to the likelihood of exposure factor category for the subsurface intrusion component if there is an area of observed exposure in one or more locations listed in section 5.2.1. Enter this value in Table 5–11.

5.2.1.1.1 *Observed exposure.* Establish observed exposure in a regularly occupied structure by demonstrating that a hazardous substance has been released into a regularly occupied structure via the subsurface. Base this demonstration on either of the following criteria:

• Direct observation:

—A solid, liquid, or gaseous material that contains one or more hazardous substances attributable to the site has been observed entering a regularly occupied structure through migration via the subsurface or is known to have entered a regularly occupied structure via the subsurface, or

—When evidence supports the inference of subsurface intrusion of a material that contains one or more hazardous substances associated with the site into a regularly occupied structure, demonstrated adverse effects associated with that release may be used to establish observed exposure.

• Chemical analysis:

—Analysis of indoor samples indicates that the concentration of hazardous substance(s) is significantly above the background concentration for the site for that type of sample (see section 2.3).

—Some portion of the significant increase above background must be attributable to the site to establish the observed exposure. Documentation of this attribution should account for possible concentrations of the hazardous substance(s) in outdoor air or from materials found in the regularly occupied structure, and should provide a rationale for the increase being from subsurface intrusion.

If observed exposure can be established in a regularly occupied structure, assign an observed exposure factor value of 550, enter this value in Table 5–11, and proceed to section 5.2.1.1.3. If no observed exposure can be established, assign an observed exposure factor value of 0, enter this value in Table 5–11, and proceed to section 5.2.1.1.2.

5.2.1.1.2 *Potential for exposure.* Evaluate potential for exposure only if an observed exposure cannot be established, but an area of subsurface contamination has been delineated. Evaluate potential for exposure based only on the presence of hazardous substances with a vapor pressure greater than or equal to one torr or a Henry's constant greater than or equal to 10^{-5} atm-m^3/mol. Evaluate potential for exposure for each area of subsurface contamination based on four factors: Structure containment (see section 5.2.1.1.2.1), depth to contamination (see section 5.2.1.1.2.2), vertical migration (see section 5.2.1.1.2.3) and vapor migration potential (see section 5.2.1.1.2.4). For each area of subsurface contamination, assign the highest value for each factor. If information is insufficient to calculate any single factor value used to calculate the potential for exposure factor values at an identified area of subsurface contamination, information collected for another area of subsurface contamination at the site may be used when evaluating potential for exposure. Calculate the potential for exposure value for the site as specified in section 5.2.1.1.2.5.

5.2.1.1.2.1 *Structure containment.* Calculate containment for eligible hazardous substances within this component as directed in Table 5–12 and enter this value into Table 5–11. Assign each regularly occupied structure within an area of subsurface contamination the highest appropriate structure containment value from Table 5–12 and use the regularly occupied structure at the site with the highest structure containment value in performing the potential for exposure calculation. For all regularly occupied structures with unknown containment features assign a structure containment value of greater than zero for the purposes of evaluating targets (see section 5.2.1.3).

TABLE 5–12—STRUCTURE CONTAINMENT

No.	Evidence of structure containment	Assigned value
1.	Regularly occupied structure with evidence of subsurface intrusion, including documented observed exposure or sampling of bio or inert gases, such as methane and radon.	10
2.	Regularly occupied structure with open preferential subsurface intrusion pathways (*e.g.,* sumps, foundation cracks, unsealed utility lines).	10
3.	Regularly occupied structure with an engineered vapor migration barrier system that does not address all preferential subsurface intrusion pathways.	7
4.	Regularly occupied structure with an engineered passive vapor mitigation system *without* documented institutional controls (*e.g.,* deed restrictions) or evidence of regular maintenance and inspection.	6
5.	Regularly occupied structure with no visible open preferential subsurface intrusion pathways from the subsurface (*e.g.,* sumps, foundation cracks, unsealed utility lines).	4
6.	Regularly occupied structure with an engineered passive vapor mitigation system (*e.g.,* passive venting) *with* documented institutional controls (*e.g.,* deed restrictions) or evidence of regular maintenance and inspection.	3
7.	Regularly occupied structure with an engineered, active vapor mitigation system (*e.g.,* active venting) *without* documented institutional controls (*e.g.,* deed restrictions) and funding in place for on-going operation, inspection and maintenance.	2
8.	Regularly occupied structure with a permanent engineered, active vapor mitigation system (*e.g.,* active venting) *with* documented institutional controls (*e.g.,* deed restrictions) and funding in place for on-going operation, inspection and maintenance.	1
9.	Regularly occupied structure with a foundation raised greater than 6 feet above ground surface (*e.g.,* structure on stilts) or structure that has been built, and maintained, in a manner to prevent subsurface intrusion.	0

5.2.1.1.2.2 *Depth to contamination.* Assign each area of subsurface contamination a depth to contamination based on the least depth to either contaminated crawl space or subsurface media underlying a regularly occupied structure. Measure this depth to contamination based on the distance between the lowest point of a regularly occupied structure to the highest known point of hazardous substances eligible to be evaluated. Use any regularly occupied structure within an area of subsurface contamination with a structure containment factor value greater than zero. Subtract from the depth to contamination the thickness of any subsurface layer composed of features that would allow channelized flow (*e.g.,* karst, lava tubes, open fractures, as well as manmade preferential pathways such as utility conduits or drainage systems).

Based on this calculated depth, assign a factor value from Table 5–13. If the necessary information is available at multiple locations, calculate the depth to contamination at each location. Use the location having the least depth to contamination to assign the factor value. Enter this value in Table 5–11.

TABLE 5–13—DEPTH TO CONTAMINATION

Depth range [1] [2]	Depth to contamination assigned value
0 to <10 ft (Including subslab and semi-enclosed or enclosed crawl space contamination)	10
>10 to 20 ft	8
>20 to 50 ft	6
>50 to 100 ft	4
>100 to 150 ft	2
>150 ft	0

[1] If any part of the subsurface profile has channelized flow features, assign that portion of the subsurface profile a depth of 0.

[2] Measure elevation below any regularly occupied structure within an area of subsurface contamination at a site. Select the regularly occupied structure with the least depth to contamination below a structure.

5.2.1.1.2.3 *Vertical migration.* Evaluate the vertical migration factor for each area of subsurface contamination based on the geologic materials in the interval between the lowest point of a regularly occupied structure and the highest known point of hazardous substances in the subsurface. Use any regularly occupied structure either within an area of subsurface contamination or overlying subsurface soil gas or ground water contamination. Assign a value to the vertical migration factor as follows:

• If the depth to contamination (see section 5.2.1.1.2.2) is 10 feet or less, assign a value of 15.

• If the depth to contamination is greater than 10 feet, do not consider layers or portions of layers within the first 10 feet of the depth to contamination (as assigned in section 5.2.1.1.2.2).

• If, for the interval between the lowest point of a regularly occupied structure and the highest point of hazardous substances in the subsurface, all layers that underlie a portion of a regularly occupied structure at the site are karst or otherwise allow channelized flow, assign a value of 15.

• Otherwise:

—Select the lowest effective porosity/permeability layer(s) from within the interval identified above. Consider only layers at least 1 foot thick.—Assign a value for individual layers from Table 5–14 using the hydraulic conductivity of the layer, if available. If the hydraulic conductivity is not available, assign a value based on the type of material in the selected layer.

—If more than one layer has the same assigned porosity/permeability value, include all such layers and sum their thicknesses. Assign a thickness of 0 feet to a layer with channelized flow features found within any area of subsurface contamination at the site.

—Assign a value from Table 5–15 to the vertical migration factor, based on the thickness and assigned porosity/permeability value of the lowest effective porosity/permeability layer(s).

Determine vertical migration only at locations within an area of subsurface contamination at the site. If the necessary subsurface geologic information is available at multiple locations, evaluate the vertical migration factor at each location. Use the location having the highest vertical migration factor value to assign the factor value. Enter this value in Table 5–11.

TABLE 5–14—EFFECTIVE POROSITY/PERMEABILITY OF GEOLOGIC MATERIALS

Type of material	Hydraulic conductivity (cm/sec)	Assigned porosity/permeability value
Gravel; clean sand; highly permeable fractured igneous and metamorphic rocks; permeable basalt; karst limestones and dolomites.	Greater than or equal to 1×10^{-3}.	1
Sand; sandy clays; sandy loams; loamy sands; sandy silts; sediments that are predominantly sand; highly permeable till (coarse-grained, unconsolidated or compact and highly fractured); peat; moderately permeable limestones and dolomites (no karst); moderately permeable sandstone; moderately permeable fractured igneous and metamorphic rocks.	Less than 1×10^{-3}	2
Silt; loams; silty loams; loesses; silty clays; sediments that are predominantly silts; moderately permeable till (fine-grained, unconsolidated till, or compact till with some fractures); low permeability limestones and dolomites (no karst); low permeability sandstone; low permeability fractured igneous and metamorphic rocks.	Less than 1×10^{-5}	3
Clay; low permeability till (compact unfractured till); shale; unfractured metamorphic and igneous rocks.	Less than 1×10^{-7}	4

TABLE 5–15—VERTICAL MIGRATION FACTOR VALUES [a]

Assigned porosity/permeability value	Thickness of lowest porosity layer(s) [b] (feet)					
	0 to 5	Greater than 5 to 10	Greater than 10 to 20	Greater than 20 to 50	Greater than 50 to 100	Greater than 100 to 150
1	15	15	14	11	8	6
2	15	14	12	9	6	4
3	15	13	10	7	5	2
4	15	12	9	6	3	1

[a] If depth to contamination is 10 feet or less or if, for the interval being evaluated, all layers that underlie a portion of the structure at the site are karst or have other channelized flow features, assign a value of 15.

[b] Consider only layers at least 1 foot thick.

5.2.1.1.2.4 *Vapor migration potential.* Evaluate this factor for each area of subsurface contamination as follows:

• If the depth to contamination (see section 5.2.1.1.2.2) is 10 feet or less, assign a value of 25.

• Assign a value for vapor migration potential to each of the gaseous hazardous substances associated with the area of subsurface contamination (see section 2.2.2) as follows:

—Assign values from Table 5–16 for both vapor pressure and Henry's constant to each hazardous substance. If Henry's constant cannot be determined for a hazardous substance, assign that hazardous substance a value of 2 for the Henry's constant component.

—Sum the two values assigned to each hazardous substance.

—Based on this sum, assign each hazardous substance a value from Table 5–17 for vapor migration potential.

• Assign a value for vapor migration potential to each area of subsurface contamination as follows:

—Select the hazardous substance associated with the area of subsurface contamination

with the highest vapor migration potential value and assign this value as the vapor migration potential factor value for the area of subsurface contamination.

Enter this value in Table 5–11.

TABLE 5–16—VALUES FOR VAPOR PRESSURE AND HENRY'S CONSTANT

Vapor pressure (torr)	Assigned value
Greater than 10	3
1 to 10	2
Less than 1	0
Henry's constant (atm-m^3/mol)	**Assigned value**
Greater than 10^{-3}	3
Greater than 10^4 to 10^{-3}	2
10^{-5} to 10^{-4}	1
Less than 10^{-5}	0

TABLE 5–17—VAPOR MIGRATION POTENTIAL FACTOR VALUES FOR A HAZARDOUS SUBSTANCE

Sum of values for vapor pressure and Henry's constant	Assigned value
0	0
1 or 2	5
3 or 4	15
5 or 6	25

5.2.1.1.2.5 *Calculation of potential for exposure factor value.* For each identified area of subsurface contamination, sum the factor values for depth to contamination, vertical migration, and vapor migration potential, and multiply this sum by the factor value for structure containment. Select the highest product for any area of subsurface contamination and assign this value as the potential for exposure factor value for the component. Enter this value in Table 5–11.

5.2.1.1.3 *Calculation of likelihood of exposure factor category value.* If observed exposure is established for the site, assign the observed exposure factor value of 550 as the likelihood of exposure factor category value for the site. Otherwise, assign the potential for exposure factor value for the component as the likelihood of exposure value. Enter the value assigned in Table 5–11.

5.2.1.2 *Waste characteristics.* Evaluate waste characteristics based on two factors: toxicity/degradation and hazardous waste quantity.

5.2.1.2.1 *Toxicity/degradation.* For each hazardous substance, assign a toxicity factor value, a degradation factor value and a combined toxicity/degradation factor value as specified in sections 2.2.3, 2.4.1.2 and 5.2.1.2.1.1 through 5.2.1.2.1.3.

5.2.1.2.1.1 *Toxicity.* Assign a toxicity factor value to each hazardous substance as specified in sections 2.2.2 and 2.4.1.1.

5.2.1.2.1.2 *Degradation.* Assign a degradation factor value to each hazardous substance as follows:

- For any hazardous substance that meets the criteria for an observed exposure, or if a NAPL is present in the subsurface below an area of observed exposure or area of subsurface contamination at a depth less than or equal to 30 feet, assign that substance a degradation factor value of 1.
- For all other situations, assign a degradation factor value using Table 5–18. Assign the depth to contamination as directed in section 5.2.1.1.2.2, except if evidence indicates that biologically active soil is not present throughout the depth beneath any regularly occupied structure. In this situation, subtract any thickness of non-biologically active soil from the estimated depth to contamination.

TABLE 5–18—DEGRADATION FACTOR VALUE TABLE

Depth to contamination (feet) [a]	Half-life		
	>100 Days	>30 days and ≤100 days	≤30 days
<10	1	1	1
10 to ≤30	1	1	0.1
>30	1	0.5	0.1

[a] When determining the depth to contamination do not include layers of non-biologically-active soil, nor subsurface intervals with channelized flow (*e.g.,* karst, lava tubes, open fractures, and manmade preferential pathways as directed in section 5.2.1.1.2.2).

Calculate the half-life for each hazardous substance that meets subsurface intrusion observed release criteria as follows:

The half-life of a substance in the subsurface is defined for HRS purposes as the time required to reduce the initial concentration of the substance in the subsurface by one-half as a result of the combined decay processes of two components: Biodegradation and hydrolysis.

Estimate the half-life ($t_{1/2}$) of a hazardous substance as follows:

$$t_{1/2} = \frac{1}{1/h + 1/b}$$

Where:

h=Hydrolysis half-life.

b=Biodegradation half-life.

If either of these component half-lives cannot be estimated for the hazardous substance from available data, delete that component half-life from the above equation.

If no half-life information is available for a hazardous substance and the substance is not already assigned a value of 1, unless information indicates otherwise, assign a value of 1.

5.2.1.2.1.3 *Calculation of toxicity/degradation factor value.* Assign each substance a toxicity/degradation value by multiplying the toxicity factor value by the degradation factor value. Use the hazardous substance with the highest combined toxicity/degradation value to assign the factor value to the toxicity/degradation factor for the subsurface intrusion threat. Enter this value in Table 5–11.

5.2.1.2.2 *Hazardous waste quantity.* Assign a hazardous waste quantity factor value as specified in section 2.4.2. Consider only those regularly occupied structures or subunits with a non-zero structure containment value. Also include all regularly occupied structures or subunits that have had mitigation systems installed as part of a removal or other temporary response action. If sufficient structure-specific concentration data is available and state of the science shows there is no unacceptable risk of exposure to populations in a regularly occupied structure or subunit in an area of subsurface contamination, that structure or subunit is not included in the hazardous waste quantity evaluation. In estimating the hazardous waste quantity, use Tables 2–5 and 5–19 and:

- For Tier A, hazardous constituent quantity, use the mass of constituents found in the regularly occupied structure(s) where the observed exposure has been identified.
  - —For multi-subunit structures, when calculating Tier A, use the mass of constituents found in the regularly occupied subunit space(s) where the observed exposure has been identified.
- For Tier B, hazardous wastestream quantity, use the flow-through volume of the regularly occupied structures where the observed exposure has been identified.
  - —For multi-subunit structures, when calculating Tier B, use the flow-through volume of the regularly occupied subunit spaces where the observed exposure has been identified.
- For Tier C, volume, use the volume divisor listed in Tier C of Table 5–19. Volume is calculated for those regularly occupied structures located within areas of observed exposure with observed or inferred

intrusion and within areas of subsurface contamination.

—In evaluating the volume measure for these listed areas of observed exposure and areas of subsurface contamination based on a gaseous/vapor intrusion or the potential for gaseous/vapor intrusion, consider the following:

- Calculate the volume of each regularly occupied structure based on actual data. If unknown, use a ceiling height of 8 feet.
- For multi-subunit structures, when calculating Tier C, calculate volume for those subunit spaces with observed or inferred exposure and all other regularly occupied subunit spaces on that level, unless available information indicates otherwise. If the structure has multiple stories, also include the volume of all regularly occupied subunit spaces below the floor with an observed exposure and one story above, unless evidence indicates otherwise.
- For multi-subunit structures within an area of subsurface contamination and no observed or inferred exposure, consider only the volume of the regularly occupied subunit spaces on the lowest story, unless available information indicates otherwise.

• For Tier D, area, if volume is unknown, use the area divisor listed in Tier D of Table 5–19 for those regularly occupied structures within areas of observed exposure with observed or inferred intrusion and within areas of subsurface contamination.

—In evaluating the area measure for these listed areas of observed exposure and areas of subsurface contamination, calculate the area of each regularly occupied structure (including multi-subunit structures) or subunit based on actual footprint area data.

- If the actual footprint area of the structure(s) is unknown, use an area of 1,740 square feet for each structure (or subunit space).
- For multi-subunit structures, when calculating Tier D, calculate area for those subunit spaces with observed or inferred exposure and all other regularly occupied subunit spaces on that level, unless available information indicates otherwise. If the structure has multiple stories, also include the area of all regularly occupied subunit spaces below the floor with an observed exposure and one story above, unless evidence indicates otherwise.
- For multi-subunit structures within an area of subsurface contamination and no observed or inferred exposure, consider only the area of the regularly occupied subunit spaces on the lowest story, unless available information indicates otherwise.

TABLE 5–19—HAZARDOUS WASTE QUANTITY EVALUATION EQUATIONS FOR SUBSURFACE INTRUSION COMPONENT

Tier	Measure	Units	Equation for assigning value [a]
A	Hazardous Constituent Quantity (C)	Lb	C
B[b]	Hazardous Wastestream Quantity (W)	Lb	W/5,000
C[b,c]	Volume (V). Regularly occupied structure(s) in areas of observed exposure or subsurface contamination	yd^3	V/2.5
D[b,d]	Area (A). Regularly occupied structure(s) in areas of observed exposure or subsurface contamination	ft^2	A/13

[a] Do not round to the nearest integer.
[b] Convert volume to mass when necessary: 1 ton=2,000 pounds=1 cubic yard=4 drums=200 gallons.
[c] Calculate volume of each regularly occupied structure or subunit space in areas of observed exposure and areas of subsurface contamination—Assume 8-foot ceiling height unless actual value is known.
[d] Calculate area of the footprint of each regularly occupied structure in areas of observed exposure and areas of subsurface contamination. If the footprint area of a regularly occupied structure is unknown, use 1,740 square feet as the footprint area of the structure or subunit space.

For the subsurface intrusion component, if the hazardous constituent quantity is adequately determined for all areas of observed exposure, assign the value from Table 2–6 as the hazardous waste quantity factor value. If the hazardous constituent quantity is not adequately determined for one or more areas of observed exposure or if one or more areas of subsurface contamination are present, assign either the value from Table 2–6 or assign a factor value as follows:

• If any target for the subsurface intrusion component is subject to Level I or Level II concentrations (see section 2.5), assign either the value from Table 2–6 or a value of 100, whichever is greater, as the hazardous waste quantity factor value for this component.

• If none of the targets for the subsurface intrusion component is subject to Level I or Level II concentrations and if there has been a removal action that does not permanently interrupt target exposure from subsurface intrusion, and if an area of subsurface contamination exists, assign a factor value as follows:

—Determine the values from Table 2–6 with and without consideration of the removal action.

—If the value that would be assigned from Table 2–6 without consideration of the removal action would be 100 or greater, assign either the value from Table 2–6 with consideration of the removal action or a value of 100, whichever is greater, as the hazardous waste quantity factor value for the component.

—If the value that would be assigned from Table 2–6 without consideration of the removal action would be less than 100, assign a value of 10 as the hazardous waste quantity factor value for the component.

• Otherwise, if none of the targets for the subsurface intrusion component is subject to Level I or Level II concentrations and there has not been a removal action, assign a value from Table 2–6 or a value of 10, whichever is greater.

Enter the value assigned in Table 5–11.

5.2.1.2.3 *Calculation of waste characteristics factor category value.* Multiply the toxicity/degradation and hazardous waste quantity factor values, subject to a maximum product of 1×10^8. Based on this product, assign a value from Table 2–7 (section 2.4.3.1) to the waste characteristics factor category. Enter this value in Table 5–11.

5.2.1.3 *Targets.* Evaluate the targets factor category for the subsurface intrusion threat based on three factors: Exposed individual, population, and resources in regularly occupied structures with structure containment factors greater than 0. Evaluate only those targets within areas of observed exposure and areas of subsurface contamination (see section 5.2.0).

In evaluating the targets factor category for the subsurface intrusion threat, count only the following as targets:

• Exposed individual—a person living, attending school or day care, or working in a regularly occupied structure with observed exposure or in a structure within an area of observed exposure or within an area of subsurface contamination.

• Population—exposed individuals in a regularly occupied structure within an area of observed exposure or within an area of subsurface contamination.

• Resources—located within an area of observed exposure or within an area of subsurface contamination as specified in section 5.2.1.3.3.

If a formerly occupied structure has been vacated due to subsurface intrusion attributable to the site, count the initial targets as if they were still residing in the structure. In addition, if a removal or temporary response action has occurred that has not completely mitigated the release, count the initial targets as if the removal or temporary response action has not permanently interrupted target exposure from subsurface intrusion. Evaluate those targets based on conditions at the time of removal of temporary response action.

For populations residing in or working in a multi-subunit structure with multiple stories in an area of observed exposure or area of subsurface contamination, count these targets as follows:

• If there is no observed exposure within the structure, include in the evaluation only those targets, if any, in the lowest occupied level. If sufficient structure-specific concentration data is available and state of the science shows there is no unacceptable risk of exposure to targets in the lowest level, those targets are not included in the evaluation.

• If there is an observed exposure in any level, include in the evaluation those targets in that level, the level above and all levels below. (The weighting of these targets is specified in Section 5.2.1.3.2.) If sufficient structure-specific concentration data is available and state of the science shows there is no unacceptable risk of exposure to targets in the level above where the observed exposure has been documented, those targets are not included in the evaluation.

5.2.1.3.1 *Exposed individual.* Evaluate this factor based on whether there is an exposed individual, as specified in sections 2.5.1, 2.5.2 and 5.2.1.3, who is subject to Level I or Level II concentrations.

First, determine those regularly occupied structures or partitioned subunit(s) within structures in an area of observed exposure subject to Level I concentrations and those subject to Level II concentrations as specified as follows (see section 5.2.0):

• Level I Concentrations: For contamination resulting from subsurface intrusion, compare the hazardous substance concentrations in any sample meeting the observed exposure by chemical analysis criteria to the appropriate benchmark. Use the health-based benchmarks from Table 5–20 to determine the level of contamination.

—If the sample is from a structure with no subunits and the concentration equals or exceeds the appropriate benchmark, assign Level I concentrations to the entire structure.

—If the sample is from a subunit within a structure and the concentration from that subunit equals or exceeds the appropriate benchmark, assign Level I concentrations to that subunit.

• Level II Concentrations: Structures, or subunits within structures, with one or more samples that meet observed exposure by chemical analysis criteria but do not equal or exceed the appropriate benchmark; structures, or subunits, that have an observed exposure by direct observation; and structures inferred to be in an area of observed exposure based on samples meeting observed exposure, are assigned Level II concentrations.

—For all regularly occupied structures, or subunits in such structures, in an area of observed exposure that are not assigned Level I concentrations, assign Level II concentrations.

Then assign a value to the exposed individual factor as follows:

• Assign a value of 50 if there is at least one exposed individual in one or more regularly occupied structures subject to Level I concentrations.

• Assign a value of 45 if there are no Level I exposed individuals, but there is at least one exposed individual in one or more regularly occupied structures subject to Level II concentrations.

• Assign a value of 20 if there is no Level I or Level II exposed individual but there is at least one individual in a regularly occupied structure within an area of subsurface contamination. Enter the value assigned in Table 5–11.

5.2.1.3.2 *Population.* Evaluate population based on three factors: Level I concentrations, Level II concentrations, and population within an area of subsurface contamination. Determine which factors apply as specified in section 5.2.1.3.1, using the health-based benchmarks from Table 5–20. Evaluate populations subject to Level I and Level II concentrations as specified in section 2.5.

TABLE 5–20—HEALTH-BASED BENCHMARKS FOR HAZARDOUS SUBSTANCES IN THE SUBSURFACE INTRUSION COMPONENT

Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk using the inhalation unit risk. For oral exposures use the oral cancer slope factor.
Screening concentration for noncancer toxicological responses corresponding to the reference dose (RfD) for oral exposure and the reference concentration (RfC) for inhalation exposures.

Count only those persons meeting the criteria for population as specified in section 5.2.1.3. In estimating the number of individuals in structures in an area of observed exposure or area of subsurface contamination if the actual number of residents is not known, multiply each residence by the average number of persons per residence for the county in which the residence is located.

5.2.1.3.2.1 *Level I concentrations.* Assign the population subject to Level I concentrations as follows:

1. Identify all exposed individuals regularly present in an eligible structure with a structure containment value greater than zero, or if the structure has subunits, identify those regularly present in each subunit, located in an area of observed exposure subject to Level I concentrations as described in sections 5.2.0 and 5.2.1.3.1. Identify only once per structure those exposed individuals that are using more than one eligible subunit of the same structure (*e.g.,* using a common or shared area and other parts of the same structure).

2. For each structure or subunit count the number of individuals residing in or attending school or day care in the structure or subunit.

3. Count the number of full-time and part-time workers in the structure or subunit(s) subject to Level I concentrations. If information is unavailable to classify a worker as full- or part-time, evaluate that worker as being full-time. Divide the number of full-time workers by 3 and the number of part-time workers by 6, and then sum these products with the number of other individuals for each structure or subunit.

4. Sum this combined value for all structures, or subunits, within areas of observed exposure and multiply this sum by 10.

Assign the resulting product as the combined population factor value subject to Level I concentrations for the site. Enter this value in line 9a of Table 5–11.

5.2.1.3.2.2 *Level II concentrations.* Assign the population subject to Level II concentrations as follows:

1. Identify all exposed individuals regularly present in an eligible structure with a structure containment value greater than zero, or if the structure has subunits, identify those regularly present in each subunit, located in an area of observed exposure subject to Level II concentrations as described in sections 5.2.0 and 5.2.1.3.1. Identify only once per structure those exposed individuals that are using more than one eligible subunit of the same structure (*e.g.,* using a common or shared area and other parts of the same structure).

2. Do not include exposed individuals already counted under the Level I concentrations factor.

3. For each structure or subunit(s), count the number of individuals residing in or attending school or day care in the structure, or subunit, subject to Level II concentrations.

4. Count the number of full-time and part-time workers in the structure or subunit(s) subject to Level II concentrations. If information is unavailable to classify a worker as full- or part-time, evaluate that worker as being full-time. Divide the number of full-time workers by 3 and the number of part-time workers by 6, and then sum these products with the number of other individuals for each structure or subunit.

5. Sum the combined population value for all structures within the areas of observed exposure for the site.

Assign this sum as the combined population factor value subject to Level II concentrations for this site. Enter this value in line 9b of Table 5–11.

5.2.1.3.2.3 *Population within area(s) of subsurface contamination.* Assign the population in area(s) of subsurface contamination factor value as follows. If sufficient structure-specific concentration data is available and state of the science shows there is no unacceptable risk of exposure to populations in a regularly occupied structure in an area of subsurface contamination, those populations are not included in the evaluation. (see sections 5.2.0 and 5.2.1.3.1):

1. Identify the regularly occupied structures with a structure containment value greater than zero and the eligible population associated with the structures or portions of structures in each area of subsurface contamination:

• For each regularly occupied structure or portion of a structure in an area of subsurface contamination, sum the number of all individuals residing in or attending school or day care, in the structure or portion of the structure in the area of subsurface contamination.

• Count the number of full-time and part-time workers regularly present in each

structure or portion of a structure in an area of subsurface contamination. If information is unavailable to classify a worker as full- or part-time, evaluate that worker as being full-time. Divide the number of full-time workers by 3 and the number of part-time workers by 6. Sum these products with the number of individuals residing in or attending school or day care in the structure.

• Use this sum as the population for the structure.

2. Estimate the depth or distance to contamination at each regularly occupied structure within an area of subsurface contamination based on available sampling data, and categorize each eligible structure based on the depth or distance to contamination and sample media as presented in Table 5–21. Weight the population in each structure using the appropriate weighting factors in Table 5–21. If samples from multiple media are available, use the sample that results in the highest weighting factor.

3. Sum the weighted population in all structures within the area(s) of subsurface contamination and assign this sum as the population within an area of subsurface contamination factor value. Enter this value in line 9c of Table 5–11.

TABLE 5–21—WEIGHTING FACTOR VALUES FOR POPULATIONS WITHIN AN AREA OF SUBSURFACE CONTAMINATION

Eligible populations [a] in structures [b] within an area of subsurface contamination	Population weighting factor
Samples From Within Structures or in Crawl Spaces	
1. Population in a structure with levels of contamination in a semi-enclosed or enclosed crawl space sample meeting observed release criteria or Population in a subunit of a multi-story structure within an area of subsurface contamination located directly above a level in an area of observed exposure or a gaseous indoor air sample meeting observed release criteria or Population within a structure where a mitigation system has been installed as part of a removal or other temporary response action.	0.9
2. Population in a structure where levels of contaminants meeting observed release criteria are inferred based on semi-enclosed or enclosed crawl space samples in surrounding structures, and a NAPL is present in those samples	0.8
3. Population in a structure where levels of contaminants meeting observed release criteria are inferred based on semi-enclosed or enclosed crawl space samples in surrounding structures, but no NAPL is present	0.4
Subsurface Samples From Less Than or Equal to 5 Feet From a Foundation	
4. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on any sampling media at or within five feet horizontally or vertically of the structure foundation, and a NAPL is present within that depth	0.8
5. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on any sampling media at or within five feet horizontally or vertically of the structure foundation, but no NAPL is present within that depth	0.4
Subsurface Samples From Greater Than 5 Feet But Less Than or Equal to 30 Feet Depth	
6. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on any underlying non-ground water subsurface sample at a depth greater than 5 feet but less than or equal to 30 feet from a structure foundation and a NAPL is present within that depth	0.4
7. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on any underlying non-ground water subsurface sample at a depth greater than 5 feet but less than or equal to 30 feet, but no NAPL is present within that depth	0.2
8. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on underlying ground water samples greater than 5 feet from the structure foundation but less than or equal to 30 feet, and a NAPL is present in those samples	0.2
9. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on underlying ground water samples greater than 5 feet from the structure foundation but less than or equal to 30 feet, but no NAPL is present in those samples	0.1
Subsurface Samples From Greater Than 30 Feet Depth	
10. Population in a structure where levels of contaminants meeting observed release criteria are found or inferred based on any underlying sample at depths greater than 30 feet	0.1

[a] Eligible populations include residents (including individuals living in, or attending school or day care in the structure), and workers in regularly occupied structures (see HRS Section 5.2.1.3).

[b] Eligible structures may include single- or multi-tenant structures where eligible populations reside, attend school or day care, or work. These structures may also be mixed use structures.

5.2.1.3.2.4 *Calculation of population factor value.* Sum the factor values for Level I concentrations, Level II concentrations, and population within the area(s) of subsurface contamination. Assign this sum as the population factor value. Enter this value in line 9d of Table 5–11.

5.2.1.3.3 *Resources.* Evaluate the resources factor as follows:

• Assign a value of 5 if a resource structure (*e.g.,* library, church, tribal facility) is present and regularly occupied within either an area of observed exposure or area of subsurface contamination.

• Assign a value of 0 if there is no resource structure within an area of observed exposure or area of subsurface contamination.

Enter the value assigned in Table 5–11.

5.2.1.3.4 *Calculation of targets factor category value.* Sum the values for the exposed individual, population, and resources factors. Do not round to the nearest integer. Assign this sum as the targets factor category value for the subsurface intrusion component. Enter this value in Table 5–11.

5.2.2 *Calculation of subsurface intrusion component score.* Multiply the factor category values for likelihood of exposure, waste characteristics, and targets and round the product to the nearest integer. Divide the product by 82,500. Assign the resulting value, subject to a maximum of 100, as the

subsurface intrusion component score and enter this score in Table 5–11.

5.3 *Calculation of the soil exposure and subsurface intrusion pathway score.* Sum the soil exposure component score and subsurface intrusion component score. Assign the resulting value, subject to a maximum of 100, as the soil exposure and subsurface intrusion pathway score (S_{sessi}). Enter this score in Table 5–11.

6.0 Air Migration Pathway

* * * * *

TABLE 6–14—HEALTH-BASED BENCHMARKS FOR HAZARDOUS SUBSTANCES IN AIR

- Concentration corresponding to National Ambient Air Quality Standard (NAAQS).
- Concentration corresponding to National Emission Standards for Hazardous Air Pollutants (NESHAPs).
- Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk for inhalation exposures.
- Screening concentration for noncancer toxicological responses corresponding to the Reference Concentration (RfC) for inhalation exposures.

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7.0 Sites Containing Radioactive Substances

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TABLE 7–1—HRS FACTORS EVALUATED DIFFERENTLY FOR RADIONUCLIDES

Ground water pathway	Status [a]	Surface water pathway	Status [a]	Soil exposure component of SESSI pathway	Status [a]	Subsurface intrusion component of SESSI pathway	Status [a]	Air pathway	Status [a]
Likelihood of Release		*Likelihood of Release.*		*Likelihood of Exposure.*		*Likelihood of Exposure.*		*Likelihood of Release.*	
Observed Release	Yes	Observed Release.	Yes	Observed Contamination.	Yes	Observed Exposure.	Yes	Observed Release.	Yes.
Potential to Release	No	Potential to Release.	No	Attractiveness/Accessibility to Nearby Residents.	No	Potential for Exposure.	Yes	Gas Potential to Release.	No.
Containment	No	Overland Flow Containment.	No	Area of Contamination.	No	Structure Containment.	No	Gas Containment.	No.
Net Precipitation	No	Runoff	No	Area of Observed Exposure.	No	Depth to Contamination.	Yes	Gas Source Type.	No.
Depth to Aquifer	No	Distance to Surface water.	No	Area of Subsurface Contamination.	No	Vertical migration.	No	Gas Migration Potential.	No.
Travel Time	No	Flood Frequency.	No			Vapor Migration Potential.	No	Particulate Potential to Release.	No.
		Flood Containment.	No					Particulate Containment.	No.
								Particulate Source Type.	No.
								Particulate Migration Potential.	No.
Waste Characteristics		*Waste Characteristics.*		*Waste Characteristics.*		*Waste Characteristics.*		*Waste Characteristics.*	
Toxicity	Yes	Toxicity/Ecotoxicity.	Yes/Yes.	Toxicity	Yes	Toxicity/Degradation.	Yes/Yes.	Toxicity	Yes.
Mobility	No	Persistence/Mobility	Yes/No	Hazardous Waste Quantity.	Yes	Hazardous Waste Quantity.	Yes	Mobility	No.
Hazardous Waste Quantity	Yes	Bioaccumulation Potential.	No					Hazardous Waste Quantity.	Yes.
		Hazardous Waste Quantity.	Yes						
Targets		*Targets*		*Targets*		*Targets*		*Targets*	
Nearest Well	Yes.[b]	Nearest Intake.	Yes.[b]	Resident Individual.	Yes.[b]	Exposed Individual	Yes.[b]	Nearest Individual.	Yes.[b]

TABLE 7–1—HRS FACTORS EVALUATED DIFFERENTLY FOR RADIONUCLIDES—Continued

Ground water pathway	Status [a]	Surface water pathway	Status [a]	Soil exposure component of SESSI pathway	Status [a]	Subsurface intrusion component of SESSI pathway	Status [a]	Air pathway	Status [a]
Population	Yes.[b]	Drinking Water Population.	Yes.[b]	Resident Population.	Yes.[b]	Population	Yes.[b]	Population	Yes.[b]
Resources	No	Resources	No	Workers	No	Resources	No	Resources	No
Wellhead Protection Area	No	Sensitive Environments.	Yes.[b]	Resources	No			Sensitive Environments.	No
		Human Food Chain Individual.	Yes.[b]	Terrestrial Sensitive Environments.	No				
		Human Food Chain Population.	Yes.[b]	Nearby Individual.	No				
				Population Within 1 Mile.	No				

[a] Factors evaluated differently are denoted by ''yes''; factors not evaluated differently are denoted by ''no''.
[b] Difference is in the determination of Level I and Level II concentrations.

* * * * *

* * * These differences apply largely to the soil exposure and subsurface intrusion pathway and to sites containing mixed radioactive and other hazardous substances. * * *

7.1 *Likelihood of release/likelihood of exposure.* Evaluate likelihood of release for the three migration pathways and likelihood of exposure for the soil exposure and subsurface intrusion pathway as specified in sections 2 through 6, except: establish an observed release, observed contamination, and/or observed exposure as specified in section 7.1.1. When an observed release or exposure cannot be established for a migration pathway or the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, evaluate potential to release as specified in section 7.1.2. When observed contamination cannot be established, do not evaluate the soil exposure component of the soil exposure and subsurface intrusion pathway.

7.1.1 *Observed release/observed contamination/observed exposure.* For radioactive substances, establish an observed release for each migration pathway by demonstrating that the site has released a radioactive substance to the pathway (or watershed or aquifer, as appropriate); establish observed contamination or observed exposure for the soil exposure and subsurface intrusion pathway as indicated below. Base these demonstrations on one or more of the following, as appropriate to the pathway being evaluated:

- Direct observation:

—For each migration pathway, a material that contains one or more radionuclides has been seen entering the atmosphere, surface water, or ground water, as appropriate, or is known to have entered ground water or surface water through direct deposition, or

—For the surface water migration pathway, a source area containing radioactive substances has been flooded at a time that radioactive substances were present and one or more radioactive substances were in contact with the flood waters.

—For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, a material that contains one or more radionuclides has been observed entering a regularly occupied structure via the subsurface or is known to have entered a regularly occupied structure via the subsurface. Also, when evidence supports the inference of subsurface intrusion of a material that contains one or more radionuclides by the site into a regularly occupied structure, demonstrated adverse effects associated with that release may also be used to establish observed exposure by direct observation.

- Analysis of radionuclide concentrations in samples appropriate to the pathway (that is, ground water, soil, air, indoor air, soil gas, surface water, benthic, or sediment samples):

—For radionuclides that occur naturally and for radionuclides that are ubiquitous in the environment:

- Measured concentration (in units of activity, for example, pCi per kilogram [pCi/kg], pCi per liter [pCi/L], pCi per cubic meter [pCi/m3]) of a given radionuclide in the sample are at a level that:
  - Equals or exceeds a value 2 standard deviations above the mean site-specific background concentration for that radionuclide in that type of sample, or
  - Exceeds the upper-limit value of the range of regional background concentration values for that specific radionuclide in that type of sample.
- Some portion of the increase must be attributable to the site to establish the observed release (or observed contamination or observed exposure), and
- For the soil exposure component of the soil exposure and subsurface intrusion pathway only, the radionuclide must also be present at the surface or covered by 2 feet or less of cover material (for example, soil) to establish observed contamination.

—For man-made radionuclides without ubiquitous background concentrations in the environment:

- Measured concentration (in units of activity) of a given radionuclide in a sample equals or exceeds the sample quantitation limit for that specific radionuclide in that type of media and is attributable to the site.
- However, if the radionuclide concentration equals or exceeds its sample quantitation limit, but its release can also be attributed to one or more neighboring sites, then the measured concentration of that radionuclide must also equal or exceed a value either 2 standard deviations above the mean concentration of that radionuclide contributed by those neighboring sites or 3 times its background concentration, whichever is lower.
- If the sample quantitation limit cannot be established:
  - If the sample analysis was performed under the EPA Contract Laboratory Program, use the EPA contract-required quantitation limit (CRQL) in place of the sample quantitation limit in establishing an observed release (or observed contamination or observed exposure).
  - If the sample analysis is not performed under the EPA Contract Laboratory Program, use the detection limit in place of the sample quantitation limit.
- For the soil exposure component of the soil exposure and subsurface intrusion pathway only, the radionuclide must also be present at the surface or covered by 2 feet or less of cover material (for example, soil) to establish observed contamination.

- Gamma radiation measurements (applies only to observed contamination or observed exposure in the soil exposure and subsurface intrusion pathway):

—The gamma radiation exposure rate, as measured in microroentgens per hour (μR/hr) using a survey instrument held 1 meter above the ground surface or floor or walls of a structure (or 1 meter away from an aboveground source for the soil exposure component), equals or exceeds 2 times the site-specific background gamma radiation exposure rate.

—Some portion of the increase must be attributable to the site to establish observed contamination or observed exposure. The gamma-emitting radionuclides do not have to be within 2 feet of the surface of the source.

For the three migration pathways and for the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, if an observed release or observed exposure can be established for the pathway (or component, threat, aquifer, or watershed, as appropriate), assign the pathway (or component, threat, aquifer, or watershed) an observed release or observed exposure factor value of 550 and proceed to section 7.2. If an observed release or observed exposure cannot be established, assign an observed release or observed exposure factor value of 0 and proceed to section 7.1.2.

For the soil exposure component of the soil exposure and subsurface intrusion pathway, if observed contamination can be established, assign the likelihood of exposure factor for resident population a value of 550 if there is an area of observed contamination in one or more locations listed in section 5.1.1; evaluate the likelihood of exposure factor for nearby population as specified in section 5.1.2.1; and proceed to section 7.2. If observed contamination cannot be established, do not evaluate the soil exposure component of the soil exposure and subsurface intrusion pathway.

At sites containing mixed radioactive and other hazardous substances, evaluate observed release (or component, observed contamination or observed exposure) separately for radionuclides as described in this section and for other hazardous substances as described in sections 2 through 6.

For the three migration pathways and the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, if an observed release or observed exposure can be established based on either radionuclides or other hazardous substances, or both, assign the pathway (or threat, aquifer, or watershed) an observed release or observed exposure factor value of 550 and proceed to section 7.2. If an observed release or observed exposure cannot be established based on either radionuclides or other hazardous substances, assign an observed release or observed exposure factor value of 0 and proceed to section 7.1.2.

For the soil exposure component of the soil exposure and subsurface intrusion pathway, if observed contamination can be established based on either radionuclides or other hazardous substances, or both, assign the likelihood of exposure factor for resident population a value of 550 if there is an area of observed contamination in one or more locations listed in section 5.1.1; evaluate the likelihood of exposure factor for nearby population as specified in section 5.1.2.1; and proceed to section 7.2. If observed contamination cannot be established based on either radionuclides or other hazardous substances, do not evaluate the soil exposure component of the soil exposure and subsurface intrusion pathway.

7.1.2 Potential to release/potential for exposure. For the three migration pathways and the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, evaluate potential to release or potential for exposure for sites containing radionuclides in the same manner as specified for sites containing other hazardous substances. Base the evaluation on the physical and chemical properties of the radionuclides, not on their level of radioactivity. For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, if the potential for exposure is based on the presence of gamma emitting radioactive substances, assign a potential for exposure factor value of 500 only if the contamination is found within 2 feet beneath a regularly occupied structure, otherwise assign a potential for exposure factor value of 0.

For sites containing mixed radioactive and other hazardous substances, evaluate potential to release or potential for exposure considering radionuclides and other hazardous substances together. Evaluate potential to release for each migration pathway and the potential for exposure for the subsurface intrusion component of the soil exposure and subsurface intrusion pathway as specified in sections 3 through 6, as appropriate.

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7.2.1 Human Toxicity. For radioactive substances, evaluate the human toxicity factor as specified below, not as specified in section 2.4.1.1.

Assign human toxicity factor values to those radionuclides available to the pathway based on quantitative dose-response parameters for cancer risks as follows:

• Evaluate radionuclides only on the basis of carcinogenicity and assign all radionuclides to weight-of-evidence category A, or weight-of-evidence category ''Carcinogenic to Humans''.

• Assign a human toxicity factor value from Table 7–2 to each radionuclide based on its slope factor (also referred to as a cancer potency factor).

—For each radionuclide, use the higher of the slope factors for inhalation and ingestion to assign the factor value.

—If only one slope factor is available for the radionuclide use it to assign the toxicity factor value.

—If no slope factor is available for the radionuclide, assign that radionuclide a toxicity factor value of 0 and use other radionuclides for which a slope factor is available to evaluate the pathway.

• If all radionuclides available to a particular pathway are assigned a human toxicity factor value of 0 (that is, no slope factor is available for all the radionuclides), use a default human toxicity factor value of 1,000 as the human toxicity factor value for all radionuclides available to the pathway.

At sites containing mixed radioactive and other hazardous substances, evaluate the toxicity factor separately for the radioactive and other hazardous substances and assign each a separate toxicity factor value. This applies regardless of whether the radioactive and other hazardous substances are physically separated, combined chemically, or simply mixed together. Assign toxicity factor values to the radionuclides as specified above and to the other hazardous substances as specified in section 2.4.1.1.

At sites containing mixed radioactive and other hazardous substances, if all radionuclides available to a particular pathway are assigned a human toxicity factor value of 0, use a default human toxicity factor value of 1,000 for all those radionuclides even if nonradioactive hazardous substances available to the pathway are assigned human toxicity factor values greater than 0. Similarly, if all nonradioactive hazardous substances available to the pathway are assigned a human toxicity factor value of 0, use a default human toxicity factor value of 100 for all these nonradioactive hazardous substances even if radionuclides available to the pathway are assigned human toxicity factor values greater than 0.

* * * * *

7.2.3 *Persistence/Degradation.* In determining the surface water persistence factor for radionuclides, evaluate this factor based solely on half-life; do not include sorption to sediments in the evaluation as is done for nonradioactive hazardous substances. Assign a persistence factor value from Table 4–10 (section 4.1.2.2.1.2) to each radionuclide based on half-life ($t_{1/2}$) calculated as follows:

$$t_{1/2} = \frac{1}{\frac{1}{r}+\frac{1}{v}}$$

Where:

r = Radioactive half-life.

V = Volatilization half-life.

If the volatilization half-life cannot be estimated for a radionuclide from available data, delete it from the equation. Select the portion of Table 4–10 to use in assigning the persistence factor value as specified in section 4.1.2.2.1.2.

At sites containing mixed radioactive and other hazardous substances, evaluate the persistence factor separately for each radionuclide and for each nonradioactive hazardous substance, even if the available data indicate that they are combined chemically. Assign a persistence factor value to each radionuclide as specified in this section and to each nonradioactive hazardous substance as specified in section 4.1.2.2.1.2. When combined chemically, assign a single persistence factor value based on the higher of the two values assigned (individually) to the radioactive and nonradioactive components.

In determining the subsurface intrusion degradation factor for radionuclides, when evaluating this factor based solely on half-life, assign a degradation factor value from section 5.2.1.2.1.2 to each radionuclide based on half-life ($t_{1/2}$) calculated as follows:

$$t_{1/2} = \frac{1}{\frac{1}{r}}$$

Where:

r=Radioactive half-life.

If no radioactive half-life information is available for a radionuclide and the substance is not already assigned a value of 1, unless information indicates otherwise, assign a value of 1.

At sites containing mixed radioactive and other hazardous substances, evaluate the degradation factor separately for each radionuclide and for each nonradioactive hazardous substance, even if the available data indicate that they are combined chemically. Assign a degradation factor value to each radionuclide as specified in this section and to each nonradioactive hazardous substance as specified in section 5.2.1.2.1.2. If no radioactive half-life information is available for a radionuclide and the substance is not already assigned a value of 1, unless information indicates otherwise, assign a value of 1. Similarly, if no half-life information is available for a nonradioactive substance, and the substance is not already assigned a value of 1, unless information indicates otherwise, assign a value of 1. When combined chemically, assign a single persistence or degradation factor value based on the higher of the two values assigned (individually) to the radioactive and nonradioactive components.

7.2.4 *Selection of substance potentially posing greatest hazard.* For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway and each migration pathway (or threat, aquifer, or watershed, as appropriate), select the radioactive substance or nonradioactive hazardous substance that potentially poses the greatest hazard based on its toxicity factor value, combined with the applicable mobility, persistence, degradation and/or bioaccumulation (or ecosystem bioaccumulation) potential factor values. Combine these factor values as specified in sections 2 through 6. For the soil exposure component of the soil exposure and subsurface intrusion pathway, base the selection on the toxicity factor alone (see sections 2 and 5).

* * * * *

7.2.5.1 *Source hazardous waste quantity for radionuclides.* For each migration pathway, assign a source hazardous waste quantity value to each source having a containment factor value greater than 0 for the pathway being evaluated. For the soil exposure component of the soil exposure and subsurface intrusion pathway, assign a source hazardous waste quantity value to each area of observed contamination, as applicable to the threat being evaluated. For the subsurface intrusion component, assign a source hazardous waste quantity value to each regularly occupied structure located within areas of observed exposure or areas of subsurface contamination. Allocate hazardous substances and hazardous wastestreams to specific sources (or areas of observed contamination, areas of observed exposure or areas of subsurface contamination) as specified in sections 2.4.2 and 5.2.0.

7.2.5.1.1 *Radionuclide constituent quantity (Tier A).* Evaluate radionuclide constituent quantity for each source (or area of observed contamination or area of observed exposure) based on the activity content of the radionuclides allocated to the source (or area of observed contamination or area of observed exposure) as follows:

• Estimate the net activity content (in curies) for the source (or area of observed contamination or area of observed exposure) based on:

—Manifests, or

—Either of the following equations, as applicable:

$$N = 9.1x10^{-7}(V)\sum_{i=1}^{n} AC_i$$

Where:

N=Estimated net activity content (in curies) for the source (or area of observed contamination or area of observed exposure).

V=Total volume of material (in cubic yards) in a source (or area of observed contamination or area of observed exposure) containing radionuclides.

AC_i=Activity concentration above the respective background concentration (in pCi/g) for each radionuclide i allocated to the source (or area of observed contamination or area of observed exposure).

n=Number of radionuclides allocated to the source (or area of observed contamination or area of observed exposure) above the respective background concentrations.

or,

$$N = 3.8x10^{-12}(V)\sum_{i=1}^{n} AC_i$$

Where:

N=Estimated net activity content (in curies) for the source (or area of observed contamination or area of observed exposure).

V=Total volume of material (in gallons) in a source (or area of observed contamination or area of observed exposure) containing radionuclides.

AC_i=Activity concentration above the respective background concentration (in pCi/1) for each radionuclide i allocated to the source (or area of observed contamination or area of observed exposure).

n=Number of radionuclides allocated to the source (or area of observed contamination or area of observed exposure) above the respective background concentrations.

—Estimate volume for the source (or volume for the area of observed contamination or area of observed exposure) based on records or measurements.

—For the soil exposure component of the soil exposure and subsurface intrusion pathway, in estimating the volume for areas of observed contamination, do not include more than the first 2 feet of depth, except: for those types of areas of observed contamination listed in Tier C of Table 5–2 (section 5.1.1.2.2), include the entire depth, not just that within 2 feet of the surface.

—For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, in estimating the volume for areas of observed exposure, only use the volume of air in the regularly occupied structures where observed exposure has been documented.

• Convert from curies of radionuclides to equivalent pounds of nonradioactive hazardous substances by multiplying the activity estimate for the source (or area of observed contamination or area of observed exposure) by 1,000.

• Assign this resulting product as the radionuclide constituent quantity value for the source (or area of observed contamination or area of observed exposure).

If the radionuclide constituent quantity for the source (or area of observed contamination or area of observed exposure) is adequately determined (that is, the total activity of all radionuclides in the source and releases from the source [or in the area of observed contamination or area of observed exposure] is known or is estimated with reasonable confidence), do not evaluate the radionuclide wastestream quantity measure in section 7.2.5.1.2. Instead, assign radionuclide wastestream quantity a value of 0 and proceed to section 7.2.5.1.3. If the radionuclide constituent quantity is not adequately determined, assign the source (or area of observed contamination or area of observed exposure) a value for radionuclide constituent quantity based on the available data and proceed to section 7.2.5.1.2.

7.2.5.1.2 Radionuclide wastestream quantity (Tier B). Evaluate radionuclide wastestream quantity for the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination) based on the activity content of radionuclide wastestreams allocated to the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination) as follows:

• Estimate the total volume (in cubic yards or in gallons) of wastestreams containing radionuclides allocated to the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination).

• Divide the volume in cubic yards by 0.55 (or the volume in gallons by 110) to convert to the activity content expressed in terms of equivalent pounds of nonradioactive hazardous substances.

• Assign the resulting value as the radionuclide wastestream quantity value for the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination).

• For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, estimate the total wastestream volume for all regularly occupied structures that have a containment value >0 and that are located within areas of observed exposure with observed or inferred intrusion, and

within areas of subsurface contamination. Calculate the volume of each regularly occupied structure based on actual data. If unknown, use a ceiling height of 8 feet.

7.2.5.1.3 Calculation of source hazardous waste quantity value for radionuclides. Select the higher of the values assigned to the source (or area of observed contamination, area of observed exposure, and/or area of subsurface contamination) for radionuclide constituent quantity and radionuclide wastestream quantity. Assign this value as the source hazardous waste quantity value for the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination). Do not round to the nearest integer.

7.2.5.2 Calculation of hazardous waste quantity factor value for radionuclides. Sum the source hazardous waste quantity values assigned to all sources (or areas of observed contamination, areas of observed exposure, or areas of subsurface contamination) for the pathway being evaluated and round this sum to the nearest integer, except: if the sum is greater than 0, but less than 1, round it to 1. Based on this value, select a hazardous waste quantity factor value for this pathway from Table 2–6 (section 2.4.2.2).

For a migration pathway, if the radionuclide constituent quantity is adequately determined (see section 7.2.5.1.1) for all sources (or all portions of sources and releases remaining after a removal action), assign the value from Table 2–6 as the hazardous waste quantity factor value for the pathway. If the radionuclide constituent quantity is not adequately determined for one or more sources (or one or more portions of sources or releases remaining after a removal action), assign a factor value as follows:

• If any target for that migration pathway is subject to Level I or Level II concentrations (see section 7.3), assign either the value from Table 2–6 or a value of 100, whichever is greater, as the hazardous waste quantity factor value for that pathway.

• If none of the targets for that pathway is subject to Level I or Level II concentrations, assign a factor value as follows:

—If there has been no removal action, assign either the value from Table 2–6 or a value of 10, whichever is greater, as the hazardous waste quantity factor value for that pathway.

—If there has been a removal action:

▪ Determine values from Table 2–6 with and without consideration of the removal action.

▪ If the value that would be assigned from Table 2–6 without consideration of the removal action would be 100 or greater, assign either the value from Table 2–6 with consideration of the removal action or a value of 100, whichever is greater, as the hazardous waste quantity factor value for the pathway.

▪ If the value that would be assigned from Table 2–6 without consideration of the removal action would be less than 100, assign a value of 10 as the hazardous waste quantity factor value for the pathway.

For the soil exposure component of the soil exposure and subsurface intrusion pathway, if the radionuclide constituent quantity is adequately determined for all areas of observed contamination, assign the value from Table 2–6 as the hazardous waste quantity factor value. If the radionuclide constituent quantity is not adequately determined for one or more areas of observed contamination, assign either the value from Table 2–6 or a value of 10, whichever is greater, as the hazardous waste quantity factor value.

For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, if the radionuclide constituent quantity is adequately determined for all areas of observed exposure, assign the value from Table 2–6 as the hazardous waste quantity factor value. If the radionuclide constituent quantity is not adequately determined for one or more areas of observed exposure, assign either the value from Table 2–6 or a value of 10, whichever is greater, as the hazardous waste quantity factor value.

7.2.5.3 Calculation of hazardous waste quantity factor value for sites containing mixed radioactive and other hazardous substances. For each source (or area of observed contamination, area of observed exposure, or area of subsurface contamination) containing mixed radioactive and other hazardous substances, calculate two source hazardous waste quantity values—one based on radionuclides as specified in sections 7.2.5.1 through 7.2.5.1.3 and the other based on the nonradioactive hazardous substances as specified in sections 2.4.2.1 through 2.4.2.1.5, and sections 5.1.1.2.2, 5.1.2.2.2 and 5.2.1.2.2 (that is, determine each value as if the other type of substance was not present). Sum the two values to determine a combined source hazardous waste quantity value for the source (or area of observed contamination, area of observed exposure, or area of subsurface contamination). Do not round this value to the nearest integer.

Use this combined source hazardous waste quantity value to calculate the hazardous waste quantity factor value for the pathway as specified in section 2.4.2.2, except: if either the hazardous constituent quantity or the radionuclide constituent quantity, or both, are not adequately determined for one or more sources (or one or more portions of sources or releases remaining after a removal action) or for one or more areas of observed contamination or areas of observed exposure, as applicable, assign the value from Table 2–6 or the default value applicable for the pathway, whichever is greater, as the hazardous waste quantity factor value for the pathway.

7.3 Targets. For radioactive substances, evaluate the targets factor category as specified in section 2.5 and sections 3 through 6, except: Establish Level I and Level II concentrations at sampling locations as specified in sections 7.3.1 and 7.3.2 and establish weighting factors for populations associated with an area of subsurface contamination in the subsurface intrusion component of the soil exposure and subsurface intrusion pathway as specified in section 7.3.3.

For all pathways (components and threats), use the same target distance limits for sites containing radioactive substances as is specified in sections 3 through 6 for sites containing nonradioactive hazardous substances. At sites containing mixed radioactive and other hazardous substances, include all sources (or areas of observed contamination, areas of observed exposure, or areas of subsurface contamination) at the site in identifying the applicable targets for the pathway.

7.3.1 *Level of contamination at a sampling location.* Determine whether Level I or Level II concentrations apply at a sampling location (and thus to the associated targets) as follows:

• Select the benchmarks from section 7.3.2 applicable to the pathway (or component or threat) being evaluated.

• Compare the concentrations of radionuclides in the sample (or comparable samples) to their benchmark concentrations for the pathway (or component or threat) as specified in section 7.3.2. Treat comparable samples as specified in section 2.5.1.

• Determine which level applies based on this comparison.

• If none of the radionuclides eligible to be evaluated for the sampling location have an applicable benchmark, assign Level II to the actual contamination at that sampling location for the pathway (or component or threat).

• In making the comparison, consider only those samples, and only those radionuclides in the sample, that meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway, except: Tissue samples from aquatic human food chain organisms may also be used for the human food chain threat of the surface water pathway as specified in sections 4.1.3.3 and 4.2.3.3.

7.3.2 *Comparison to benchmarks.* Use the following media specific benchmarks (expressed in activity units, for example, pCi/l for water, pCi/kg for soil and for aquatic human food chain organisms, and pCi/m3 for air) for making the comparisons for the indicated pathway (or threat):

• Maximum Contaminant Levels (MCLs)—ground water migration pathway and drinking water threat in surface water migration pathway.

• Uranium Mill Tailings Radiation Control Act (UMTRCA) standards—soil exposure component of the soil exposure and subsurface intrusion pathway only.

• Screening concentration for cancer corresponding to that concentration that corresponds to the 10^{-6} individual cancer risk for inhalation exposures (air migration pathway and subsurface intrusion component of the soil exposure and subsurface intrusion pathway) or for oral exposures (ground water migration pathway; drinking water or human food chain threats in surface water migration pathway; and soil exposure and subsurface intrusion pathway).

—For the soil exposure component of the soil exposure and subsurface intrusion pathway, include two screening concentrations for cancer—one for ingestion of surface materials and one for external radiation exposures from gamma-emitting radionuclides in surface materials.

Select the benchmark(s) applicable to the pathway (component or threat) being

evaluated. Compare the concentration of each radionuclide from the sampling location to its benchmark concentration(s) for that pathway (component or threat). Use only those samples and only those radionuclides in the sample that meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway, except: Tissue samples from aquatic human food chain organisms may be used as specified in sections 4.1.3.3 and 4.2.3.3. If the concentration of any applicable radionuclide from any sample equals or exceeds its benchmark concentration, consider the sampling location to be subject to Level I concentrations for that pathway (component or threat). If more than one benchmark applies to the radionuclide, assign Level I if the radionuclide concentration equals or exceeds the lowest applicable benchmark concentration. In addition, for the soil exposure and subsurface intrusion pathway, assign Level I concentrations at the sampling location if measured gamma radiation exposure rates equal or exceed 2 times the background level (see section 7.1.1).

If no radionuclide individually equals or exceeds its benchmark concentration, but more than one radionuclide either meets the criteria for an observed release (or observed contamination or observed exposure) for the sample or is eligible to be evaluated for a tissue sample (see sections 4.1.3.3 and 4.2.3.3), calculate a value for index I for these radionuclides as specified in section 2.5.2. If I equals or exceeds 1, assign Level I to the sampling location. If I is less than 1, assign Level II.

At sites containing mixed radioactive and other hazardous substances, establish the level of contamination for each sampling location considering radioactive substances and nonradioactive hazardous substances separately. Compare the concentration of each radionuclide and each nonradioactive hazardous substance from the sampling location to its respective benchmark concentration(s). Use only those samples and only those substances in the sample that meet the criteria for an observed release (or observed contamination or observed exposure) for the pathway except: Tissue samples from aquatic human food chain organisms may be used as specified in sections 4.1.3.3 and 4.2.3.3. If the concentration of one or more applicable radionuclides or other hazardous substances from any sample equals or exceeds its benchmark concentration, consider the sampling location to be subject to Level I concentrations. If more than one benchmark applies to a radionuclide or other hazardous substance, assign Level I if the concentration of the radionuclide or other hazardous substance equals or exceeds its lowest applicable benchmark concentration.

If no radionuclide or other hazardous substance individually exceed a benchmark concentration, but more than one radionuclide or other hazardous substance either meets the criteria for an observed release (or observed contamination or observed exposure) for the sample or is eligible to be evaluated for a tissue sample, calculate an index I for both types of substances as specified in section 2.5.2. Sum the index I values for the two types of substances. If the value, individually or combined, equals or exceeds 1, assign Level I to the sample location. If it is less than 1, calculate an index J for the nonradioactive hazardous substances as specified in section 2.5.2. If J equals or exceeds 1, assign Level I to the sampling location. If J is less than 1, assign Level II.

7.3.3 Weighting of targets within an area of subsurface contamination. For the subsurface intrusion component of the soil exposure and subsurface intrusion pathway, assign a weighting factor as specified in section 5.2.1.3.2.3 except when a structure in an area of subsurface contamination is delineated or inferred to be delineated by gamma radiation exposure rates meeting observed release criteria with a depth to contamination of 2 feet or less. For those populations residing, working, or attending school or day care in a structure delineated or inferred to be delineated by gamma radiation exposure rates meeting observed release criteria with a depth to contamination of 2 feet or less, assign a weighting factor of 0.9.

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Part IV

Architectural and Transportation Barriers Compliance Board

36 CFR Part 1195

Standards for Accessible Medical Diagnostic Equipment; Final Rule

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1195

RIN 3014–AA40

Standards for Accessible Medical Diagnostic Equipment

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Final rule.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) is issuing accessibility standards for medical diagnostic equipment. The standards for medical diagnostic equipment (MDE Standards) contain minimum technical criteria to ensure that medical diagnostic equipment, including but not limited to, examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment used by health care providers for diagnostic purposes are accessible to, and usable by, individuals with disabilities. The MDE Standards will allow independent entry to, use of, and exit from the equipment by individuals with disabilities to the maximum extent possible. The MDE Standards do not impose any mandatory requirements on health care providers or medical device manufacturers. However, other agencies, referred to as enforcing authorities in the MDE Standards, may issue regulations or adopt policies that require health care providers subject to their jurisdiction to acquire accessible medical diagnostic equipment that complies with the MDE Standards.

DATES: The final rule is effective February 8, 2017.

FOR FURTHER INFORMATION CONTACT: Earlene Sesker, U.S. Access Board, 1331 F Street NW., Suite 1000, Washington, DC 20004–1111. Telephone numbers: 202–272–0022 (voice) or 202–272–0091 (TTY). Email address: *sesker@access-board.gov.* Or Rex Pace, U.S. Access Board, 1331 F Street NW., Suite 1000, Washington, DC 20004–1111. Telephone numbers: 202–272–0023 (voice) or 202–272–0050 (TTY). Email address: *pace@access-board.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Legal Authority

The Access Board is an independent federal agency established by Section 502 of the Rehabilitation Act (29 U.S.C. 792). The Access Board is responsible for developing accessibility guidelines and standards under various laws to ensure that individuals with disabilities have access to and use of buildings and facilities, transportation vehicles, and information and communication technology. Pursuant to these laws, other federal agencies have adopted the Access Board's guidelines and standards as mandatory requirements for entities subject to their jurisdiction.

On March 23, 2010, Section 4203 of the Patient Protection and Affordable Care Act (ACA) amended Title V of the Rehabilitation Act, which established the rights and protections for individuals with disabilities, by adding Section 510. Public Law 111–148, 124 Stat. 570). Section 510 of the Rehabilitation Act charges the Access Board, in consultation with the Commissioner of the Food and Drug Administration, with issuing standards that set forth the minimum technical criteria to ensure that medical diagnostic equipment (diagnostic equipment) used in (or in conjunction with) ''physician's offices, clinics, emergency rooms, hospitals, and other medical settings, is accessible to, and usable by, individuals with accessibility needs, and shall allow independent entry to, use of, and exit from the equipment by such individuals to the maximum extent possible.'' 29 U.S.C. 794f.

The statute gives examples of diagnostic equipment, including ''examination tables, examination chairs (including chairs used for eye examinations or procedures, and dental examinations or procedures), weight scales, mammography equipment, x-ray machines, and other radiological equipment commonly used for diagnostic purposes by health professionals.'' 29 U.S.C. 794f. This list is not considered exhaustive, but is illustrative of types of medical diagnostic equipment.

Section 510 of the Rehabilitation Act instructs the Access Board to promulgate technical standards regarding accessibility of medical diagnostic equipment, but does not give the Access Board authority to enforce these standards. Compliance with the MDE Standards becomes mandatory only when an enforcing authority adopts the MDE Standards as mandatory for entities subject to its jurisdiction. Additionally, the enforcing agencies will determine the application and scope of these standards, such as who must comply and the extent to which medical diagnostic equipment used by covered entities must comply with these MDE Standards. As discussed below, the U.S. Department of Justice (DOJ) may adopt the MDE Standards as mandatory requirements for health care providers pursuant to its authority under Titles II and III of the Americans with Disabilities Act. Other federal agencies may adopt the standards as mandatory requirements for health care providers pursuant to their authority under Section 504 of the Rehabilitation Act.

Private parties, including individuals with disabilities, have also entered into settlement agreements with health care providers to enforce the ADA and Section 504 of the Rehabilitation Act.

The Commissioner of the Food and Drug Administration designated the Director of the Center for Devices and Radiological Health (FDA–CDRH) to consult with the Access Board on the development of the MDE Standards. The Access Board has worked throughout the process with the FDA–CDRH in developing these Standards.

B. Summary of Major Provisions and Organization of Technical Criteria

The Access Board has divided the MDE Standards into separate technical criteria based on how the diagnostic equipment is used by the patient: (1) Supine, prone, or side lying position (M301); (2) seated position (M302); (3) while seated in a wheelchair (M303); and (4) standing position (M304). For each category the Access Board has provided technical criteria to allow independent access to and ensure the diagnostic equipment was usable by patients with disabilities to the maximum extent possible. The technical requirements for diagnostic equipment used by patients in the supine, prone, or side-lying position and diagnostic equipment used by patients in the seated position focus on ensuring the patient can transfer from a mobility device onto the diagnostic equipment. The other two categories, M303 and M304, focus on the necessary technical requirements to allow the patient to use the diagnostic equipment while seated in their wheeled mobility device, or while standing, respectively.

The MDE Standards also include technical criteria for supports (M305), for instructions or other information communicated to patients through the equipment (M306), and for operable parts used by patients (M307).

C. Costs and Benefits

The MDE Standards are advisory and are not binding until adopted by an enforcing authority. The Access Board's mandate was to establish only the minimum technical criteria, however enforcing authorities may establish scoping requirements in the future. As

such, the final rule does not directly impose any obligations on health care providers or medical device manufacturers. Only when another federal agency, through separate rulemaking, adopts the MDE Standards (in whole or in part) as mandatory for entities under its jurisdiction, will compliance be required. At this point, the Access Board does not know whether enforcing authorities will adopt the MDE Standards, nor (if they do) to what extent health care practices or particular types of medical diagnostic equipment will be required to comply with the Standards' technical requirements. For this reason, the Board cannot estimate the incremental monetary or quantitative impacts of the final rule.

Nevertheless, the Board is able to characterize qualitatively some of the potential impacts of these Standards. If enforcing agencies adopt the MDE Standards as mandatory for entities regulated under their jurisdiction, the Standards could affect health care providers, medical device manufacturers, and individuals with disabilities. Once health care providers and facilities are required to acquire accessible medical equipment, they could incur compliance costs, to the extent that their equipment is not already accessible. Medical device manufacturers would then decide whether to incur incremental costs to meet the demand for accessible equipment, and some or many manufacturers may have an economic incentive to produce accessible equipment. Finally, given the many barriers to health care that patients with mobility and communication disabilities encounter due to inaccessible medical diagnostic equipment, individuals with disabilities will benefit from access to and use of diagnostic equipment meeting the MDE Standards. Consequently, they may be able to receive health care comparable to that received by their non-disabled counterparts.

In addition, the Standards could yield some immediate benefits, even before any adoption by implementing agencies in formal rulemaking. First, the technical specifications for accessible MDE incorporated in the Standards will benefit enforcing agencies that are considering similar accessibility requirements for entities under their jurisdiction. Although enforcing agencies have full authority over whether to adopt the Access Board's final rule (in whole or in part), the technical specifications in the MDE Standards reflect the input from a diverse set of stakeholders and provide solid groundwork for any future rulemaking pertaining to the accessibility of medical diagnostic equipment. Second, the Standards will serve as a best-practice document for the medical device industry and for health care providers and facilities. While the MDE Standards are non-binding, health care providers can use this final rule as guidance on how to provide equitable access to medical diagnostic equipment for people with mobility and communication disabilities. Manufacturers can also use the MDE Standards as they target their research and development efforts at producing diagnostic equipment that can be used by a larger segment of population—one that includes more people with disability and older adults.

The Board thus concludes that the potential benefits of the MDE Standards justify its potential costs; that the MDE Standards will impose the least burden on society, consistent with achieving the regulatory objectives; and that the regulatory approach selected will maximize net benefits.

II. Rulemaking History

Section 510 of the Rehabilitation Act requires the Access Board to issue standards for medical diagnostic equipment to ensure such equipment is accessible to, and usable by, individuals with disabilities no later than 24 months after the date of the enactment of the ACA. 29 U.S.C 794f.[1] On July 29, 2010, after the Rehabilitation Act was amended, the Access Board held a public meeting that featured panel discussions and presentations by experts and researchers on medical equipment accessibility, health care providers, medical device manufacturers, and other interested parties to provide information for developing the proposed standards. The transcript of the meeting is available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/background/public-information-meeting.*

On February 9, 2012, the Access Board formally commenced the rulemaking process and issued a notice of proposed rulemaking proposing accessibility standards for medical diagnostic equipment. Notice of Proposed Rulemaking—Medical Diagnostic Equipment Accessibility Standards, 77 FR 6916 (February 9, 2012) (hereinafter MDE NPRM). The proposed standards contained minimum technical criteria to ensure that medical diagnostic equipment, including, but not limited to, examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment used by health care providers for diagnostic purpose is accessible to, and usable by, individuals with disabilities. *Id.* The Access Board held two public hearings during the comment period, March 14, 2012 in Washington, DC and May 8, 2012 in Atlanta, GA. At the public hearings, 27 witnesses presented testimony regarding the need for accessibility standards for medical diagnostic equipment, the difficulty of obtaining health care for persons with disabilities, the current state of medical equipment and, the ability of medical diagnostic equipment to meet the proposed standards. The transcripts of the public meetings are available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

The public comment period for the proposed rule ended on June 6, 2012. Comments were submitted by persons with disabilities, governmental agencies, disability rights organizations, and representatives of the medical diagnostic equipment industry and the medical community. In all, 59 comments were received; twenty-four from individuals, thirteen from the medical diagnostic equipment industry and the medical community, nine from disability rights organizations, four from accessibility consultants, three from academics, two from state and federal organizations, and four duplicate submissions. The public comments are available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

On March 13, 2012, the Access Board published a notice of intent to establish an advisory committee to advise the Board on matters addressed in the MDE NPRM and issues raised in the public comments. Notice of Intent to Establish Advisory Committee—Medical Diagnostic Equipment Accessibility Standards, 77 FR 14706 (March 13, 2012). On July 5, 2012, the Access Board established the Medical Diagnostic Equipment Accessibility Standards Advisory Committee (MDE Advisory Committee). Notice of Establishment; Appointment of Members—Medical Diagnostic Equipment Accessibility Standards Advisory Committee, 77 FR 39656 (July 5, 2012). The MDE Advisory Committee was comprised of individuals from 24 organizations representing a range of stakeholders and ex officio members from the FDA, Department of Justice, and the

[1] Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 570 (2010).

Department of Veterans Affairs.[2] The MDE Advisory Committee met from September 2012 through May 2013 and much of the work occurred within five subcommittees that addressed the major categories of MDE and the issues raised by commenters: Examination Tables and Chairs; Stretchers; Diagnostic Imaging Equipment; Mammography Equipment; and Weight Scales. In June 2013, the MDE Advisory Committee presented 54 recommendations to the Access Board. The committee members reached a consensus on all of their recommendations, except for the recommended lowest or minimum height for adjustable-height transfer surfaces. The MDE Advisory Committee made recommendations regarding transfer surface height, transfer surface size, transfer sides, transfer supports, armrests, stirrups, lift compatibility, wheelchair spaces, and standing supports. The final report of the Medical Diagnostic Equipment Accessibility Standards Advisory Committee (December 6, 2013), is available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report* (hereinafter, MDE Advisory Committee Report).

III. Summary of Comments

In all 60 comments were received; the comments are available at: *https://www.regulations.gov/docket?D=ATBCB-2012-0003.* Overall the comments provided detailed responses to the questions posed in the preamble to the MDE NPRM. They provided many alternatives and recommended changes to the proposed requirements, which are discussed throughout this preamble. The disability rights organizations generally supported the proposed rule and recommended multiple ways to increase accessibility. The manufacturers provided a great deal of information on what types of accessible equipment is currently on the market, what the providers are requesting for accessible equipment, and the limitations of certain diagnostic equipment in meeting some of the requirements in the proposed standards. Most of these comments and recommendations are discussed below in the Significant Changes and the Section-by-Section Analysis. In addition, some commenters also raised concerns with the accessibility of diagnostic equipment to providers who have disabilities, weight and patient load, the need for training of staff on how to properly assist patients with disabilities, and requirements to ensure the room is accessible. While valid and important issues about accessibility, most of these concerns are outside the purview of the Access Board as they relate to issues unrelated to the equipment itself or the built environment, and therefore, have not been addressed by the MDE Standards.

In the preamble to the MDE NPRM, the Access Board identified the following barriers to accessibility, as documented in the Rehabilitation Engineering Research Center on Accessible Medical Instrument National Survey,[3] including equipment characteristics that affect patients ability to access and use medical equipment, such as: Dimensions of the equipment (*e.g.,* height, width, length,) contact surfaces (*e.g.,* stiffness, comfort, color contrast), supports for transferring onto and off of equipment and positioning their bodies on the equipment (*e.g.,* handholds, armrests, side rails), controls (*e.g.,* ease of operation), and displays and devices (*e.g.,* legibility and understandability). The Access Board sought public input on what other barriers affect the accessibility and usability of medical diagnostic equipment. NPRM, 77 FR at 6919, question 2. Nine commenters responded (two manufacturers, four accessibility consultants, three disability rights organizations, and an individual) and provided examples of additional barriers that they believe should be addressed in future updates of the MDE Standards. These recommendations included the accessibility of offices of healthcare providers, user positioning, communication, device operation, feature controls, compatibility of medical diagnostic equipment with assistive technology, weight capacity, and adding space to accommodate a patient's durable medical equipment. Additionally, the commenters noted that the proposed standards focused mostly on individuals with mobility disabilities and recommended providing standards to encompass individuals with autism, Alzheimer's, sensory disabilities, cognitive disabilities, and bariatric patients.

The technical criteria in the final rule addresses most of the barriers that were identified in the study as affecting the accessibility and usability of medical diagnostic equipment. However, at this time it is not possible for the MDE Standards to address every barrier. The Access Board is very interested in the additional barriers raised by public commenters and believes that further research is needed on some of the recommendations; such as equipment characteristics of stiffness, comfort, and color contrast of contact surfaces, and ensuring the accessibility of people with sensory and cognitive disabilities, and pediatric and bariatric patients. Section 510 of the Rehabilitation Act requires the Access Board to periodically review and amend the standards, as appropriate. The Access Board will address other barriers in future updates to the MDE Standards.

Additionally, commenters noted other areas of medical diagnostic equipment and issues of patient accessibility and recommended multiple changes or additions to the final rule. Specifically, commenters recommended adding weight capacity or patient load requirements, ensuring that the room is accessible, developing a manner to evaluate and measure the accessibility of equipment to give to patients, requiring staff training on how to use accessible equipment and how to provide assistance to people with disabilities, and requiring patient support surfaces. Based on the Access Board's review of these issues, many of the commenters concerns are outside the scope of this rulemaking but are issues that may be addressed by enforcing authorities when they provide scoping and application requirements in adopting the MDE Standards. Additionally, the Board may elect to address the accessibility of examination rooms and other spaces containing diagnostic equipment under its authority to develop guidelines for buildings and facilities subject to the ADA and ABA. The other issues of weight capacity and patient support surfaces will be added to the additional barriers list above, and considered for inclusion when the MDE Standards are updated.

The Access Board received nine comments asserting that figures help the reader to better understand the technical

[2] The ADA National Network, Boston Center for Independent Living, Brewer Company, Conference of Radiation Control Program Directors, Inc., Duke University and Medical Center, Equal Rights Center, Evan Terry Associates, P.C., GE Healthcare, Harris Family Center for Disability and Health Policy at Western University of Health Sciences, Hausmann Industries, Inc., Hill-Rom Company, Inc., Hologic, Inc., Medical Positioning, Inc., Medical Technology Industries, Inc., Midmark Corporation, National Council on Independent Living, Paralyzed Veterans of America, Phillips Healthcare, Scale-Tronix, Inc., Siemens Medical Solutions USA, Inc., Stryker Medical, Sutter Health, United Spinal Association, and University of the Sciences in Philadelphia, Department of Occupational Therapy. 77 FR 39656.

[3] This survey was conducted in 2004 to collect information on the types of medical equipment that is most difficult for individuals with disabilities to access and use. The results of the focus group sessions are reported in Molly Follette Story, Erin Schwier, and June Issacson Kailes, ''Perspectives of Patients with Disabilities on the Accessibility of Medical Equipment: Examination Tables, Imaging Equipment, Medical Chairs, and Weight Scales,'' Disability and Health Journal 2 (2009), 169–179.

criteria; these commenters recommended some minor changes to the advisory figures and strongly supported the usefulness of the figures. The Office of the Federal Register does not permit advisory materials to be published in the Code of Federal Regulations. Consequently, as the figures are advisory, only the version of the final rule posted on the Access Board's Web site will include advisory text and figures. The online version of the final rule, as well as other materials related to this rulemaking, can be found here *http://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking.*

IV. Significant Changes to the MDE NPRM

This section of the preamble addresses significant changes made from the MDE NPRM to the final rule in response to the comments received, recommendations from the MDE Advisory Committee, and other information that has come to the Access Board's attention during the rulemaking process. Individual provisions of the rule are discussed in detail under the Section-by-Section Analysis below.

A. Chapter 2: M201 Scoping

In the final rule, Chapter 2 establishes that the enforcing authority will determine the number and types of diagnostic equipment to which the MDE Standards will apply. There was only one significant change to this section, which added a general exception for diagnostic equipment that is unable to meet one or more of the requirements in the final rule.

1. General Exception

The MDE NPRM proposed several limited exceptions to certain provisions addressing the limitations of current technology and design. Through testimony at the public hearings, comments, and MDE Advisory Committee discussions, the manufacturers of imaging equipment consistently raised concerns about inherent barriers to compliance with the proposed MDE Standards due to the location of imaging and mechanical components necessary to achieve the diagnostic aims. Some specific examples include: Dual Energy X-Ray Absorptiometry (DXA) machines, with a mechanism that moves imaging components along a track beneath the patient surface precluding height adjustability for the transfer surface; prone biopsy tables that must be of a sufficient height to permit health care providers access beneath the patient surface to perform procedures, precluding the equipment from meeting the minimum transfer surface height; and mammography machines with low dose radiation detectors that are larger in size than conventional configurations and required to be in locations that partially obstruct clearances for knee and toe space beneath the breast platform. While the MDE NPRM proposed several specific technical exceptions in Chapter 3, the exceptions did not address the manufacturers' overall concerns regarding imaging equipment. Section 510 of the Rehabilitation Act requires the MDE Standards to provide independent access ''to the maximum extent possible.'' The Access Board interprets this language as recognizing that, in some situations, current technology may preclude diagnostic equipment from meeting all of the technical requirements in the MDE Standards. Therefore, the Access Board has added a general exception to Chapter 2 allowing compliance to the maximum extent practicable for the rare circumstance where full compliance would alter diagnostically required structural or operational characteristics of the equipment, and would prevent the use of the equipment for its intended diagnostic purpose. Any equipment utilizing this exception is still required to meet all other applicable provisions of the MDE Standards. We anticipate that this exception will be employed on a very limited basis for a few specialized equipment types, primarily imaging equipment. This provision is not intended to exempt a piece of diagnostic equipment from the MDE Standards as a whole. Limitations resulting from existing equipment designs or manufacturing practices that could be altered to meet the requirements are not a basis for invoking this exception; only diagnostically required structural or operational characteristics that cannot be made to comply with the technical requirements without preventing the use of the equipment for its intended diagnostic purpose are covered by this provision.

B. M301 Diagnostic Equipment Used by Patients in a Supine, Prone, or Side-Lying Position and M302 Diagnostic Equipment Used by Patients in a Seated Position

In the final rule M301 and M302 provide the technical requirements for diagnostic equipment used in the supine, prone, or side-lying position, and diagnostic equipment used by patients in the seated position. Sections M301 and M302, which ensure that patients can transfer from their mobility devices onto the diagnostic equipment, share many technical requirements. Therefore, the Significant Changes Section addresses the transfer surface and lift compatibility requirements for M301 and M302 together. New exceptions pertaining to weight scales and to the type of equipment that must comply with M301 and the decision to remove the armrest requirements from M302, are also discussed below.

1. Transfer Surface

a. Transfer Surface Adjustability

The MDE NPRM proposed that the same transfer surface height range of 17 inches minimum to 19 inches maximum be applied to both diagnostic equipment used in the supine, prone, or side-lying position and diagnostic equipment used in the seated position (proposed M301.2.1 and M302.2.1, respectively). The Board considered it likely that diagnostic equipment would be adjustable in height to serve practitioners' needs however, the transfer surface could be fixed within the proposed height range. The Access Board sought public comment in the MDE NPRM preamble on whether the final standards should require the height of the transfer surface to be adjustable from 17 inches minimum to 25 inches maximum. NPRM, 77 FR at 6922–6933, questions 13 and 14. The majority of commenters, including manufacturers and disability advocates, supported both an adjustability requirement and the proposed high transfer height, but disagreed on what should be the low transfer height.

The MDE Advisory Committee recommended a high transfer height of at least 25 inches and recommended that the transfer surface be adjustable in small, virtually continuous increments. MDE Advisory Committee Report, 67–71, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* However, the MDE Advisory Committee did not achieve consensus on what should be the minimum low height. *Id.*

After considering the public comments and the recommendations from the MDE Advisory Committee, the Access Board has decided to include in the final rule the following requirements for diagnostic equipment used in the supine, prone or side-lying position, and for diagnostic equipment used in the seated position: An adjustable transfer height range with a minimum high and low height; four intermediate transfer heights within the adjustable range; and a specific method to measure the transfer heights. These new

requirements are incorporated into the transfer height provision for diagnostic equipment used in the supine, prone, or side-lying position, and for diagnostic equipment used in the seated position, in the final rule (M301.2.1 and M302.2.1, respectively). These provisions have been renamed ''Adjustability,'' and are discussed in detail below.

(1) Adjustability: Minimum High Transfer Height

In the preamble to the MDE NPRM, the Access Board sought comment in question 14 on whether the final rule should require an adjustable height range of 17 inches to 25 inches; whether equipment currently met this proposed requirement and, if not, what would the cost be to achieve that range; and whether intermediate heights should also be required within the adjustable height range. NPRM, 77 FR at 6923. While 20 commenters responded to question 14, only four commenters explicitly addressed the proposed minimum high height of 25 inches. Of these, two commenters (an accessibility consultant and a state agency concerned with accessibility) concurred with a minimum high height of 25 inches. One commenter, a manufacturer, recommended increasing the minimum high height to 28 inches for all diagnostic equipment except magnetic resonance imaging (MRI) equipment, which has limitations that may prevent it from reaching 28 inches. Another manufacturer gave examples of the height ranges of its beds and stretchers, each of which met the 25-inch minimum high height.

After reviewing the comments and other evidence before it, the MDE Advisory Committee recommended a high transfer height requirement of 25 inches noting that:

> [t]he anthropometric data referenced . . . in the Wheeled Mobility Anthropometry Project shows seat heights for people who use mobility devices are above 19 inches. For manual wheelchair user's seats measured up to 23.9 inches; for power wheelchair users up to 28.9 inches; and for scooter users to 25.3 inches. Seat heights for males were typically higher than for females. All the male manual wheelchair users and 92 percent of the male power wheelchair users had seat heights equal to or less than 25 inches. Therefore, transfer surfaces that are adjustable to a 25-inch maximum during patient transfer accommodate most patients who use mobility devices. Since one key factor in ease of transfer is locating the transfer surface near or at the same height as the seat of the wheeled mobility device, moving the minimum high point for adjustability of transfer surfaces, improves access for many. This particularly benefits persons using powered mobility devices and scooters with higher seat heights.

MDE Advisory Committee Report, 69, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board was persuaded by the arguments of commenters and the MDE Advisory Committee in favor of requiring a minimum high transfer surface height of 25 inches. A 25-inch minimum high height will ensure that the transfer surface can be raised up to the height of the vast majority of wheelchair seat heights, which are 25 inches high or lower. The final rule requires a minimum high transfer surface height of 25 inches for both diagnostic equipment used in the supine, prone or side-lying position (M301.2.1), as well as diagnostic equipment used in the seated position (M302.2.1). Nothing in the rule prohibits a manufacturer from providing a high transfer height above 25 inches as long as transfer is provided within the range specified up to 25 inches.

(2) Adjustability: Minimum Low Transfer Height

The Access Board received many comments from disability rights organizations, individuals, accessibility consultants, and a health care provider supporting the need for lower height adjustable tables. Specifically, these commenters explained the need for adjustable height tables to facilitate and promote independent or semi-independent transfer. These commenters explained the delay in diagnosis and treatment when patients are unable to transfer from their wheeled mobility device to the examination surface and are inadequately examined while remaining in their wheelchair. These commenters also explained that adjustable tables would enhance both the safety of patients, by reducing the risk of falls and injury incurred from assisted transfer, as well as reducing injury to medical staff and caregivers by lessening the likelihood of back and other lifting injuries. One individual commenter recalled being bruised when she was dragged onto medical equipment that was too high, while another commenter noted that the risk to healthcare workers increases when access to medical diagnostic equipment is not optimized.

In addressing what the low transfer height should be, 12 commenters responded to question 14 specifically addressing the proposed minimum low transfer surface height. Six commenters (an individual, a state agency concerned with accessibility, two accessibility consultants and two disability rights advocates, one whose comment was supported by 50 disability rights organizations) supported requiring a low transfer height of 17 inches. These commenters asserted that the lower height would provide more accessibility, safety for both patients and healthcare providers, and allow more patients to transfer independently or semi-independently. One commenter, a medical association, supported allowing a minimum low height range of 17 to 19 inches recommending as much latitude for manufacturers as possible. The remaining six commenters (manufacturers and a medical association) voiced strong concerns about the cost of complying with a minimum low height of 17 inches, the potential consequences of being unable to raise the equipment up to a height comfortable for practitioners, and whether current technology and designs would allow diagnostic equipment to reach such a low height. Additionally, some of the manufacturers and medical associations voicing support for a minimum low height of 19 inches, indicated that either their equipment currently meets or would be capable of meeting a 19-inch low height requirement.

Like the public commenters, the MDE Advisory Committee was divided on this issue and was unable to reach consensus regarding a minimum low transfer surface height. MDE Advisory Committee Report, 70, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Individual Committee members' recommendations for a low transfer surface height requirement were split across three options: 17 inches, 18 inches (viewed as compromise to some and a preferred minimum height by others), and 19 inches. *Id.* at 139–143. The Committee devoted considerable time to examining available evidence, consulting experts, and discussing the merits of the three height options. *Id.* Additionally, the Examination Tables and Chairs Subcommittee held six meetings, discussed this issue in-depth, and developed a Subcommittee recommendation for the MDE Advisory Committee of 19 inches as the minimum transfer surface height standard, with 17 inches as the ''best practice.'' *Id.* The MDE Advisory Committee members heard presentations from several clinicians and manufacturers on the topic of minimum transfer surface

height.[4] Advisory Committee members also considered a presentation from Edward Steinfeld, ArchD on the findings from the Anthropometry of Wheeled Mobility Project, which was conducted at the Center for Inclusive Design and Environmental Access (IDeA) at the State University of New York at Buffalo.[5] *Id.*

After careful consideration of the available information, the MDE Advisory Committee was unable to agree upon a recommendation for a transfer surface height, and Committee members were invited to submit minority reports supporting their view of the issue.[6] The MDE Advisory Committee Report states that ''[a] full reading of these Minority Reports is critical to understanding the range of views guiding the various stakeholder organizations that served on the MDE Advisory Committee about the recommendation for the minimum transfer height.'' *Id.* at 143. (The minority reports are available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports*).

The minority reports submitted by the disability advocates and academics supported a minimum low height of 17 inches. *See* Minority Reports from Boston Center for Independent Living Inc., National Network for ADA Centers, and Medical Diagnostic Equipment Advisory Committee,[7] available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* These minority reports explained the importance of accessible care and of ensuring as many independent transfers as possible. *Id.* The reports noted that both patients and providers risk injuring themselves during assisted transfer. *Id.* In their reports, disability advocates and academics asserted that a 17-inch low height provides the greatest number of individuals the opportunity to transfer independently. *Id.* Additionally, the reports pointed to current accessibility standards for toilet seats, shower seats, and tub seats, which require a height of 17 inches minimum and 19 inches maximum. *Id.* These reports argued that if the MDE Standards moved away from this range, then the Access Board must adopt the lowest end of the range, 17 inches, to provide the most accessibility. *Id.* Additionally, the National Council on Independent Living asserted that:

> Most manufacturers on the Committee had a 19 to 21-inch surface available currently, with at least one having a product at 18. Their argument has always been that providing the lowest transfer heights would be an extraordinary expense and burden on the business community (their consumer), not based on how it benefitted a patient with a disability. This effort was never supposed to be about the manufacturers or the doctors. It is the charge of this committee to answer questions and come up with recommendations for accessibility, based by some members on engineering and others by experience. NCIL's 30-plus years of experience as advocates for people with disabilities dictates that we continue to strongly insist that the U.S. Access Board maintain the low accessible height at 17 inches above the floor in order for medical and diagnostic equipment to be accessed by the greatest number of people.

Minority Report from National Council on Independent Living (Sept. 27, 2013), available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.*

The minority reports submitted by manufacturers supported a minimum low height of 19 inches. *See* Minority Reports from Hologic, Inc., Midmark Corporation, MITA Advisory Committee Members,[8] and Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report),[9] available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* Similar to the minority reports supporting a minimum low height of 17 inches, these minority reports relied on the existing accessibility standards, such as those for shower seats, tub seats, amusement park rides, toilets, and benches. However, unlike the minority reports from members supporting a minimum 17-inch low height, these reports asserted that because 19 inches is a permissible transfer height under existing accessibility standards, it is similarly acceptable for medical diagnostic equipment. The manufacturers also noted that currently there are not any accessible diagnostic tables on the market that meet a 17-inch low height requirement. The Brewer Company, LLC stated that:

> Brewer has been manufacturing adjustable height examination tables since 2002. These tables were designed specifically for wheelchair accessibility by meeting the 19-inch height referenced in the ADA/ABA Accessibility Guidelines. Brewer is ISO 13485 certified. ISO requires a robust method for recording customer, end user, and clinician feedback. In the 11 years we have been selling adjustable height examination tables we do not have a single complaint on record regarding the accessibility of our 19″ low height tables. There have been no

[4] Clinician presenters included Barbara Ridley, RN, FNP, Cathy Ellis, PT, Medical Diagnostic Equipment; Michael Yochelson, MD, Medical Diagnostic Equipment; Lauren Snowden, PT, DPT, Practitioner Perspective on Transfers to Examination Services; Nuket Curran, PT, Diagnostic Equipment & Patient Accessibility: Closing the ''Gap''; Douglas Coldwell, MD, Medical Imaging; Theresa Branham, RT, ARRT, Technologist Perspective to Patient Access. MDE Advisory Committee Report, 141–142, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Manufacturer presenters included Willa Crolius, Institute of Human Centered Design, No Formal Presentation, presented videos showing transfer; Michelle Lustrino, Mechanical Engineer, Hologic, Inc., Mammography Industry: Accessibility Standards; Glen Nygard, Senior Principal Engineer, Hologic, Inc., Dual-Energy X-ray Absorptiometry (DXA) for Osteoporosis Assessment; Elisabeth George, Vice President of Global Regulations & Standards Chair of Technical and Regulatory Affairs Committee, Phillips Healthcare, Medical Imaging; John Jaeckle, Chief Regulatory Affairs Strategist Chair of CT-Xray Committee, GE Healthcare, MITA, & John Metellus, Product Marketing Manager, Siemens Healthcare, Equipment with Bores and X-ray Devices Accessibility; Bob Menke & John Wells, Midmark Corporation, Examination Table Accessibility Standards; Jeff Baker, Brad Baker, & Darren Walters, Medical Technology Industries, Inc., Performance and Efficacy Considerations for Examination Chairs. Id.

[5] The Access Board and the National Institute on Disability and Rehabilitation Research sponsored the Wheeled Mobility Anthropometry Project to collect measurements of approximately 500 people using a variety of mobility devices, including manual wheelchairs, power wheelchairs, and scooters. The Wheeled Mobility Anthropometry Project was conducted by the Center for Inclusive Design and Environmental Access. The final report on the Wheeled Mobility Anthropometry Project was issued in 2010 and is available at *http://www.udeworld.com/anthropometrics.html.*

[6] The Committee Members who submitted minority reports includes: Boston Center for Independent Living; The ADA National Network; Brewer Company; Duke University and Medical Center; Equal Rights Center; Harris Family Center for Disability and Health Policy at Western University of Health Sciences; Hausmann Industries, Inc.; Hologic, Inc.; Medical Technology Industries, Inc.; Midmark Corporation; National Council on Independent Living; Paralyzed Veterans of America; Phillips Healthcare; Siemens Medical Solutions USA, Inc.; United Spinal Association; University of the Sciences in Philadelphia. The Minority Reports are available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.*

[7] Endorsed by Harris Family Center for Disability and Health Policy at Western University of Health Sciences, The ADA National Network, Equal Rights Center, National Council on Independent Living, Paralyzed Veterans of America, United Spinal Association, Duke University and Health System, and University of the Sciences in Philadelphia, Department of Occupational Therapy.

[8] Joint Report prepared by medical diagnostic imaging equipment industry members of the MDE Advisory committee, including GE Healthcare, Phillips Healthcare, Siemens Healthcare, and Hologic, Inc.

[9] Submitted by The Brewer Company, Hausmann Industries, Medical Technology Industries, Inc., and Midmark Corporation.

requests for a lower table. In addition, market growth of the adjustable height tables with 19 inch low heights provides further evidence that these tables are meeting the accessibility needs of patients requiring independent wheelchair transfer.

Minority Report from The Brewer Company, LLC (Oct. 1, 2013), available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* The exam table manufacturers asserted that they would incur costs to comply with a 17-inch low height, but would not incur costs to comply with a 19-inch low height requirement. *See* Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report) (Sept. 27, 2013), available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports* (characterizing a table with a 19-inch transfer height as a ''baseline 0%'' cost increase for ''accessible equipment as currently available on the market'').

In their joint minority report, examination table manufacturers asserted, ''Based on our analysis, we determined that transfer surface height requirements lower than 19 inches would increase the cost of designing and manufacturing examination tables, reduce the rate of adoption of accessible equipment, and increase the health provider's cost of purchasing accessible equipment.'' *Id.*

With respect to the cost of compliance for the tables on imaging equipment, some manufacturers noted the inherent difficulty of redesign, the potential cascading impacts of adopting a low height of 17 inches, and the difficulty in that imaging equipment undergoes many years of work before they become commercially available. *See* Minority Report of GE Healthcare, Phillips Healthcare, Siemens Healthcare, and Hologic, Inc., available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report/appendix-a-minority-reports.* Specifically, the imaging equipment manufacturers asserted that:

given the integrated nature of the table to the system and its imaging performance, that a change of even a few inches in minimum transfer surface low height constitutes a significant engineering change to the device. Any such change must ensure there are no adverse effects to image quality, system performance, and patient safety. Complete scanner re-testing and re-certification under our formal FDA quality system and design controls are needed to verify overall system performance and safety.

Moreover, the most significant of these design changes can result in cascading alterations to the scanner, potentially leading to unacceptable heating in the case of MR, impacts on image signal/quality, and changes in dose levels to ensure the same, effective, high quality images and increased examination times, that is, additional workflow steps.

Id.

After carefully considering the totality of comments received and the MDE Advisory Committee materials, the Access Board has concluded that there is insufficient information to designate a single minimum low height requirement at this time. Specifically, there is insufficient data on the extent to which and how many individuals would benefit from a transfer height lower than 19 inches. Due to this lack of sufficient information, coupled with the lack of consensus among the MDE Advisory Committee and the commenters, the Access Board has decided to establish, for five years only, a range for the minimum low height requirement of 17 inches to 19 inches. During the five-year period following issuance of the final rule, any low transfer height between 17 and 19 inches will meet the MDE Standards. The Access Board acknowledges that this is a temporary solution, and has commissioned a study to quantify the portion of the population that would benefit from a low transfer height below 19 inches. A pilot study was completed prior to the publication of this final rule. A sunset provision has been included in the final rule that will repeal this low height range five years after the date of publication in the **Federal Register**, leaving only the requirements for the high transfer height and the additional transfer positions below the high transfer height. The Access Board intends to amend this portion of the final rule with a subsequent rulemaking to establish a minimum low transfer surface height once the study has been completed and before the sunset provision takes effect.

(3) Adjustability: Transfer Surface Intermediate Heights

In the MDE NPRM there was no requirement for the transfer surface to have intermediate transfer heights. Under the proposed rule, diagnostic equipment would be in compliance if it provided a low transfer height anywhere within the range of 17 inches minimum and 19 inches maximum. In addition to the matter of low transfer height, the Access Board sought public comment in question 14(c) on whether the final rule should require intermediate heights between a minimum low transfer height and a minimum high transfer height. NPRM, 77 FR at 6923. Three commenters responded (two accessibility consultants and a disability rights advocate) and supported the idea of requiring intermediate heights within a minimum low height and minimum high height of the transfer surface. One commenter, an accessibility consultant, recommended intervals of ½ to 1 inch, indicating that ½ inch increments would be more practical to match the varying heights of wheelchairs and mobility devices, which is critical for many patients in performing independent transfers. The MDE Advisory Committee recommended adjustable height in small, virtually continuous increments. To support this recommendation, the MDE Advisory Committee explained:

that adjustability greatly increases the overall accessibility of equipment for all persons. Adjustable height MDE, such as exam tables, imaging tables and chairs, will make it possible to position the transfer surface near the height of the seat of the mobility device. For some, independent transfers are only possible when there is minimal or no change in vertical height between the seat of the mobility device and the transfer surface. People may prefer or, in some cases, require, transfer to a slightly lower surface moving the transfer surface lower than the seat of the mobility device; then adjusting the transfer surface to above the seat for the return transfer. MDE Advisory Committee Report, 68, available at *https://www.access-board/guidelines-and-standardshealth-/about-this-rulemaking/advisory-committee-final-report.*

The Access Board has decided to require that the height of the transfer surface be adjustable within the range for the minimum low and high heights in at least four unspecified intermediate heights, but has determined that the intermediate heights should be set a minimum of one inch apart. While the Access Board agrees that continuous adjustment is preferable, requiring such adjustability could preclude the use of certain types of lifting devices such as hydraulic systems that work in increments. The intent is to permit manufacturers flexibility in setting intermediate heights and not prohibitively restrict designs to those of particular manufacturers or equipment.

(4) Adjustability: Method of Measurement

The MDE NPRM proposed that the measurement of the height of the transfer surface for both diagnostic equipment used in the supine, prone, or side-lying position and diagnostic equipment used in the seated position, be taken from the floor to the top of the transfer surface (proposed M301.2.1 and M302.2.1, respectively). The Access

Board sought comment in question 13 in the MDE NPRM preamble, on whether the measurement should be taken with the upholstery in static (uncompressed) conditions, or with a certain amount of deflection. NPRM, 77 FR at 6922. The Access Board received eleven comments in response, most of which agreed with measuring the transfer surface in a static condition. A few commenters disagreed: One manufacturer recommended measuring in static conditions, but allowing a ¾ inch bolster in no more than 25 percent of the short side of the transfer surface to be permitted to be outside the height requirement; two commenters (medical association and manufacturer) asserted that the method of measurement should be dependent on the type of diagnostic equipment and left up to the manufacturers; and two commenters (state agency concerned with accessibility and accessibility consultant) recommended that the transfer surface meet the criteria in both dynamic and static conditions. The MDE Advisory Committee concurred with those comments recommending that the measurement be made with the upholstery in a static condition to ensure a consistent point of measurement. The MDE Advisory Committee explained that ''[s]ince many transfer surfaces are not perfectly flat, measuring to the highest point in an uncompressed state provides this consistent point of measurement.'' MDE Advisory Committee Report, 71, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Access Board agrees with the Advisory Committee's rationale and the final rule requires that the height be measured from the floor to the top of the uncompressed transfer surface. This method will ensure consistent measurement across all diagnostic equipment. Taking the measurement at the highest point on the transfer surface allows for small bolsters or contours and does not significantly increase the overall height of the transfer for people with disabilities.

b. Transfer Surface Location

The MDE NPRM proposed the same location and transfer sides of the transfer surface for diagnostic equipment used by patients in the supine, prone, or side-lying position (M301) and diagnostic equipment used by patients in the seated position (M302). This transfer surface was located at the end of the diagnostic equipment and provided options to transfer from a mobility device onto one short side and one long side of the transfer surface. (proposed M301.2.3 and M302.2.3, respectively). Numerous commenters objected on the basis that this type of transfer is not always possible for certain types of medical diagnostic equipment; the MDE Advisory Committee agreed with commenter concerns. The Access Board is persuaded by many of the concerns raised by commenters and the MDE Advisory Committee. In the final rule the structure and content of the transfer surface provision has been revised for diagnostic equipment used by patients in the supine, prone, or side-lying positions to provide two types of transfer surfaces; end transfer surfaces and side transfer surfaces. For diagnostic equipment used by patients in the seated position, the Access Board has decided to retain the proposed rule requirements for transfer surface location and transfer sides, but has added an exception to the transfer sides provision in the final rule to address the concerns raised by commenters and the MDE Advisory Committee.

(1) Transfer Surface Location for Diagnostic Equipment Used in the Supine, Prone, or Side-Lying Position

Multiple commenters expressed concerns that transfer cannot always occur at the end of the diagnostic equipment as contemplated by the requirements in the proposed rule. One commenter elaborated that stretchers and hospital beds are always entered from one or the other long side of the bed, not the foot end, due to obstructions at the head and foot ends that cannot be removed. Another commenter recommended allowing transfer space at both the center and the end of the transfer surface.

Evidence presented to the MDE Advisory Committee during its deliberations revealed that it is not always possible to transfer from adjoining sides at the end of the diagnostic equipment in the prone, supine, or side-lying position on certain types of equipment such as stretchers and imaging equipment with scanning beds. MDE Advisory Committee Report, 75–82, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* This is because many models of this equipment can be obstructed on the head or foot ends by necessary components such as emergency extraction handles, the gantry design, or integral patient positioning features. *Id.* For equipment with long patient examination surfaces such as stretchers and the scanning beds of many types of imaging machines, the foot end is not intended as a transfer point; patients transfer onto the surface on either of the long sides, approaching the equipment more towards the center. *Id.* Additionally, a transfer approach at the foot location may not be practical for many people with disabilities who would have to move themselves or be moved across a significant length of the surface to place their bodies into a position for effective imaging. *Id.* The MDE Advisory Committee recommended permitting an alternative transfer surface which was rotated in its orientation such that the width paralleled the examination surface's length and its depth spanned the examination surface's width, and was located near the center point of the diagnostic equipment surface. *Id.*

Based on the comments received and the MDE Advisory Committee recommendations, the Access Board has concluded that for diagnostic equipment used by patients in supine, prone, or side-lying positions two transfer surface orientations are possible depending on the intended location from which the transfer is to be made. These orientations are now identified as an end transfer surface and side transfer surface. This necessitated adding the definition of ''end transfer surface'' and ''side transfer surface'' to the defined terms (M102.1) in the final rule and resulted in the removal of the proposed M301.2.3 Transfer Sides, as that is now described within the two types of transfer surfaces provided. The end transfer surface accommodates the transfer method conceived of in the proposed rule; where the transfer occurs at one end of the examination surface and allows the patient the option to transfer at the end and on one adjoining side of the examination surface. The side transfer surface responds to the concerns raised by commenters and the MDE Advisory Committee to accommodate diagnostic equipment where transfer occurs within the length of the examination surface and allows patient transfer at the sides of the examination surface. Side transfer surfaces most typically will be imaging equipment, stretchers, hospital beds, and other equipment where the end is obstructed and cannot be used for transfer. Accordingly, the Access Board has reorganized the requirements regarding the transfer surface for M301 into two types based on where the transfer is to occur: ''End Transfer'' or ''Side Transfer.'' This revision to provide options for two types of transfer surfaces necessitated adding additional technical criteria addressing transfer surface size (M301.2.3) and transfer supports (M305.2), as well as adding the

definition of ''end transfer surface'' and ''side transfer surface'' to the defined terms (M102.1) in the final rule. These new requirements are addressed below in the applicable section in the Section-by-Section Analysis.

(2) Transfer Surface Location for Diagnostic Equipment Used in the Seated Position

Commenters also raised concerns with the provisions in the MDE NPRM related to transferring to medical diagnostic equipment used by patients in the seated position. Commenters stated that there is certain diagnostic equipment used by patients in the seated position where transfer at the end of the seat by two adjoining sides is not feasible. Specifically, commenters raised concerns about diagnostic equipment with fixed footrests, such as podiatry and dentistry chairs. Transfer onto these types of diagnostic equipment must be made from either long side, similar to the side transfer surface described above. One commenter explained that fixed footrest chairs are meant to treat patients with their legs extended parallel to the ground. If entered as suggested in the proposed rule the patient would have to enter the chair by positioning themselves onto this fixed footrest section that is at a downward angle and would require the patient to slide up an inclined surface to be properly positioned on the diagnostic equipment.

The MDE Advisory Committee agreed with a majority of the commenters that some examination chairs which have fixed footrests prevent transfer as conceived of in the proposed rule. The Committee noted that:

> the footrests obstruct access to the foot end of the chair. Examples of chairs that fit this category are most dental chairs and podiatry chairs. The current design allows only one long side for transfer, which limits some patient transfers where a patient can use only one side of the body due to paralysis on one side or other such conditions. To address this issue, the recommendation requires chairs with footrest obstructions to allow patient transfers from both [long] sides of the chair. The solution creates the option for either a left or right transfer. MDE Advisory Committee Report, 83, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board agrees that diagnostic equipment used by patients in the seated position with fixed footrests requires a different transfer approach than those without fixed footrests. Therefore, the Access Board has added an exception to the transfer sides provision (M302.2.4) in the final rule to permit diagnostic equipment with fixed footrests to provide options to transfer from opposing sides of the transfer surface.

The American Dental Association proposed a complete exemption of dental chairs from the MDE Standards, asserting that the Access Board has not provided any evidence that dental offices are inaccessible, citing to the national survey in MDE NPRM ''that collected information on the types of medical equipment that are most difficult for individuals with disabilities to access and use. The American Dental Association urge[d] the Access Board to refrain from proposing costly new requirements based on examination chairs that are only 'moderately difficult' for disabled patients to use.'' The American Dental Association explains that ''dental chairs already have many accessibility features built in and manufacturers as well as health care providers have an economic incentive to produce and procure accessible medical diagnostic equipment and therefore, the American Dental Association does not believe that additional regulations are necessary, particularly with respect to dental examination chairs.'' Comment of American Dental Association, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (Apr. 4, 2012), available at *https://www.regulations.gov/document?D=ATBCB-2012-0003-0037.*

The Access Board does not concur with the comment urging that dental chairs should receive a blanket exemption. The record is replete with evidence that individuals with disabilities do encounter barriers to dental care as a result of inaccessible dental chairs. For example, one commenter, a disability rights organization representing 37,000 members, explained that it asked its members ''and others with disabilities about the barriers they encounter when seeking medical care and treatment. The most frequent responses involved access to examination chairs, dentist chairs, scales and mammography and colonoscopy equipment.'' Comment of United Spinal Association, Notice of Proposed Rulemaking for Medical Diagnostic Equipment, (June 4, 2012), available at *https://www.regulations.gov/document?D=ATBCB-2012-0003-0029.* Additionally, at the public hearing on May 8, 2012, a commenter raised concerns about the ability to obtain dental care when unable to transfer onto the dental chair. The public hearing transcript is available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.* Accordingly, the Access Board has concluded that dental chairs are appropriately covered by this rule.

c. Transfer Surface Size for Diagnostic Equipment Used by Patients in the Supine, Prone, or Side-Lying Position

The MDE NPRM proposed a transfer surface size for diagnostic equipment used in the supine, prone, or side-lying position of 30 inches wide and 15 inches deep minimum (proposed M301.2.2). These dimensions were based on the dimensions specified in the 2004 ADA and ABA Accessibility Guidelines for rectangular seats in roll-in showers (36 CFR part 1191, App. D 610.3.1) and the ANSI/AAMI HE 75 which notes that a standard examination table is 27 inches wide and a bariatric table is approximately 30 to 32 inches wide and recommends wider surfaces to make repositioning easier. ANSI/AAMI HE 75, section 16.4.7, available at *http://www.aami.org/he75.* The Access Board sought input in question 15 in the MDE NPRM preamble on whether this size transfer surface was sufficient to effectuate transfer. NPRM, 77 FR at 6923–6924. Of the 12 commenters who responded, only two supported the transfer surface size in the proposed rule. Four of the remaining commenters (manufacturers) felt that the transfer surface width should be decreased, while five (disability rights organizations, a medical association, and an individual) believed a larger surface was needed. The last commenter, recommended one size transfer surface for both seated and supine, prone, or side-lying diagnostic equipment. Commenter recommendations for transfer surface width ranged from 24 inches to 36 inches, while no commenters addressed the proposed depth of 15 inches. Those advocating for a larger width were concerned about the ability of the patient to reposition after transfer and about accommodating obese patients. Those commenters supporting a smaller transfer surface raised concerns about the ability to transfer with a large surface preventing the patient from reaching transfer supports on the opposite side of the transfer surface, while still seated in the wheeled mobility device. The commenters were also concerned that making existing tables comply would require entire base redesigns as product stability would have to be re-evaluated with a wider table. Commenters also raised concerns that a larger transfer surface would conflict with bore size limitations on imaging equipment and that it could limit the health care provider's access to the patient for proper exam. Finally, two commenters, in response to question

15(e), agreed that an adjustable feature such as an extendable platform, should be permitted to meet the transfer surface dimensions so long as it does not move when a load is applied and it is a permanent part of the device.

The MDE Advisory Committee discussions mirrored the comments to the MDE NPRM with recommendations ranging from 24 inches to 36 inches for the width of the transfer surface. The MDE Advisory Committee reviewed evidence about transfer surface size to include: Numerous video clips showing various transfers (both assisted and unassisted); industry exhibited tables to show current table and chair widths; and the findings of the Wheeled Mobility Anthropometry Project presented by Dr. Edward Steinfeld of the IDeA Center at the University of Buffalo. MDE Advisory Committee Report, 72–76, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Wheeled Mobility Anthropometry Project provided an analysis of transfer surface dimensions based on data collected from the study. The study is available at *http://www.udeworld.com/anthropometrics.html.* The data indicated that the minimum width of a table transfer surface could be as narrow as 28 inches and still accommodate 95 percent of the users sampled. *Id.* Some members of the MDE Advisory Committee noted that there was little gain in usability by increasing the transfer surface width from 28 inches to 30 inches, and that the significant gain in usability came from increasing the surface to 36 inches to accommodate very large or obese patients. MDE Advisory Committee Report, 72–76, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* While the committee members expressed concern about the need to provide accessibility criteria for obese patients, it decided that there is insufficient data to determine specific criteria at this time and recommended accessibility for bariatric patients be addressed in a subsequent rulemaking. *Id.* The Access Board concurs with the MDE Advisory Committee that while there is a need to address the accessibility needs of obese patients, more research is necessary before requirements can be developed. The MDE Advisory Committee also noted that if the surface is too wide it can become challenging for smaller sized persons to effectuate transfer, and thus by making all accessible equipment 36 inches wide, some patients would be unable to reach across the table to grasp the transfer support on the other side to utilize the support in the transfer process. *Id.* The MDE Advisory Committee recommended decreasing the required transfer surface width to 28 inches minimum for all diagnostic equipment used by patients in a supine, prone, or side-lying position. *Id.* at 73.

The MDE Advisory Committee made multiple recommendations for the transfer surface depth of diagnostic equipment used by patients in the supine, prone, or side-lying position. *Id.* at 74–76. The MDE Advisory Committee differentiated between equipment whose transfer surface was located on the end of the equipment with transfer sides on one short side and one long side of adjoining sides and stretchers and imaging equipment, which the MDE Advisory Committee noted transfer takes place in the center on either of the long sides. *Id.* For all diagnostic equipment used by patients in a supine, prone, or side-lying position, except imaging equipment, the MDE Advisory Committee recommended increasing the transfer surface depth to 17 inches, explaining that existing equipment already encompasses this dimension. *Id.* The MDE Advisory Committee included stretchers in this requirement, even though they have a transfer orientation akin to imaging equipment. *Id.* For imaging equipment, the MDE Advisory Committee recommended a transfer surface size of 28 inches long minimum by 28 inches deep minimum. The MDE Advisory Committee also recommended the addition of an exception for imaging equipment transfer surface size; to allow a decrease in depth to no less than 21 inches where it is technically infeasible to reach the 28 inches minimum. *Id.* at 75–76. The Committee explained that ''all x-ray tables meet the 28-inch table [depth] . . . because of physical design constraints such as bore size, not all tables used with equipment with bores meet the 28-inch-[deep] criteria, but all meet the 21-inch minimum.'' *Id.*

As discussed above in Section IV.B.1.b (Significant Changes—Transfer Surface Location) the restructure of the transfer surface to include two types of transfer surfaces; end transfer surface and side transfer surface, necessitates new technical requirements for the new side transfer surface. Accordingly, based on the comments received and the recommendations from the MDE Advisory Committee, the final rule establishes different sizes for each of the end and side transfer surfaces. The final rule requires that diagnostic equipment with an end transfer surface be a minimum size of 28 inches wide and 17 inches long. The Access Board has decreased the minimum width of the transfer surface from 30 inches to 28 inches based on the evidence presented to the advisory committee that 28 inches is sufficient to accommodate 95 percent of the users and will ensure that patients are able to utilize the transfer supports on the opposite side of the transfer surface. The Access Board has increased the length of the end transfer surface from 15 inches to 17 inches based on the evidence that diagnostic equipment currently on the market is already built to this dimension. In the final rule, the Access Board does not see a reason to prohibit an adjustable feature, such as a table with extendable sides, from meeting the size requirements of the transfer surface but believes it is unlikely that any diagnostic equipment would contain such a feature.

For diagnostic equipment with side transfer surfaces, the Access Board has decided to require a transfer surface size of 28 inches wide by 28 inches long, minimum. While the MDE Advisory Committee recommended only increasing the transfer surface size for imaging equipment to 28 inches deep by 28 inches wide minimum, the Access Board has concluded that diagnostic equipment used by patients in the supine, prone, or side-lying position with side transfer surfaces involve the same transfer dynamics whether they are imaging equipment, hospital beds, or stretchers and therefore should be subject to the same transfer surface size requirement.

Additionally, the Access Board concurs with the MDE Advisory Committee recommendation to provide an exception for the transfer surface size of imaging equipment in the final rule given the physical limitations affecting surface depth for imaging equipment with bores and the fact that it is unclear when technological advances in bore size may permit larger patient examination surfaces. However, the Access Board has narrowed the application of this exception only to imaging equipment with bores. The Access Board has determined that this exception, as recommended, was intended to account for the space constraints of imaging equipment with bores and wants to ensure the exception stays as narrow as possible. Therefore, in the final rule, the Access Board has provided an exception which permits the imaging bed of imaging equipment with bores' to be a minimum of 21 inches wide but requires the transfer surface to be the full width of the examination surface. As this exception applies regardless of whether the

imaging equipment has an end transfer surface or a side transfer surface, an exception has been added to each requirement (M301.2.3.1 and M301.2.3.2, respectively). Additionally, the Board has added two definitions to the final rule, ''imaging equipment with bores'' and ''imaging bed'' to assist with the application of this exception. (M102.1 final rule).

d. Unobstructed Transfer

The MDE NPRM proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer (proposed M301.2.3 and M302.2.3). As explained in the MDE NPRM preamble, the unobstructed access requirement was to ensure that armrests, side rails, stirrups, or other equipment parts attached to the diagnostic equipment did not impede the patient's ability to transfer. NPRM, 77 FR at 6923. The final rule retains the proposed requirements for unobstructed transfer for diagnostic equipment used in a supine, prone, or side-lying position, as well as diagnostic equipment used in the seated position, and has added a new exception described below.

In the preamble to the MDE NPRM the Access Board noted that it was considering permitting equipment parts to extend a maximum of three inches horizontally beyond the edge of the transfer side. The Access Board explained that ''[t]he 2004 ADA and ABA Accessibility Guidelines provide a gap of 3 inches between the edge of the shower seat and the shower compartment entry, and the gap does not appear to interfere with transferring onto and off of the shower seat.'' NPRM, 77 FR at 6924. The Access Board sought input from the public in the MDE NPRM preamble question 17, on whether equipment parts should be permitted to extend a maximum of three inches horizontally beyond the edge of the transfer sides, provided that they did not extend above the top of the transfer surface. *Id.* Six of the eleven commenters who responded to this question supported permitting equipment parts to extend up to three inches horizontally beyond the edge of the transfer surface. However, these commenters were primarily manufacturers who also expressed concerns about the cost of equipment redesign if a provision permitting the three-inch gap was not included in the final standards. The other five commenters, disability rights advocates and an accessibility consultant, did not support allowing equipment parts to extend up to three inches horizontally, unless they were removable. These commenters raised concerns that the equipment parts would impede transfer. Additionally, a manufacturer, responding to question 9 in the MDE NPRM, explained that all beds, stretchers, and cots have side rails that can be moved to allow unobstructed access for transfer.

The MDE Advisory Committee reviewed the comments. The Committee observed that transfer supports provide handholds that facilitate transfers onto and off of the equipment, and that some types of diagnostic equipment have components that create a gap between the transfer surface and the outer edge of the equipment on the side used for transfer. MDE Advisory Committee Report, 78–82, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee reviewed the 2010 ADA Standards for shower compartment seat requirements, which allows a three-inch gap between the edge of a seat and the shower compartment entry, to determine if these gaps presented a problem to individuals attempting to transfer. The MDE Advisory Committee also considered anthropometric data from the Impact of Transfer Setup on the Performance of Independent Transfers study by the VA Pittsburgh Healthcare System in collaboration with the Human Engineering Research Laboratories at the University of Pittsburgh. *Id.* This study examined the transfer experience with an adjustable height transfer surface. This study is available at *http://herl.pitt.edu/ab/.* The MDE Advisory Committee explained that ''[t]he results showed that 95% of subjects could transfer when the seat and surface are at the same height with a 3.5-inch gap. This data helped inform the recommendation for the exception since the 3-inch criteria is less than that used in the research and should assure effective transfers for most.'' MDE Advisory Committee Report, 79, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended allowing a maximum three-inch obstruction protruding from the transfer sides, ''placing a limit on the size of the gap between the transfer surface and the outer edge of the equipment on the side used for transfer,'' that applies to both the long length (width) and short length (depth) transfer sides. *Id.* The Committee also recommended special consideration for stretchers, to incorporate the provision of IEC 60601–2–52 to establish a maximum vertical obstruction at no less than one inch below the top of the transfer surface. *Id.*

Based on the comments received and the MDE Advisory Committee recommendations, the Access Board is persuaded that a gap of up to three inches between the transfer side and the wheeled mobility device will not impede transfer given that accessible diagnostic equipment will be required to be adjustable. In addition, the Access Board is not persuaded that special consideration for stretchers is necessary in order to accommodate the IEC 60601–2–52 prohibition against vertical obstructions within one inch of the top of the patient surface. The final rule would not permit obstruction above the patient surface; consequently, by meeting the IEC requirements manufacturers will meet the MDE Standards.

Accordingly, the final rule includes an exception permitting obstructions of no more than three inches deep beyond the transfer side of the transfer surface provided that such obstructions do not protrude above the top of the transfer surface. A common example of this type of obstruction is articulating side rails on stretchers that move out of the way during transfer, but create a gap between the transfer surface and the mobility device. The exception allowing obstructions of up to three inches is included in each of the new provisions for unobstructed transfer for diagnostic equipment used in the supine, prone, or side-lying position (M301.2.4), and diagnostic equipment used in the seated position (M302.2.5), as Exception 1.

As noted above, the Access Board has retained the original exception from the MDE NPRM, permitting temporary obstructions provided that they can be repositioned out of the way during transfer. In the final rule, the Board moved this provision to Exception 2 to accommodate the new exception discussed above, and added language to specify that this exception may also apply to obstructions that qualify for Exception 1. For example, side rails that create a gap of three inches from the transfer side of the diagnostic equipment to the mobility device when moved out of the way for transfer, but also protrude above the top of the transfer surface when in place as a side rail.

2. Armrests Requirement

In the MDE NPRM, the Access Board required diagnostic equipment used by patients in the seated position to

provide armrests (proposed M302.3.2). The only commenter that addressed whether armrests should be required was a manufacturer who requested that beds, cots, and stretchers be excluded from the requirements as they are required to have side rails per IEC 60601–2–52. The MDE Advisory Committee addressed the armrest provision during their discussions of transfer supports and explained that ''armrests serve a similar function, and occupy the same physical space as the transfer supports as described in the MDE NPRM. The MDE NPRM requires transfer supports for all chairs, so the additional equipment for armrests for chairs was not only redundant, but could potentially create a physical conflict between the two devices.'' MDE Advisory Committee Report, 104, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended that armrests not be required, but if provided they cannot obstruct transfer supports. Additionally, the Committee noted that transfer supports meeting the final requirements, would provide support like that of armrests and enhance patient stability if left in place after a transfer from a mobility device. *Id.*

After review of the comment and the recommendations of the MDE Advisory Committee, the Access Board is persuaded that requiring armrests as well as transfer supports is redundant and has the potential to cause conflict between the two devices. Therefore, the Access Board has removed the provision requiring armrests from the final rule.

3. Lift Compatibility Exception

The MDE NPRM proposed that diagnostic equipment used by patients in the supine, prone or side-lying position and diagnostic equipment used by patients in the seated position be usable with portable patient lifts. The proposed rule specified base clearance requirements to ensure lift compatibility (M301.4 and M302.4, respectively). The preamble to the MDE NPRM sought comment on whether the final rule should exempt certain diagnostic equipment from these requirements if the equipment was specifically designed to be used with a fixed overhead lift. NPRM, 77 FR at 6927, question 27.

Eleven commenters responded to question 27. Six of the ten commenters (one manufacturer, three medical associations, and two government entities) concurred with the proposed scenario that if equipment was designed for use with overhead lifts then that equipment should be exempted from the proposed base clearance requirements. One commenter, a manufacturer, agreed that equipment designed for use with an overhead lift should be excepted, and also stated that portable floor lifts should be designed to be compatible with exam and procedure tables, not that the tables be redesigned to be compatible with floor lifts. Four of the commenters (three disability rights organizations and an accessibility consultant) were opposed to this exemption and expressed concern that the overhead lift would not be available when needed if the diagnostic equipment was moved to another room or the lift was not functioning. The final commenter, a manufacturer, opposed the exemption unless the overhead lift was included as part of the equipment when sold.

The MDE Advisory Committee reviewed this issue and recommended the use of overhead lifts as an alternative for imaging equipment where portable floor lifts are not feasible. Specifically, the MDE Advisory Committee explained:

> Overhead lifts can provide an alternate means of access instead of clearances around the bases of imaging equipment required for portable lifts. Table structural design and/or room layout may be such that providing the clearances in and around the base may be either technically difficult or impractical. In these cases, a ceiling-mounted lift may be a better method for some types of imaging equipment because the portable lift would need to access the diagnostic imaging table from the side or far end. Some imaging systems already use overhead lifts to assist patients . . . [Overhead lifts] may offer flexibility over a portable lift because it can transfer the patient from either side placing the patient in the desired imaging orientation, and the ability to move completely out of the way when not needed. MDE Advisory Committee Report, 107, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

After review of the comments received and the recommendations from the MDE Advisory Committee, the Access Board has concluded that fixed overhead lifts may be appropriate and even preferred in certain circumstances. However, the Access Board believes that the determination of the circumstances where an exception is warranted and the types of diagnostic equipment that should be excepted from the portable floor lift requirement is more appropriately left to the enforcing authority. Accordingly, the final rule provides a limited exception to the lift compatibility requirements for fixed overhead lifts in situations where: (1) A fixed overhead lift is provided; (2) the diagnostic equipment is clearly labeled as not compatible with portable floor lifts; and (3) the use of the overhead lift with that diagnostic equipment is specifically permitted by the enforcing authority. The exception applies only if all three conditions are met.

4. Exception From the Requirements of M301 for Certain Examination Chairs That Comply With M302

The Access Board proposed in M101.2 in the MDE NPRM to require diagnostic equipment to meet the standards for each patient position supported, meaning that if diagnostic equipment was designed to support a patient in multiple positions then the equipment would have to meet the technical criteria for each of those positions. The Access Board sought public input in question three in the preamble in the MDE NPRM, on whether organizing the technical criteria functionally by patient position was clear. 77 FR at 6919.

Fifteen commenters responded, with only two disability advocates and one medical association agreeing that the division of the MDE Standards was clear. The manufacturers raised concerns about applying the MDE Standards for multiple patient positions to a single piece of equipment. Multiple commenters recommended that when diagnostic equipment that fits in multiple categories, one category should take precedence. Medical Association and Accessibility Consultants recommended reorganizing the standards by types of facilities or by feature and one manufacturer recommended harmonizing M301 and M302 into one requirement. Additionally, commenters raised concerns about diagnostic chairs which could be reclined into a supine position after transfer; such as podiatry and dental chairs. These commenters argued that requiring the equipment to be designed to accommodate transfer in both positions would not achieve any objective benefit and would impose transfer surface width requirements that would not be appropriate and would be overly burdensome. The MDE Advisory Committee did not make a recommendation on this provision. However, the subcommittee for tables and chairs did explain that while the primary function of examination chairs is to support patients in a seated position, they are also capable of being reclined. The ability to recline is a secondary, rather than a primary purpose. The subcommittee asserted that these types of chairs should be covered by M302.

In response to the comments and Advisory Committee discussions, the Access Board acknowledges that one of the most important features of making diagnostic equipment used by patients in either the supine, prone, or side-lying position or the seated position accessible, is to ensure the patient has the opportunity to transfer independently to the maximum extent possible. The Access Board concurs with the commenters that there are certain examination chairs, such as dentistry and podiatry chairs, where the patient is only intended to transfer while the chair is in a seated position but is then reclined into a supine position while the diagnostic procedure is being performed. The Access Board concurs with commenters that in this limited situation it is unnecessary for the examination chair, which complies with the technical requirements in M302, to also have to comply with the technical requirements in M301. Therefore, in the final rule the Access Board has added an exception to M301.1 which states that examination chairs that comply with M302 and, after the patient transfers into the seat, reclines to facilitate diagnosis, do not have to comply with M301. Additionally, the Board has added a new definition for examination chair in M102.1 in the final rule to assist with the application of this exception. The other commenter concerns regarding the proposed application provision, M101.2, are addressed below in the Section-by-Section Analysis.

5. Exception From the Requirements of M302 for Weight Scales With Integral Seats

The MDE NPRM proposed that diagnostic equipment which could be used by patients in multiple positions must comply with the technical criteria for all positions in which it could be used (proposed M101.2). In the preamble in the MDE NPRM the Access Board proposed an exception to this requirement for folding seats on diagnostic equipment used by patients seated in a wheelchair. The MDE NPRM proposed that this type of diagnostic equipment would have to meet the technical requirements of M302 (diagnostic equipment used by patients in the seated position) and M303 (diagnostic equipment used by patients seated in a wheelchair), with the exception of the lift compatibility requirements in M302.4. NPRM, 77 FR at 6927. The Board explained that because the patients can use the equipment while seated in their wheelchairs, the seat does not have to provide the clearance necessary to be usable with a portable floor lift. *Id.*

In the MDE NPRM preamble the Access Board sought comment with two questions, 28 and 37. Question 37 asked whether a folding or removable seat should be required on weight scales for use in the standing position. NPRM, 77 FR at 6930. Four commenters responded: Three concurred (an accessibility consultant, disability rights organization, and a state agency concerned with accessibility); and one commenter (a manufacturer) agreed it should be an option, but not a requirement. Six commenters responded to question 28, which asked whether a folding seat provided on diagnostic equipment with a wheelchair space should be required to comply with the technical criteria in proposed M302 for transfer surfaces and supports. NPRM, 77 FR at 6927. Five of the commenters (three disability rights organizations, a state agency concerned with accessibility, and an accessibility consultant) asserted that if a seat is provided it should have to comply with the technical provisions for diagnostic equipment used by a patient in the seated position. One of these commenters explained that not all people with disabilities who need to transfer are wheelchair users and some wheelchair users may choose to transfer, even if the device is designed for use in a wheelchair. The remaining commenter, a medical association, noted that it was unaware of any diagnostic equipment with a folding seat, but asserted that if patients can use the equipment in wheelchairs, then they should not be transferred onto the folding seat, and the chair should not have to meet the requirements in proposed M302.

The MDE Advisory Committee discussed weight scales, noting the importance of obtaining a patient's weight for medical treatment and the difficulty patients in wheelchairs confront with obtaining an accurate weight. *See* MDE Advisory Committee Report, 66, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* However, the MDE Advisory Committee did not make specific recommendations for requiring a folding seat on diagnostic equipment used in the standing position, nor did it make any specific recommendations for an exception to M302 for seats on weight scales with wheelchair spaces. The Subcommittee on Weight Scales, in explaining its recommendations on size and ramp slope, recognized that ''space constraints are of consideration . . . as medical equipment and adequate space in the acute care or in the medical office setting are often competing. Scales that can be wall mounted or that are portable would facilitate where there are space constraints.'' Subcommittee Report—Weight Scales, 7, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report/appendix-b-supporting-documents.*

After reviewing the comments and the Subcommittee on Weight Scales Report, the Access Board has determined that weight scales that are designed to be used by patients seated in a wheelchair, but also provides a seat integral to the equipment, present a unique situation which warrants an exception to the general provision of M302.1 in the final rule. The primary purpose of the technical requirements for diagnostic equipment used by patients in the seated position is to facilitate independent transfer from a mobility device onto the diagnostic equipment. Some wheelchair accessible scales also provide a seat for patients who ambulate onto the scale, but due to stability or fatigue issues, may need to sit in order to be weighed. On many of these scales the seat folds down into the wheelchair space to accommodate the ambulatory patient who needs to sit. The MDE Advisory Committee notes that space is already at a premium for weight scales. To require a seat integral to the weight scale to meet the provisions of M302, when it already meets the requirements of M303 would require the weight scale platform to be significantly larger than a weight scale which just provides a wheelchairs space. To accommodate both a wheelchair space and seat permitting transfer from a mobility device, the platform would have to be large enough to accommodate individuals in their mobility devices and also provide enough space to allow for a side or perpendicular transfer from the mobility device onto the seat. Because weight scales with wheelchair spaces and seats are intended to be used by patients remaining in their wheelchairs or ambulating onto the scale, the Access Board has concluded that it is not necessary to require the weight scale to provide the wheelchair space for the patient to use the weight scale in a wheelchair and also provide the space for the patient to wheel onto the weight scale and then transfer onto the seat. Accordingly, the Access Board has excepted integral seats on weight scales that also contain wheelchair spaces meeting all the requirements of M303 from complying with M302. Due

to the addition of this exception from all of the M302 requirements, the exception in proposed M302.4, which exempted the folding seat from complying with the lift compatibility requirements, has been removed from the final rule as it is now encompassed under the new exception.

The Access Board acknowledges the comments recommending that accessible diagnostic equipment used in the standing position also provide a seat. However, the Access Board has declined to include such a provision in the final rule because of the potential space impact and because, it will ultimately be up to the enforcing authority to determine what types of diagnostic equipment and how many of each type must be provided in medical settings. However, if diagnostic equipment used in a standing position does provide a seat, but does not provide a wheelchair space, then it would have to comply with the requirements of M302 and M304 in the final rule.

C. M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

M303 contains the technical requirements for diagnostic equipment used by patients seated in wheelchairs. In the final rule the Access Board made four significant changes to this section: Two significant changes to accommodate the unique challenges of mammography equipment; one significant change to the ramped running slope requirement; and a final significant change to the width and depth of wheelchair spaces.

1. Width and Depth of Wheelchair Spaces

The MDE NPRM proposed to require diagnostic equipment to have a wheelchair space that is at least 36 inches wide (proposed M303.2.2). The MDE NPRM further proposed two alternative depth requirements: 48 inches for wheelchair spaces that are entered from the front or rear, and 60 inches for wheelchair spaces entered from the side (proposed 303.2.3). The MDE NPRM preamble also noted that the Access Board was considering adding exceptions in the final rule to the width and depth requirements for wheelchair spaces on raised platforms. NPRM, 77 FR at 6928–6929. The Access Board sought input in questions 31, 32, and 33, regarding the required size of wheelchair spaces on raised platforms, the use of scooters on raised platforms, and the associated costs. *Id.*

No commenters responded to questions 31 and 33; four commenters responded to question 32. Question 32 asked whether equipment with wheelchair spaces on raised platforms, such as weight scales, can accommodate patients who use scooters, and if they currently cannot, should the width and depth be changed so the equipment is usable by patients who use scooters. One commenter (a disability rights organization) asserted that if diagnostic equipment is accessible for wheelchairs it should also be accessible to scooters and recommended enlarging the space beyond 36 inches. Another disability rights organization opined that most weight scales in healthcare settings are inaccessible to wheelchair users, asserting that even the ''accessible'' weight scales are only 24 inches wide by 30 inches deep and are too small to accommodate manual wheelchairs and definitely would not accommodate the longer wheelbases of many power wheelchairs and scooters. This commenter recommended taking a ''universal design'' approach with a requirement of 34 inches wide by 58 inches deep for raised platforms on weight scales. The other two commenters (an academic and state agency concerned with accessibility) agreed that diagnostic equipment with wheelchair spaces on raised platforms should be usable by scooters, but did not provide any suggested dimensions.

The MDE Advisory Committee recommended a minimum platform size of 32 inches clear width and 40 inches clear length (depth). The Committee noted that their proposed recommendation sought to address the unique considerations of weight scales with raised platforms. The Committee stated that this size ''accommodates both manual and power wheeled mobility devices including small and mid-size scooters.'' MDE Advisory Committee Report, 109, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee relied on the Wheeled Mobility Anthropometry Project findings of wheelbase measurements and the Wheeled Mobility Anthropometry Project's recommendation of a minimum flat surface of 40 inches in length for platforms to accommodate wheeled mobility devices, including scooters. *Id.* at 110. The Committee explained that ''[t]o have an accurate weight, the entire wheelbase (either 3 or 4 wheels) of a mobility device must rest on and make contact with the platform. The foot pedals, footrests, scooter deck and tip wheels can overhang or extend beyond the platform and still get an accurate weight.'' *Id.*

In order to reconcile the public comments and the MDE Advisory Committee recommendations, the final rule retains the proposed M303.2.2 requirement for minimum width of 36 inches for wheelchair spaces, but provides an exception to permit wheelchair spaces on raised platforms to be a minimum of 32 inches wide. This width restriction assumes that the elbows and hands of persons using mobility devices would overhang the width of the platform and they would still be able to propel themselves. Because the final rule also requires raised platforms over 1½ inches in height to provide edge protection that is a minimum of 2 inches high from the surface of the platform (*See* M303.2.6 final rule), it was necessary to restrict the height of this edge protection for platforms using the exception of 32 inches wide to 4 inches. This height restriction is to ensure that a clear space is provided above any edge protection to allow the mobility device's casters and footrests or other components to extend over the edge protection.

For the depth of the wheelchair space, the final rule has retained both alternative depth requirements in proposed M303.2.3: 60 inches for wheelchair spaces entered from the side, and 48 inches for wheelchair spaces entered from the front or rear, discussed below in Section VI.10.c (Section-by-Section Analysis—M303.2.3). However, the Access Board has included an additional requirement for wheelchair spaces that are entered from the front or rear and permit pass-through from one end to the other. This provision requires wheelchair spaces that permit pass-through to have a minimum depth of 40 inches. Less space is required in these circumstances because the wheelchair user does not have to turn around or back out to exit the diagnostic equipment, but can enter and exit continuing on in one direction. Due to the addition of the new requirement, the Board reorganized this provision in the final rule to M303.2.3.1 (front or rear entry depth), M303.2.3.2 (Pass Through Entry), and M303.2.3.3 (side entry depth).

2. Equipment Clearances for Breast Platforms

The MDE NPRM proposed knee and toe clearance requirements for diagnostic equipment used by patients seated in wheelchairs that paralleled the knee and toe clearance requirements from the 2004 ADA and ABA Accessibility Guidelines. NPRM, 77 FR at 6929. The proposed rule included a requirement that 17 inches minimum and 25 inches maximum of the 48-inch

wheelchair space depth include knee and toe clearance. The knee and toe clearance would be permitted to be located beneath the diagnostic equipment, such as an optometrist diopter. The proposed rule contained a different requirement for breast platforms on mammography equipment, that of the 48-inch depth minimum of the wheelchair space, the knee and toe clearance under a breast platform would be 25 inches deep (proposed M303.2.4).

Two commenters, one manufacturer and one disability rights organization, commented on the knee and toe clearance under breast platforms. The disability rights organization raised concerns that existing machines do not provide deep enough clearance and that during the examination the breast platform will hit the patient's knees. The manufacturer also raised concerns with the size of the knee and toe clearance and recommended basing the requirements in relation to the height of the breast platform. Additionally, this commenter raised concerns that mammography equipment must have a stabilizing flange or foot at its base to prevent the equipment from tipping when the gantry is extended. This flange protrudes into the knee and toe clearance. Specifically, this commenter explained that the flange can be designed for optimal accessibility, but is necessary for the safety of the equipment.

The MDE Advisory Committee reviewed this provision and gave multiple recommendations regarding the necessary clearances for breast platforms. The Advisory Committee noted that mammography equipment presents a unique challenge for individuals seated in wheelchairs because the mammography exam requires the patient's breasts to be placed on top of the breast platform thereby requiring the knees and toes to go deeper beneath the equipment. The MDE Advisory Committee recommended changes to the proposed requirements for knee and toe clearance to create a deeper knee space under breast platforms. The MDE Advisory Committee did not suggest revisions to the proposed knee and toe clearances for diagnostic equipment used by patients seated in wheelchairs, other than for mammography equipment.

The knee and toe clearance requirements were adopted from the 2004 ADA and ABA Accessibility Guidelines and typically will allow a person seated in a wheelchair to pull underneath a work surface or equipment component or permit forward access to a control located above equipment overhanging the knee and toe space. We are persuaded by the MDE Advisory Committee report that mammography equipment presents a unique use and requires different specifications for the knee and toe clearance to ensure that the patient's breast can rest on top of the platform. The knee and toe clearance underneath mammography equipment must provide sufficient space to allow the patient to get close enough for their breast to be placed on the breast platform in order for the diagnostic procedure to be performed. Thus, the Access Board has reorganized the equipment clearances provision in the final rule into two separate requirements; breast platforms and other equipment. The requirements for breast platforms (M303.2.4.2 in the final rule) account for obstructions in the knee and toe clearance necessary to stabilize the mammography equipment and the location of the patient's body within the depth of the wheelchair space, such that more of the overall space is allocated to knees and toes. As discussed above, these factors result in an exception to allow equipment components of a low profile to extend into the toe end of the wheelchair space. The requirements for other equipment (M303.2.4.2 in the final rule) are substantively unchanged from the NPRM, and are discussed below in the Section VI.C.10.d (Section-by-Section Analysis—M303.2.4).

a. Knee and Toe Clearance

The proposed rule recommended a knee and toe clearance depth for breast platforms of 25 inches. There were no comments received on this requirement. The MDE Advisory Committee recommended increasing the overall knee and toe space to a minimum 28 inches deep. MDE Advisory Committee Report, 115–116, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee asserted that a minimum of 28 inches in overall knee and toe clearance would accommodate 95 percent of the population. *Id.*

The Access Board concurs with the MDE Advisory Committee's conclusion that an increase in the overall knee and toe clearance under breast platforms is warranted. However, the Board is concerned that if the Advisory Committee's recommendation is adopted without change, it would significantly impact the requirement in the final rule for a 48-inch deep wheelchair space. Because at least 25 inches of the space must accommodate knees and toes, only 23 inches remains to accommodate that portion of the occupied wheelchair not including knees and toes. If the Access Board were to require 28 inches minimum knee and toe clearance, only 20 inches would remain. After reviewing all the evidence before the MDE Advisory Committee, the Access Board has decided to make a number of changes to the requirements for the knee and toe clearances for breast platforms. These new requirements are described in the Section VI.C.10.d (Section-by-Section Analysis—M303.2.4). The requirements are intended to ensure that there is adequate space for a patient seated in a wheelchair to position underneath the equipment and align themselves against the breast platform so that the diagnostic procedures can be performed.

b. Exception for Base Support Allowance and Unobstructed Knee and Toe Space

In the proposed rule, obstructions were not permitted within the knee and toe clearance space. This is consistent with the requirement in the existing accessibility guidelines and standards. One manufacturer commented on this provision, asserting that mammography equipment poses unique challenges and requires separate consideration. The commenter explained that the gantry of a mammography machine includes a base lip which is required for structural and seismic stability, and protrudes into the knee and toe clearance. This commenter recommended revisions to allow for a base lip on mammography equipment.

The MDE Advisory Committee recommended allowing obstructions into the knee and toe clear space, up to a height and depth that still permits the footrests of wheelchairs to pass over it. Specifically, the Committee recommended allowing base supports to be a maximum of 1½ inches high and allowing an additional sloped region above the base support at a depth of 25 inches from the front edge of the breast platform at 1½ inches above the floor, which can extend to a height of 4 inches above the floor at a depth of 28 inches. The MDE Advisory Committee explained its recommendation, noting that:

> The base support is of fundamental importance to mammography equipment and provides structural support, seismic stability, and installation safety. It does obstruct the floor space in front of the gantry and, thus, may limit how close a wheelchair can get to the equipment. To respond to this issue, industry proposed a configuration that would cause minimal obstruction to the floor space in front of the gantry and would allow footrests to ride over it.
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> To discuss the maximum base support height, the sub-committee looked at anthropomorphic data regarding footrest

heights. The footrest height data measures the height from the floor to the top surface of the footrest at its proximal outside corner. To determine the necessary clearance for the footrests, the Committee used the footrest height data and subtracted the thickness of the footrests (~0.5 inch). Allowing a maximum base support height of 1.5 inches will provide room for the structural components necessary for an effective base support design and will also be accessible by around 92% of manual chair users and over 95% of power chair users. MDE Advisory Committee Report, 123–127, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the need for permitting base components in the knee and toe clear space for mammography equipment. While the Access Board recognizes that this is a deviation from existing accessibility guidelines and standards, the Board believes that mammography equipment presents special challenges due to the diagnostic, structural, and seismic requirements of the diagnostic equipment. In the final rule, the Access Board has created an exception to the height requirement for breast platforms. This exception permits the profile of base components to extend into the wheelchair space at a height of 1½ inches maximum between 17 inches minimum and 25 inches maximum in depth measured from the leading edge of the breast platform. In addition, the Access Board has found that the profile of the base components should increase toward the rear of the clearance space where a patient's foot and toes will be higher than the heel supporting portion of the footrest. Therefore, the final rule requires that from 25 inches to 28 inches measured from the leading edge of the breast platform, the height of the component above 1½ inches must be beveled at a rate of 2.5:3. This exception preserves a 17-inch minimum of unobstructed floor space measured from the leading edge of the breast platform.

3. Exception to Ramp Running Slope

The MDE NPRM proposed that where there is a change in level at the entry of a wheelchair space that is greater than 1½ inches, the entry shall be ramped and have a running slope not steeper than 1:12 (proposed M303.3). The Access Board explained in the MDE NPRM preamble that this provision is consistent with the 2004 ADA and ABA Accessibility Guidelines' technical criteria for changes in level. NPRM, 77 FR at 6929. No commenters addressed this provision. The MDE Advisory Committee, during its discussion of wheelchair spaces on weight scales, extensively addressed the permissible slopes of ramps on raised platforms. Specifically, the Committee noted:

[It] considered the needs of a ramped surface to access the platform on the accessible scale. Because there are different types of scales with different platform heights, the Committee developed a three tiered ramp slope proposal to fit different situations. The Committee reviewed and discussed the provisions on slopes for ramps as they apply to architectural elements in the built environment. The maximum slope for a ramp in the 2010 Standards is a rise of 1 vertical inch for each 12 inches of horizontal distance slope. Under very limited conditions in the built environment, the 2010 Standards allow a steeper ramp for a limited rise. A ramp in the built environment to which this exception applies may use a 1:2 grade slope on a short rise ramp.

Industry experts spoke to the concern for facility space often expressed by healthcare entities. The space constraints affect the desirability of accessible scales since space is often expensive and tight in many medical facilities. Scales that can be wall mounted or portable enhance the flexibility of scales and allow use in tight environments. Currently, these types of accessible scales use the short rise ramp to facilitate easy storage or mounting.

Existing technology for weight cell load allows for a platform profile to go as low as ¾ to 1½ inches. As the height of the platform lowers, the length of the ramp can decrease. The trend in the scale industry is to develop lower weight cell technology. However, industry currently does not know if lower profiles are possible. MDE Advisory Committee Report, 111–112, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The MDE Advisory Committee recommended a three tiered approach for allowable ramp runs on raised platforms: Allowing a slope of 1:2 at 0 to 1½ inches, a slope of 1:8 at a height greater than 1½ inches to 2½ inches, and a slope of 1:12 at a height greater than 2½ inches. *Id.*

The Access Board agrees with the MDE Advisory Committee that additional allowances in the slope of ramp runs of diagnostic equipment used by patients seated in a wheelchair with raised platforms, primarily weight scales, is appropriate. However, for usability and safety reasons, the Access Board has determined that slopes of such ramp runs should not exceed the long standing maximum slope for accessible ramps of 1:8 that is allowable in certain circumstances in the 2004 ADA and ABA Accessibility Guidelines. The Board also notes that the Guidelines only permit changes in level up to ½ inch *e.g.,* thresholds to be steeper than 1:8.

Therefore, the Access Board has decided to add an exception in the final rule to the requirement that ramped entry wheelchair spaces have ramp runs with a running slope no steeper than 1:12 (M303.3.3.1). This exception permits a running slope not steeper than 1:8 for ramp runs with a maximum height of 2½ inches. Consistent with the MDE Advisory Committee recommendations, ramp runs over 2½ inches in height will have to comply with the general requirement of running slopes of not steeper than 1:12.

4. Breast Platform Adjustability

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair that have components which are used to examine specific body parts to be capable of examining the body parts of a patient while seated in a wheelchair (proposed M303.4). Additionally, the Access Board proposed specific technical requirements for breast platforms of mammography equipment. The MDE NPRM proposed a height range for breast platforms of 30 inches minimum and 42 inches maximum above the floor (proposed M303.4.1). In the preamble to the MDE NPRM, the Access Board sought input in question 36, on whether the breast platform height range proposed was sufficient to accommodate a patient seated in a wheelchair. NPRM, 77 FR at 6930.

Three commenters responded to this question. One commenter, a medical association, concurred with the proposed provisions. Two other commenters, a disability rights organization and a manufacturer disagreed. The disability rights organization recommended adopting a minimum height range of 24 to 26 inches. The manufacturer indicated that the proposed height range of 30 inches to 42 inches is sufficient, but also noted that several manufacturers lower the breast platform to 25 to 28 inches due to requests for accessibility. This manufacturer also recommended requiring a minimum range of travel for the breast platform instead of a specific minimum and maximum height.

The MDE Advisory Committee recommended changing the breast platform height requirement from a specified height range to a required minimum range bounded by a required high height of 42 inches and a required low height of 26 inches which

constitutes the minimum range of travel allowed. MDE Advisory Committee Report, 132, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee Report noted that industry representatives explained that:

> equipment currently manufactured ranges anywhere between 25 and 28 inches for the lowest measurement of the breast platform. There were various reasons cited for each of the positions. Recommendations from accessibility experts who developed mammography protocols for women with disabilities identified a need for a breast platform height of 24 inches. Because this recommendation evolved from technologist experience on equipment with less knee space, disability advocates supported the rationale for 26 inches as the minimum. One member cited the diversity of body types and sizes for persons with disabilities as the rationale for the 26 inches. Another member emphasized the importance of considering patients of short stature in addition to considering patients seated in a wheelchair. Many industry organization members supported the 28-inch minimum. Reasons cited included providing more flexibility for manufacturers and concern that the lower minimum could result in more leg injuries as the technologist lowered the breast platform so close to the lap of the patient using a wheelchair.

The MDE Advisory Committee recommended, by strong majority, a minimum low height of 26 inches and a minimum high height of 42 inches. After review of the comments and the MDE Advisory Committee recommendations, the Access Board has accepted the MDE Advisory Committee's recommendation of low and high minimum heights. The Access Board believes that this requirement will ensure that the breast platform can be lowered or raised to the proper height for a patient seated in a wheelchair and is also within the range requested from manufacturers for patient accessibility. Therefore, the final rule requires at M303.4.1 that breast platforms have a minimum low height of 26 inches, a minimum high height of 42 inches, and be continually adjustable between the minimum low and high heights.

5. Edge Protection

The MDE NPRM proposed edge protection on the ramps leading up to the raised platform (proposed M303.3.3.4), but did not require edge protection on the raised platforms themselves. The Access Board sought public input with question 30 in the MDE NPRM preamble, on whether there is diagnostic equipment with wheelchair spaces on raised platforms that does not provide edge protection.

The Access Board received two comments from disability rights organizations. These commenters recommended requiring edge protection on platforms and one commenter suggested that the edge protection should not encroach into the wheelchair space on the platform and should be designed according to the edge protection requirements from the 2010 ADA Standards.

The Advisory Committee made two recommendations for requiring edge protection on raised platforms; for single ramped entry platforms, the Committee recommended requiring a minimum two-inch high edge protection on the back of the platform opposite the entry ramp and on the two sides of the platform, and for double ramped entry platforms, the Committee recommended a minimum two-inch high edge protection on both sides of the platform. The Advisory Committee explained that edge protection ''provides an additional safety feature and guides users of wheeled mobility devices onto the platform.'' The edge protection prevents the patient from over-shooting the platform, driving off either side, tipping, or falling. MDE Advisory Committee Report, 112–113, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the Advisory Committee that edge protection is necessary on raised platforms to provide a mechanism to ensure that wheelchair users do not fall off the platform. Therefore, the final rule requires in M303.2.6 that platforms with wheelchair spaces that are raised more than 1½ inches in height to provide a minimum 2-inch-high edge protection, measured from the surface of the platform, on each side of the platform not providing entry to or exit from the diagnostic equipment.

D. M304 Diagnostic Equipment Used by Patients in a Standing Position

M304 provides the technical requirements for diagnostic equipment used by patients in a standing position. There was only one significant change made to the requirement of standing supports on the diagnostic equipment.

1. Standing Supports

The proposed rule included a provision requiring standing supports on each side of the standing surface and compliance with the technical requirements for standing supports in proposed M305.3 (proposed M304.3). Question 38 in the MDE NPRM preamble requested input on the standing support configurations currently provided, their effectiveness for patients with disabilities, whether alternative criteria would be appropriate, whether angled standing supports are effective, and whether there are any industry standards for structural strength requirements. NPRM, 77 FR at 6931.

Two commenters responded to this question. One commenter, a medical association, indicated that standing supports for imaging equipment vary widely based on the type of environment and specific imaging equipment being used. For example, the standing support on a chest x-ray machine and mammography equipment is much different than a support on a fluoroscopic room table that can be moved from a recumbent to standing position. The second commenter, a manufacturer, expressed concerns that the proposed rule was treating supports on breast platforms as standing supports, explaining that this was not the supports' intended purpose. This commenter argued that these supports are actually arm supports intended to ensure proper patient positioning during the diagnostic exam, and were not intended as an accessibility feature to assist the patient in standing.

The MDE Advisory Committee addressed the issue of standing supports for mammography equipment as well as that of standing supports for wheelchair spaces with raised platforms. For mammography equipment, the MDE Advisory Committee came to a consensus agreeing with the commenter that the ''standing supports'' on mammography equipment were actually positioning supports and the ''primary use of these supports is for positioning of the arms during the imaging process to keep them out of the field of view of the image.'' MDE Advisory Committee Report, 135, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee noted that ''[i]ndustry representatives posited that if a patient has limitations or balance issues severe enough to need standing assistance, then the healthcare provider should position her in a seated position for safe imaging.'' *Id.* The MDE Advisory Committee recommended removing the requirements for standing supports on mammography equipment and instead adding a requirement for positioning supports. Additionally, the MDE Advisory Committee noted that:

since the supports mount to the c-arm on many types of mammography equipment, they will move up and down with the breast platform. In these cases, they do not need to be as long as 18 inches to provide sufficient flexibility for patients to reach them. Industry representatives also indicated that there are controls in the area where these positioning supports are located. It is important that the patients' hands do not accidentally hit these controls when they are holding the positioning supports. For this reason, industry will sometimes intentionally shorten the length of these handholds to less than the 18-inch proposal. Considering these factors, the full Committee agreed that a 12-inch long positioning support would be sufficient if it moved with the movable breast platform. *Id.*

The MDE Advisory Committee made two recommendations for standing supports on raised platforms with wheelchair spaces: One for single-ramped entry raised platforms, and a second for dual-ramped entry raised platforms. These recommendations would apply when the diagnostic equipment is designed to accommodate both persons seated in wheelchairs and standing persons. For single-ramped entry raised platforms, the MDE Advisory Committee recommended maintaining the requirement for standing supports on both sides of the diagnostic equipment. To address concerns raised by industry representative on the MDE Advisory Committee regarding the space on the platform needed to attach two sets of standing supports which must be outside the minimum clear space required for a wheelchair, the Committee recommended that dual-ramped entry raised platforms require only one standing support on one side of the platform. The MDE Advisory Committee explained that patients may have a stronger side, right or left, and therefore with only one standing support provided, they would need to be able to use their preferred side to hold onto the standing support. With a single entry ramp, supports on both sides are necessary to allow patients to choose to use the right or left side of their body, but on a dual entry ramp the patient can enter or exit on opposing sides to allow them to use their preferred side of their body with only one support. *Id.*

The Access Board concurs with the commenters and the MDE Advisory Committee that the supports on mammography equipment were intended as positioning supports, not standing supports. However, the Board has determined that an exception is not necessary due to the restructuring of this requirement in the final rule. In the final rule, standing supports are only required on diagnostic equipment used by patients in a standing position that provide a surface on which a patient would stand. This is discussed in greater detail below in Section V.C. (Section-by-Section Analysis—M304.2). Additionally, as discussed below in Section IV.E.1. (Significant Changes—Positioning Supports), the Access Board has elected not to include positioning supports for mammography equipment in the final rule.

With regard to the MDE Advisory Committee recommendations regarding standing supports on diagnostic equipment with raised platforms, the Access Board has decided to include an exception in the final rule for diagnostic equipment with entry and exit that permit pass-through from one end to the other to provide a standing support on only one side of the standing surface, provided that the standing support complies with the requirements in M305.3 for standing supports in a horizontal position. This exception would not just apply to diagnostic equipment on a raised platform designed both for people seated in wheelchairs and in standing positions, it would also apply to equipment designed solely for patients in a standing position and would apply regardless of whether the standing surface is raised on a platform or combined with a wheelchair space. For all other standing surfaces, the Access Board has retained the original requirement of standing supports on two sides of the standing surface from the proposed rule. While the MDE Advisory Committee spoke in terms of raised platforms, the Access Board believes the exception should be permitted where entry and exit permits pass-through from one end to the other, regardless of whether the standing surface is raised. Accordingly, the Access Board has decided to apply this exception to all diagnostic equipment which permits this type of entry and exit in final rule (M304.2.2).

E. M305 Supports

M305 provides the technical requirements for supports on medical diagnostic equipment. There were multiple significant changes made to the transfer supports section, including the addition of new requirements as well as the removal of structural strength requirements from the final rule. Additionally, changes were made to the vertical and horizontal standing supports requirements.

1. Transfer Supports

The MDE NPRM proposed requirements for transfer supports that applied to all transfer surfaces (proposed M305.2). The requirements were the same for transfer surfaces on diagnostic equipment used by patients in the supine, prone, or side-lying position, as well as diagnostic equipment used by patients in the seated position. The proposed standards required transfer supports to be located within reach of the transfer surface and not obstruct transfer, be capable of resisting vertical and horizontal forces of 250 pounds applied to all points, and not rotate in their fittings. The latter two requirements were taken from the 2004 ADA and ABA Accessibility Guidelines for grab bars. 36 CFR part 1191, App. D. In the preamble to the MDE NPRM, the Access Board posed multiple questions about whether the final rule should include more specific requirements regarding location, length, size, height, and angle for transfer supports; and whether transfer supports should be allowed to rotate in their fittings. The Access Board received 31 comments to these questions and the MDE Advisory Committee made 10 recommendations regarding the transfer support section.

In response to the comments and the recommendations of the MDE Advisory Committee, and in consideration of the changes to the final rule regarding types of transfer surfaces, the Access Board has made multiple changes and additions to the transfer support requirements, located at M305.2. Specifically, the Access Board has added technical specifications to the requirements for location (M305.2.1) and length (M305.2.2) based on the type of transfer support required; has added new technical requirements for height (M305.2.3), cross section (M305.2.4), absence of surface hazards (M305.2.5), gripping surfaces (M305.2.6), and clearance (M305.2.7); and has made changes to the fittings provision (M305.2.8). These new and revised provisions are based on the 2004 ADA and ABA Accessibility Guidelines for grab bars and handrails, 36 CFR part 1191, App. D. Finally, the Access Board has removed the requirement for structural strength for transfer supports and has decided not to add any positioning support requirements in the final rule. Each requirement is discussed in detail in the Section-by-Section Analysis below.

a. Structural Strength

The MDE NPRM proposed to require transfer supports to be capable of resisting vertical and horizontal forces of 250 pounds at all points (proposed M305.2.2). The Access Board sought input in question 18, on whether current transfer supports are capable of

resisting vertical and horizontal forces of 250 pounds at all points. NPRM, 77 FR at 6925. Four commenters (three manufacturers and one accessibility consultant) addressed this requirement: The accessibility consultant concurred with the proposal and the other three commenters opposed this provision. Two of those opposing the 250-pound requirement asserted that very few supports would be able to withstand 250 pounds of force applied to all points in all directions and that the requirements should differ depending on the force vector or live load applied. The remaining opposing commenter supported compliance with the prevailing industry standard IEC 60601 instead of the proposed provision.

The MDE Advisory Committee recommended revising the language proposed in the MDE NPRM to require transfer supports to resist vertical and horizontal forces of 250 pounds at locations determined by the intended use of the equipment. The Committee indicated that ''during committee discussions manufacturers stated that industry is required to test the most vulnerable spots on the transfer support. Industry must follow testing parameters found in other standards.'' MDE Advisory Committee Report, 103, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

After reviewing the comments received and the recommendations from the MDE Advisory Committee, the Access Board has decided to remove this section in the final rule. The prevailing standard used by industry, IEC 60601 adopted under the ANSI/AAMI ES 60601 series in the U.S., contains provisions that address the structural strength of supports. ANSI/AAMI ES60601–1:2005/(R)2012, available at *http://my.aami.org.* The IEC 60601 Standard applies to a wide range of medical equipment including much of the diagnostic equipment covered by the MDE Standards and contains allowances for risk assessment not found in accessibility standards, such that support features on diagnostic equipment that will sustain transfers in a safe manner even without a specific provision in the MDE Standards. *Id.* Accordingly, it is not necessary for the Access Board to address the structural strength of transfer supports in the final rule as it is already covered by industry standards.

b. Positioning Supports

The Access Board noted in the MDE NPRM preamble that it was considering adding positioning supports to the final rule and sought public input with question 24 on whether positioning supports should be required in the final rule. NPRM, 77 FR at 6927. Six commenters responded: Two commenters (disability rights organizations) recommended adding positioning supports; two commenters (manufacturers) recommended providing positioning supports within reach of the patient; one commenter (an accessibility consultant) recommended flexibility to allow for design based on use; and the final commenter (a manufacturer) raised concerns about the technical impact for MRI machines. Additionally, as discussed above in Section IV.D.1 (Significant Changes—Standing Supports) and below in Section V.C.17 (Section-by-Section Analysis—M305.2), the MDE Advisory Committee made recommendations to add requirements for positioning supports on mammography equipment and imaging equipment with transfer surfaces having depths greater than 24 inches.

After review of the comments and the MDE Advisory Committee's recommendations, the Access Board has decided not to require positioning supports in the final rule. Although the Access Board considers positioning supports to be helpful, even necessary in some instances, given the wide range of diagnostic equipment addressed by the final rule, we have insufficient information on which to base a meaningful requirement that could apply to all types of equipment. Additionally, where transfer supports are provided, they can also serve to assist patients to position themselves.

2. Standing Supports

The proposed rule provided technical criteria for vertical and horizontal standing supports. For horizontal standing supports, the Access Board proposed a gripping surface of 4 inches long minimum, the top of which would be required to be located 34 inches minimum and 38 inches maximum above the standing surface (proposed M305.3.1). For vertical standing supports, the Access Board proposed a gripping surface of 18 inches long minimum, the bottom of which would be required to be located 34 inches minimum and 37 inches maximum above the standing surface (proposed M305.3.2). In the preamble to the MDE NPRM the Access Board sought input with question 38 on: (a) The current configurations of standing supports, and their effectiveness for persons with disabilities; (b) if there were any alternative technical criteria that would be appropriate; (c) whether angled supports are effective; and (d) whether there are industry standards for the structural strength of standing supports. NPRM, 77 FR at 6931. The Access Board received two comments, one of which addressed standing supports on mammography equipment (discussed above in Section IV.D.1 (Significant Changes—Standing Supports)) and one commenter (medical association) who noted that angled standing supports would be effective and that they are unaware of any industry standards regarding structural strength.

The MDE Advisory Committee reviewed the standing supports provision and while it supported the technical criteria in the proposed rule, the MDE Advisory Committee recommended adding additional criteria for standing supports on raised platforms with wheelchair spaces based on the recommended changes in requirements for standing supports for such diagnostic equipment (discussed above in Section IV.D.1 (Significant Changes—Standing Supports)). The Committee recommended that for single-ramped entry raised platforms with wheelchair spaces, the standing supports located on two sides of the platform have a minimum of 34 inches between supports, be integrated into the platform, and be a minimum of 32 inches in length (at least 80 percent of the platform length) at the platform entry edge. MDE Advisory Committee Report, 136–137, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* For standing supports on dual-ramped entry raised platforms with wheelchair spaces, the MDE Advisory Committee recommended the standing support, required on one side of the platform, be integrated into the platform and stretch the full length of the platform (40-inch minimum). *Id.*

The Access Board concurs with most of the MDE Advisory Committee's recommendations; however, although the Committee's recommendations pertained to diagnostic equipment with wheelchair spaces and standing spaces on raised platforms, the Access Board has decided to apply the recommended criteria to all diagnostic equipment for patients in a standing position that also contains a wheelchair space, regardless of whether the equipment standing surface is raised. In addition, the exception permitting only one standing support is conditioned on that support being positioned horizontally in relation to the standing surface, not vertically. Additionally, the Access Board has adopted the Committee's recommendation regarding the length of

these standing supports necessitating the Access Board to restructure the standing support provision, dividing it into length and height. In the final rule the Access Board permits diagnostic equipment that is required to have standing supports that also provides a wheelchair spaces with one entry to have standing supports with a gripping surface length equal to or greater than 80 percent of the overall length of the platform. For such diagnostic equipment with wheelchair spaces that permit pass-through from one end to the other, the final rule requires the length of the gripping surface of the standing support to be at least equal to the length of the platform.

V. Section-by-Section Analysis

A. Chapter 1: Application and Administration

In the final rule Chapter 1 establishes the purpose and the general requirements for the application of the MDE Standards. This chapter received 21 comments and no recommendations from the MDE Advisory Committee. The Access Board made a few editorial changes to some of the provisions, and added one provision M101.3 Existing Diagnostic Equipment, which is discussed below.

M101 General

This is an introductory section.

M101.1 Purpose

The MDE NPRM proposed that the purpose of the MDE Standards was to establish technical criteria for diagnostic equipment that is accessible to and usable by patients with disabilities and to provide patients with disabilities independent access to and use of diagnostic equipment to the maximum extent possible. One commenter, a manufacturer, responded to the proposed provision. The commenter asserted that this provision was unclear without a list of applicable disabilities and an explanation on how the maximum extent possible would be determined.

In response to the commenter, the Access Board notes that the term ''disability'' is defined in the Americans with Disabilities Act (ADA), 42 U.S.C. 12102. None of the Standards and Guidelines promulgated by the Access Board include a list of applicable disabilities. Rather, they rely on the definition of disability provided in the ADA. As for determining whether diagnostic equipment provides independent access and egress to the maximum extent possible, that is a decision left to the enforcing authorities that adopt and implement this standard. The Access Board, therefore, declines to implement the commenter's suggested changes. The Access Board has, however, made two editorial changes to this provision clarifying that ''medical diagnostic equipment'' is referred to as ''diagnostic equipment,'' and that these standards are referred to as ''MDE Standards'' throughout the rule text.

M101.2 Application

In the NPRM the Access Board proposed that the MDE Standards would be applied to diagnostic equipment based on the patient position the equipment is designed to support. Additionally, this provision stated that where the equipment was designed to support more than one patient position, the MDE Standards for each patient position supported would be applied to the equipment. Fifteen commenters responded to this provision asserting that some diagnostic equipment should not have to comply with more than one patient position requirement. These concerns have resulted in two added exceptions to the final rule. The first is to exempt examination chairs which comply with M302 and can be reclined to facilitate diagnosis after the patient transfers onto the seat from complying with M301. (M301.1, Exception). This exception is discussed above in Section IV.B.4 (Significant Changes—Exception from the Requirements of M301 for Certain Examination Chairs that Comply with M302). Additionally, the final rule also exempts weight scales which contain a wheelchair space complying with M303 and that have a seat integral to the equipment from complying with M302 (M302.1, Exception). This exception is discussed above in Section IV.B.5. (Significant Changes—Exception from the Requirements of M302 for Weight Scales with Integral Seats). In the final rule, the application provision was revised due to the addition of the exceptions and a few editorial changes were made for clarity. This provision now requires that sections M301 through M304 of the MDE Standards be applied to diagnostic equipment based on the patient position that the equipment supports during patient transfer and diagnostic use and sections M306 and M307 will be applied to diagnostic equipment that contains communication features or operable parts that are provided for patient use.

M101.3 Existing Diagnostic Equipment

The MDE NPRM did not address when or how the MDE Standards would be applied to existing medical diagnostic equipment. Commenters raised concerns about the cost of immediate compliance for the more expensive imaging equipment, noting the high cost and the concern that rooms are designed specifically for such equipment. Specifically, at the public hearing on March 14, 2012, two commenters recommended phasing in these requirements for imaging equipment based on when it is replaced. The public hearing transcript is available at *https://www.regulations.gov/docket?D=ATBCB-2012-0003.*

The MDE Standards are advisory and are not binding until adopted by an enforcing authority. The Access Board's mandate was to establish only the minimum technical criteria, however enforcing authorities may establish scoping requirements in the future. In response to the commenters' concerns regarding existing equipment, the Access Board has decided to add a new provision which clarifies that the MDE Standards do not address the accessibility of existing diagnostic equipment and that the enforcing authority will determine whether and how diagnostic equipment will be regulated.

M101.4 Equivalent Facilitation

The MDE NPRM proposed to permit the use of alternative designs or technologies that are substantially equivalent to or provide greater accessibility and usability than strict compliance with provisions in the MDE Standards. One commenter, a manufacturer, requested that the Access Board include examples of acceptable methods for providing equivalent facilitation.

The Access Board is unable to provide examples of acceptable methods of equivalent facilitation, as this section is intended to encompass those design solutions which the Access Board is unaware at the time that this rule is published. Additionally, the final determination of whether a particular design or technology meets this provision will be determined by the enforcing authorities. Therefore, the only change to this provision was to adjust the section number to allow for the addition of the new provision, M101.3 Existing Diagnostic Equipment.

M101.5 Dimensions

The MDE NPRM proposed that the MDE Standards be based on adult dimensions and anthropometrics. One commenter and the MDE Advisory Committee raised concerns about providing standards for obese patients and pediatric patients. While the Access Board acknowledges that these are additional issues of accessibility, the

final rule follows the MDE NPRM framework and provides technical requirements based on adult dimensions and anthropometrics, only. At this point in time the Access Board is focusing on adult dimensions and anthropometrics however, the Access Board may address potential expansions of the MDE Standards to other groups in future rulemakings. The only change to this provision was adjustment of the section number to allow for the addition of the new provision, M101.3 Existing Diagnostic Equipment.

M101.6 Dimensional Tolerances

The MDE NPRM proposed that dimensions were to be subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions. In the preamble of the MDE NPRM, the Access Board sought public input in question five on available information or resources concerning conventional industry tolerances for medical diagnostic equipment. NPRM, 77 FR at 6920. Six commenters responded to the question. Three commenters (two manufacturers and one medical association) indicated that tolerances vary based on the manufacturer, product design, and manufacturing process and that they are unaware of any industry standard. One commenter, a manufacturer, referenced ASME Y14.5–1994 for dimensional tolerances. Another commenter, a medical association, asserted that tolerances are in operator manuals. The final commenter, a manufacturer, recommended providing tolerances when dimensions are specified and recommended defining a specific tolerance, such as +/− 0.5 inch for linear dimensions.

After considering the comments received, the Access Board has decided to retain the original provision. The Access Board was persuaded by arguments from the commenters that there is not one industry-wide standard that can be applied to all MDE and concurs that the Access Board should not attempt to establish manufacturing tolerances. Where available, tolerances are best addressed by industry standards for the specific materials and methods employed in the manufacturing process. The only change to this provision was to adjust the section number to allow for the addition of a new section, M101.3 Existing Diagnostic Equipment.

M101.7 Units of Measurement

In the MDE NPRM there was no explanation of the units of measurement used throughout the rule text. In order to avoid confusion and to align this final rule with the other accessibility guidelines and standards promulgated by the Access Board; this provision has been added to explain that the values stated in each system (U.S. customary and metric units) may not be exact equivalents, and each system must be used independently of the other.

M102 Definitions

This is an introductory section.

M102.1 Defined Terms

The MDE NPRM proposed definitions for enforcing authority, medical diagnostic equipment, operable parts, and transfer surface. The Access Board sought input in question six in the preamble of the MDE NPRM, on whether there were other terms in the proposed standards that should be defined. NPRM, 77 FR at 6920. Ten commenters responded to this question. One commenter, a medical association, did not offer other terms that should be defined, but stated that there were many instances where the Board used acronyms without a definition. However, this commenter failed to provide any examples. Another commenter, a disability rights organization, suggested modifying the definition of medical diagnostic equipment to clarify that the standard is intended for all medical equipment in which any part of the equipment is used for diagnostic purposes for any amount of time. Another commenter, a manufacturer, recommended changing the term ''operable part'' to ''applied part'' and adding a new definition of operable part as ''caregiver operated parts,'' asserting that this aligns with IEC 60601. Other commenters (manufacturers, medical associations, disability rights organizations, and an individual) suggested the following terms be defined: health care provider, breast platform, patient support surface, transfer supports, positioning supports, prone position, supine position, examination tables, diagnostic purposes, maximum extent possible, landing area, exam table, procedure table, and procedure chair.

After review of the comments, the Access Board declines to add any of the suggested terms to the defined terms section. The definition of medical diagnostic equipment was taken directly from Section 510 of the Rehabilitation Act and thus for consistency has not been altered. 29 U.S.C. 794f. Some of the definitions proposed by commenters are not terms used in the MDE final rule and, therefore, providing the requested definitions would serve no purpose. The definitions for other proposed terms used in the final rule are the same as the ordinarily accepted meanings in the context that applies, and the Access Board does not believe that the reader would be significantly aided in understanding the final rule by adding the requested definitions. However, the Access Board has decided to add six additional terms to this section; end transfer surface, examination chair, imagining equipment with bores, imagining bed, side transfer surface, and wheelchair space. As described above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location), the Access Board has added definitions for ''end transfer surface'' and ''side transfer surface'' to this provision to describe the two types of transfer surfaces for diagnostic equipment used by patients in the supine, prone, or side-lying position. The ''wheelchair space'' definition was taken from the 2004 ADA and ABA Accessibility Guidelines and adopted in the MDE final rule to provide consistency across Access Board rulemakings. Examination chair, imagining equipment with bores, and imagining bed were added to help clarify application of exceptions added in the final rule. (*See* M301.1, M301.2.3, and M305.2.2.2). Finally, the Access Board also made a minor editorial change to the title of ''operable part'' so that all components and parts are referred to in the plural.

M102.2 Undefined Terms

The MDE NPRM proposed that the meaning of terms not defined in proposed M102.1 or in regulations or policies issued by an enforcing authority, be defined by collegiate dictionaries in the sense that the context implies. There were no comments and no MDE Advisory Committee recommendations on this provision. In the final rule, the Access Board has changed this provision to indicate that the meaning of terms not defined in M102.1 will be given their ordinarily accepted meaning in the context that applies.

M102.3 Interchangeability

The MDE NPRM proposed that singular and plural words, terms, and phrases are used interchangeably. There were no comments on this requirement and no changes have been made.

B. Chapter 2: Scoping

In the final rule, Chapter 2 establishes that the enforcing authority will determine the number and types of diagnostic equipment to which the MDE Standards will apply. The Access Board did not receive any comments regarding Chapter 2 as written; however, several commenters expressed concern

regarding the ability of certain types of diagnostic equipment to comply with the MDE Standards. These concerns, discussed above in Section IV.A.1. (Significant Changes—General Exception), resulted in the addition of the M201.2 General Exception, described below. In addition, the Access Board made one editorial change to M201.1.

M201 General

This is an introductory section.

M201.1 Enforcing Authority

The MDE NPRM proposed to explain that the enforcing authority would specify the minimum number of types of accessible diagnostic equipment that would be required to comply with the MDE Standards. There were no public comments regarding this provision. The Access Board has decided to make an editorial change to this section to clarify that the enforcing authority will specify the minimum number and types of accessible diagnostic equipment that will be required to comply with the MDE Standards.

M201.2 General Exception

The MDE NPRM did not propose a general exception for diagnostic equipment that was not capable of meeting the MDE Standards. As described in Section IV.A.1. (Significant Changes—General Exception), the Access Board received public comments and MDE Advisory Committee recommendations regarding certain types of diagnostic equipment that are unable to meet all of the requirements in the MDE Standards. In response, the Access Board has added a new provision excepting diagnostic equipment from compliance with an applicable requirement in the MDE Standards in the rare circumstance where compliance would alter diagnostically required structural or operational characteristics of the equipment, and would prevent the use of the equipment for its intended diagnostic purpose. Any equipment falling under this exception must comply with the provision(s) in question to the maximum extent practicable, and must fully comply with all other provisions not utilizing this exception.

C. Chapter 3: Technical Requirements

In the final rule, Chapter 3 establishes the technical requirements for accessible medical diagnostic equipment based on how the diagnostic equipment is used by the patients, including: Diagnostic equipment used by patients in a supine prone, or side-lying position (M301); diagnostic equipment used by patients in a seated position (M302); diagnostic equipment used by patients seated in a wheelchair (M303); and diagnostic equipment used by patients in a standing position (M304). Chapter 3 also provides technical criteria for supports (M305), communication (M306), and operable parts (M307). This chapter underwent significant reorganization and changes as described in Section IV.B through IV.E (Significant Changes—M301 through M305). Additionally, the Access Board made editorial changes which are described below in the applicable Section-by-Section Analysis.

M301 Diagnostic Equipment Used by Patients in a Supine, Prone, or Side-Lying Position

M301 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a supine, prone, or side-lying position such as, examination tables, imaging tables, hospital beds, and stretchers.

M301.1 General

The MDE NPRM proposed that all diagnostic equipment used by patients in a supine, prone, or side-lying position must comply with the technical requirements of proposed section M301. As discussed in Section IV.B.4. (Significant Changes—Exception from the Requirements of M301 for Certain Examination Chairs that Comply with M302), in response to public comment and recommendations from the MDE Advisory Committee, in the final rule the Access Board has added an exception to this requirement for examination chairs that can be reclined to facilitate diagnosis after the patient transfers. This new exception exempts these diagnostic chairs from compliance with M301's requirements, as long as the examination chairs comply with the requirements in M302.

M301.2 Transfer Surface

This is an introductory section.

M301.2.1 Adjustability

The MDE NPRM proposed a transfer surface height range for diagnostic equipment used by patients in the supine, prone, or side-lying position of 17 inches minimum and 19 inches maximum. The Access Board received multiple comments on this provision and the MDE Advisory Committee provided four recommendations. As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), in the final rule the Access Board has renamed this provision and now requires the transfer surface height to be adjustable to: (1) A low transfer height of 17 inches minimum and 19 inches maximum; (2) a high transfer height of 25 inches; (3) at least four additional transfer heights located between the low and high transfer heights, separated by one inch minimum increments; and (4) the transfer surface height will be measured from the floor to the top of the uncompressed transfer surface.

M301.2.2 Sunset Provision

As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), this is a new provision that was added to the final rule in conjunction with the new requirement of a low height range in M301.2.1. It provides a sunset for the low transfer height provision of five years from the date of publication of this rule in the **Federal Register**. The Access Board intends to complete the necessary research to determine an appropriate minimum low transfer height prior to the effective date of the sunset, and will update this provision in a subsequent rulemaking.

M301.2.3 Size

The MDE NPRM proposed a transfer surface size for diagnostic equipment used in the supine, prone, or side-lying position of 30 inches wide and 15 inches deep minimum. (proposed M301.2.2). The Access Board received multiple comments on this provision as well as multiple recommendations from the MDE Advisory Committee. As discussed in Section IV.B.1.c (Significant Changes—Transfer Surface Size), in the final rule the Access Board has revised this provision to account for the two types of transfer surfaces (end and side), requiring end transfer surfaces to be a minimum of 28 inches wide and 17 inches long and side transfer surfaces to be a minimum of 28 inches wide and 28 inches long and has added an exception for transfer surfaces for imagining equipment with bores.

M301.2.4 Unobstructed Transfer

In the MDE NPRM the Access Board proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer. Examples of temporary obstructions include folding armrests, removable side rails, retractable footrests, and stirrups. NPRM, 77 FR at 6924. There were no comments received on the proposed provision and the MDE Advisory Committee did not make any recommendations. The final rule retains the requirement for unobstructed

transfer, but has reworded the requirement to specify that each transfer surface must provide two unobstructed sides for the patient to transfer.

Additionally, the Access Board sought public input on whether an additional exception to the requirement of unobstructed transfer should be added. NPRM, 77 FR at 6924. Specifically, the Access Board asked whether equipment parts should be permitted to extend a maximum of three inches horizontally beyond the edge of the transfer sides, provided they do not extend above the top of the transfer surface. The Access Board received multiple comments and recommendations from the MDE Advisory Committee on this topic. As discussed above in the Section IV.B.1.d. (Significant Changes—Unobstructed Transfer), the final rule includes a second exception to the unobstructed transfer provision which permits obstructions of no more than three inches to extend beyond the transfer side of the transfer surface, provided that such obstructions do not protrude above the top of the transfer surface.

M301.3 Supports

This is an introductory section. An editorial change was made to this section as a result of the change in M301.3.2, described below, to replace the word ''stirrups'' with the term ''leg supports.''

M301.3.1 Transfer Supports

The MDE NPRM proposed to require transfer supports to be provided for use with transfer sides on diagnostic equipment used by patients in the supine, prone, or side-lying position, and that these transfer supports comply with the technical requirements for transfer support in M305.2. There were no public comments and no recommendations by the MDE Advisory Committee on this provision. The only change in the final rule was to update the cross reference to applicable transfer surfaces to accommodate the changes made to transfer surfaces, described above in Section IV.B.1. (Significant Changes—Transfer Surface).

M301.3.2 Leg Supports

In the MDE NPRM, the Access Board proposed to place the requirements for stirrups on diagnostic equipment used by patients in the supine, prone, or side-lying position in M301. In the final rule the Access Board has decided to move the technical requirements for stirrups to M305, which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that when stirrups are provided on diagnostic equipment used in the supine, prone, or side-lying position leg supports must also be provided and comply with the technical requirements in M305.4. Additionally, in the final rule, the Access Board has made an editorial change in terminology, from stirrups to leg supports, in response to an MDE Advisory Committee recommendation to draw a distinction between stirrups which often only support the feet and leg supports which would support the legs when the patient's feet are in the stirrups and to provide consistency with the headings of other support provisions which are based on the body part supported.

M301.3.3 Head and Back Support

In the MDE NPRM the Access Board proposed to place the requirements for head and back support for diagnostic equipment used by patients in the supine, prone, or side-lying position in M301. In the final rule, the Access Board has decided to move the technical requirements for head and back support to M305, which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that where diagnostic equipment is used in a reclined position it must provide head and back support that complies with the technical requirements in M305.5.

M301.4 Lift Compatibility

The MDE NPRM proposed to require that diagnostic equipment used by patients in the supine, prone, or side-lying position be usable with a patient lift and comply with either the proposed clearance in base (proposed M301.4.1) or clearance around base (proposed M301.4.2) technical requirements. One manufacturer commented on this provision, asserting that the proposed requirement was unclear and should clearly state that the diagnostic equipment only has to be compatible with either the clearance around base or the clearance in base provisions. The Access Board considered this comment, but finds that the language is clear as written. This provision clearly states that diagnostic equipment shall comply with clearance in base or clearance around base. In the final rule the Access Board has made an editorial change to clarify the type of lift; namely portable patient lift, and a change to clarify that the clearance provisions only apply when the diagnostic equipment is being used with the portable patient lift.

Additionally, question 27 in the MDE NPRM preamble requested input on whether the final rule should provide an exception from the lift compatibility requirements where the diagnostic equipment is designed for use with overhead lifts. As discussed above in Section IV.B.3. (Significant Changes—Lift Compatibility Exception), the Access Board has decided to add this exception for diagnostic equipment that meets the following three criteria: Fixed overhead patient lifts are provided for use with the diagnostic equipment; the use with the fixed overhead patient lift with the diagnostic equipment is permitted by an enforcing authority; and the diagnostic equipment is clearly labeled as not compatible with portable patient lifts.

M301.4.1 Clearance in Base

The MDE NPRM proposed certain clearance requirements beneath the diagnostic equipment to allow sufficient space for the legs of a portable patient lift to fit underneath the equipment so that the patient could be raised out of their mobility device, moved over to the medical diagnostic equipment, and then be lowered onto the transfer surface. The proposed requirement could be met by providing an open area beneath the equipment, or by configuring the equipment with a wide slot recessed into the base enclosure. NPRM, 77 FR at 6927. The MDE NPRM proposed a clearance in the base of 44 inches wide minimum, 6 inches high minimum measured from the floor, and 36 inches deep minimum measured from the edge of the examination surface. Where the width of the equipment is less than 36 inches wide, the proposed rule required the clearance to extend the full width of the equipment. *Id.* Additionally, the Access Board proposed to permit equipment components to be located within 8 inches maximum of the centerline of the clearance width. *Id.* The Access Board sought input in question 25 in the MDE NPRM preamble, on whether the proposed dimensions for the clearance in base requirement is sufficient to allow for the use of portable floor lifts. *Id.*

Six commenters responded to the question. One commenter, a manufacturer, concurred with the proposed provision. Another commenter, a medical association, explained that portable lifts are a problem in older outpatient facilities due to limited space. Another commenter, a manufacturer, raised concerns about requiring floor based patient lifts with MRI systems, explaining the concern about the significant structural support required in the patient bed which makes the under bed clearance impractical and the concern about requiring non-ferrous materials in the MRI room. This commenter explained a preference for

fixed overhead lifts. Three commenters (two manufacturers and one medical association) raised concerns with the six-inch vertical clearance measured from the floor requirement. One manufacturer explained that the proposed six-inch vertical clearance requirement would encompass 100 percent of all portable patient lifts on the market, and that several portable patient lifts only require 2.5 inches clearance, such as those designed to be used with stretchers. This commenter asserted that the proposed six-inch vertical clearance would require redesign of every medical bed and stretcher on the market, and recommended reducing the required clearance. One commenter (medical association) noted that it would be difficult to meet the six-inch clearance from the floor when the table is lowered to 17 inches to allow for transfer. The final commenter explained that a standard that only required either compliance with clearance in the base or clearance around the base, was attainable, but warned that if both were required it would impose significant redesign costs and would increase product costs. This commenter further posited that it would be more cost effective to redesign the lift than the diagnostic equipment. These three commenters also raised concerns that this provision was in conflict with the prevailing standard used by manufacturers for medical beds and stretchers, IEC 60601–2–52, which contains requirements for lift clearance under the equipment.

The MDE Advisory Committee recommended reducing the equipment base clearance for stretchers from 44 inches wide minimum to 39 inches wide minimum. The Committee noted that this was to harmonize the MDE Standards with IEC 60601–2–52, which provides requirements for stretchers and includes lift clearance at the 39-inch width. MDE Advisory Committee Report, 106–107, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board has reviewed the comments and the recommendations from the MDE Advisory Committee and is persuaded by the arguments in favor of harmonizing the lift clearance requirements with the IEC 60601–2–52. Accordingly, the Access Board has adopted the recommendation from the MDE Advisory Committee, but has decided to apply the reduction in lift clearance width to all medical diagnostic equipment that complies with the clearance in base provision because a lift that deploys effectively under a stretcher should also function properly under other less constrained diagnostic equipment. Secondly, the Access Board has decided to retain the six-inch height clearance requirement but agrees with the commenters that the diagnostic equipment should not have to meet the six-inch height clearance requirement when in position for independent transfer. Therefore, the final rule clarifies that the lift compatibility requirements only apply when the diagnostic equipment is being used with the portable lift, as a lift will only be used when independent transfer is not possible.

M301.4.2 Clearance Around Base

The MDE NPRM proposed certain requirements to provide clearance around the base of the diagnostic equipment to allow the legs of the portable floor lift to straddle the base of the diagnostic equipment with a solid base that sits on or close to the floor. The proposed rule required a minimum clearance of 6 inches high measured from the floor and 36 inches deep measured from the edge of the examination surface. NPRM, 77 FR at 6927. The width of the base permitted within this clearance would be 26 inches maximum at the edge of the examination surface and was permitted to increase at a rate of 1 inch in width for every 3 inches in depth. *Id.* In addition, where the width of the examination surface is less than 26 inches, the clearance depth would be the full width of the examination surface. *Id.* The Access Board sought public input in question 26 in the MDE NPRM, on whether the proposed dimensions for clearance around the base of the equipment was sufficient to allow for the use of portable floor lifts. *Id.*

Two commenters, both manufacturers, responded to this question. One commenter recommended clarifying that the exam table must be compatible with a patient lift and meet the six-inch clearance, but not when the table is at its lowest level for independent transfer. This manufacturer indicated that its adjustable table does not have a six-inch minimum clearance when at its lowest position, but does meet the standard when the table is raised. The other commenter asserted that the proposed dimensions are not sufficient to accommodate the various portable floor lifts and recommended that the Access Board instead provide technical criteria for the portable patient lift to be usable with diagnostic equipment since it is more cost effective to change the floor lift, than to change the diagnostic equipment. Additionally, this manufacturer reported that all but one of its examination and procedure tables currently meet the clearance around base provision, but opined that if the proposed increase in width of the transfer surface of examination tables and chairs to 30 inches by 15 inches is adopted then it would be required to redesign the examination tables and chairs to have a larger base which would interfere with the ability to meet this clearance around base provision. The MDE Advisory Committee did not address this provision, and thus provided no recommendations on the clearance around the base requirements.

The Access Board has reviewed the comments and has decided to retain the provision from the proposed rule. In the final rule, the Access Board has decided to decrease the size of the transfer surface (See final M301.2.3) and thus the commenter's concern regarding an increase in base size is not applicable. As described above, M301.4 does not require the 6-inch height clearance to be maintained when the equipment is lowered to the minimum low height for independent transfer as required by M301.2.1, because portable patient lifts will only be used when independent transfer is not possible. Finally, a portable patient lift is not medical diagnostic equipment and, therefore, not within the purview of the Access Board's regulatory jurisdiction. However, portable patient lifts are integral to ensuring that patients with disabilities who are unable to independently transfer are otherwise able to use the medical diagnostic equipment. Therefore, the Access Board has provided the technical criteria necessary for the portable floor lift to be usable with medical diagnostic equipment.

M302 Diagnostic Equipment Used by Patients in a Seated Position

M302 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a seated position such as examination chairs.

M302.1 General

The MDE NPRM proposed that all diagnostic equipment used by patients in a seated position must comply with the technical requirements of proposed section M302. As discussed in Section IV.B.5. (Significant Changes—Exception from the Requirements of M302 for Weight Scales with Integral Seats), in response to public comment and evidence presented to the MDE Advisory Committee, in the final rule the Access Board has added an exception to this requirement for weight

scales that contain wheelchair spaces and also provide a seat integral to the equipment. This new exception exempts these weight scales from compliance with M302's requirements for the seat, as long as the wheelchair space complies with the requirements in M303.

M302.2 Transfer Surface

This is an introductory section.

M302.2.1 Adjustability

The MDE NPRM proposed a transfer surface height range for diagnostic equipment used by patients in a seated position of 17 inches minimum and 19 inches maximum. The Access Board received multiple comments on this provision and the MDE Advisory Committee provided four recommendations. As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability) in the final rule the Access Board has renamed this provision and now requires the transfer surface to be adjustable to: (1) A low transfer position height at or between 17 inches and 19 inches; (2) a high transfer position of 25 inches; (3) at least four additional transfer positions located between the low and high transfer positions and separated by one inch minimum increments; (4) measured from the floor to the top of the uncompressed transfer surface.

M302.2.2 Sunset Provision

As discussed in Section IV.B.1.a. (Significant Changes—Transfer Surface Adjustability), this is a new provision added to the final rule in conjunction with the new requirement of a low height range in M302.2.1. It provides a sunset for the low transfer height provision of five years from the date of publication of this rule in the **Federal Register.** The Access Board intends to complete the necessary research to determine an appropriate minimum low transfer height prior to the effective date of the sunset, and will update this provision in a subsequent rulemaking.

M302.2.3 Size

The MDE NPRM proposed a transfer surface size for diagnostic equipment used by patients in the seated position of 21 inches wide and 15 inches deep (proposed M302.2.2). The Access Board also solicited comment in question 16 on whether the transfer surface size proposed for seated position diagnostic equipment was sufficient to facilitate independent transfer. NPRM, 77 FR at 6924. Two of the seven commenters who responded supported the proposed requirements. One commenter, a manufacturer, although in agreement with the 21-inch width, stated that the 15 inches deep requirement should be increased to 17 inches, a disability advocate recommended increasing the width to 23 inches, two of the commenters, accessibility consultant and disability advocate, stated that the proposed dimensions were insufficient citing concerns for persons of larger stature or who are obese and may be unable to safely transfer to a surface of that size. One commenter, a manufacturer, recommended harmonizing with the requirements for the seated position with those of the supine, prone, or side-lying position transfer surface size.

The MDE Advisory Committee considered the dimensions for rectangular seats in roll-in showers from the 2010 ADA Standards for Accessible Design and the ''ideal'' chair width recommended in Architectural Graphic Standards for auditorium seating. MDE Advisory Committee Report, 77, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee also reviewed anthropometric data from a variety of sources. *Id.* Many Committee members expressed concern about the adequacy of the transfer surface depth. *Id.* The Committee recommended increasing the minimum depth of the transfer surface from 15 inches to 17 inches, noting that existing equipment already meets or exceeds this dimension. *Id.* The Committee recommended retaining the 21-inch width requirement, noting that it was sufficient to facilitate independent transfer. *Id.*

Based on the commenters' responses and the MDE Advisory Committee recommendations, the Access Board has decided to increase the transfer surface size for equipment used by patients in a seated position to 17 inches deep and retain the 21-inch-wide requirement from the proposed rule.

M302.2.4 Transfer Sides

In the MDE NPRM, the transfer side provision for diagnostic equipment used by patients in the seated position required transfer surfaces to have the option to transfer from a mobility device onto one short side (depth) and one long side (width) of the surface, and provide unobstructed transfer to the surface. The Access Board received multiple comments and recommendations from the MDE Advisory Committee, which are discussed above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location). In the final rule, the Access Board retained this provision, but made editorial changes to clarify the location of the transfer sides and to relocate the language concerning unobstructed transfer into a new section M302.2.5. The transfer sides are still intended to allow a patient to choose to transfer onto either of two adjoining sides of the transfer surface. Additionally, based on comments and recommendations from the MDE Advisory Committee, the Access Board has decided to add an exception to this provision to accommodate chairs with fixed footrests which prevent transfer onto the adjoining sides. This is discussed in Section IV.B.1.b. (Significant Changes—Transfer Surface Location). As explained above, in order to provide patients with the ability to choose what side of their body they use to transfer, chairs with fixed footrests will provide the ability to transfer from either opposing side of the transfer surface. This allows the patient to choose to transfer from their right or left side and prevents the patient from having to transfer onto a fixed footrest.

M302.2.5 Unobstructed Transfer

In the MDE NPRM the Access Board proposed that each transfer side provide unobstructed access to the transfer surface, with an exception to permit temporary obstructions as long as they could be repositioned during transfer. This requirement is identical to the unobstructed transfer requirement in M301.2.4, and this provision is discussed in the Section V.C.2.d. (Section-by-Section Analysis—M301.2.4). The final rule retains the requirement for unobstructed transfer, but has been reworded to specify that each transfer surface must provide two unobstructed sides for the patient to transfer.

Additionally, as discussed above in the Section IV.B.1.d. (Significant Changes—Unobstructed Transfer), the final rule includes a second exception to the unobstructed transfer provision which permits obstructions of no more than three inches to extend beyond the transfer side of the transfer surface, provided that such obstructions do not protrude above the top of the transfer surface.

M302.3 Supports

This is an introductory section. An editorial change was made to this section as a result of the change in M302.3.2, described below, to replace the word ''stirrups'' with the term ''leg supports.''

M302.3.1 Transfer Supports

In the MDE NPRM the Access Board proposed that transfer supports must be provided for use with transfer sides on

diagnostic equipment used by patients in the seated position, and that these transfer supports must comply with the technical requirements in M305.2 of the proposed rule. There were no comments on this provision and no recommendations by the MDE Advisory Committee. Based on the restructure of the transfer surface provisions, described above in Section IV.B.1.b. (Significant Changes—Transfer Surface Location), and the additional technical criteria added to the transfer supports provisions, discussed above in Section IV.E.1 (Significant Changes—Transfer Supports), the Access Board has made editorial changes to this section. The technical requirements for transfer supports is in M305.2 of the final rule and has been reorganized to mirror the two types of transfer surfaces (end and side) in the final rule for diagnostic equipment used by the patient in the supine, prone, or side-lying position. The transfer surface required for diagnostic equipment used by patients in the seated position is similar to the new end transfer surface and therefore, diagnostic equipment used by patients in the seated position is required to comply with the transfer support provisions for end transfer supports. Additionally, the Access Board has included cross-references to the new transfer support requirements in M305.2.

M302.3.2 Leg Supports

The MDE NPRM did not propose to require stirrups to provide a method of supporting, positioning, and securing the patient's legs for diagnostic equipment used by patients in the seated position. However, in response to question 23, on whether diagnostic equipment used by patients in a seated position that provide stirrups should have to provide such support, the Board received six comments. NPRM, 77 FR at 6926. All six commenters concurred that when stirrups are provided for use with diagnostic equipment used by patients in the seated position, a method must be provided for supporting, positioning, and securing the patient's legs. The MDE Advisory Committee did not address this provision.

The Access Board concurs with the commenters, and the final rule requires that where stirrups are provided on seated diagnostic equipment, leg supports must also be provided and must comply with the technical requirements for leg supports in M305.4. This will ensure that patients with limited leg strength and control will be able to keep their legs in the appropriate position for examination.

M302.3.3 Head and Back Support

In the MDE NPRM the Access Board proposed to place the requirements for head and back support for diagnostic equipment used by patients in the seated position in M302. In the final rule the Access Board has decided to move the technical requirements for head and back support to M305 which includes all of the technical requirements for supports. Therefore, in the final rule, this provision instructs that where diagnostic equipment is used in a reclined position it must provide head and back support that complies with the technical requirements in M305.5.

M302.4 Lift Compatibility

The MDE NPRM proposed to require that diagnostic equipment used by patients in the seated position be usable with a patient lift and comply with either the proposed clearance in base (proposed M302.4.1) or clearance around base (proposed M302.4.2) technical requirements. This requirement is identical to the lift compatibility requirement for diagnostic equipment used by patients in the supine, prone, or side-lying position, and is discussed in the Section-by Section Analysis for M301.4. In the final rule the Access Board has made an editorial change to clarify the type of lift; namely portable patient lift, reduced the lift clearance to 39 inches and clarified that the clearance provisions only apply when the diagnostic equipment is being used with the portable patient lift. *See* Section V.C.4. (Section-by-Section Analysis—M301.4.) Additionally, as discussed above in Section IV.B.3. (Significant Changes—Lift Compatibility Exception), the Access Board has added an exception for diagnostic equipment that meets the following three criteria: Fixed overhead patient lifts are provided for use with the diagnostic equipment; the use with the fixed overhead patient lift with the diagnostic equipment is permitted by an enforcing authority; and the diagnostic equipment is clearly labeled as not compatible with portable patient lifts.

M303 Diagnostic Equipment Used by Patients in a Wheelchair

M303 in the final rule establishes the technical requirements for diagnostic equipment used by patients seated in a wheelchair, such as weight scales with wheelchair spaces and mammography equipment.

M303.1 General

This is an introductory section.

M303.2 Wheelchair spaces

This is an introductory section.

M303.2.1 Orientation

The MDE NPRM proposed to require wheelchair spaces to be designed so that a patient in a wheelchair using diagnostic equipment would be oriented in the same direction that other non-wheelchair using patients using the equipment are typically oriented. NPRM, 77 FR at 6927. The Access Board received one comment about this requirement. The commenter, an accessibility consultant, recommended that patient positioning be addressed along with orientation of the wheelchair, noting that there are many cases where it is insufficient to simply position the user facing the same direction as a non-wheelchair user. The commenter asserted that body positioning is key for obtaining accurate results when using diagnostic devices, such as x-ray equipment, and recommends amending the rule text to require wheelchair spaces to be designed so that the patient orients and positions their body in the same position as someone who is not in a wheelchair. There was no recommendation from the MDE Advisory Committee on this requirement. The Access Board has retained the original requirement in the final rule. The Board did not include requirements for patient body positioning because the diagnostic equipment cannot override the position in which an individual is seated in his or her wheelchair. Wheelchairs often are contoured to fit the specific and unique needs of the user and to provide support where it is needed. However, the design of a wheelchair space often influences whether a wheelchair user can orient with respect to diagnostic components. For example, without knee and toe space beneath an optometrist diopter, the patient cannot look into the lens.

M303.2.2 Width

The MDE NPRM proposed to require that diagnostic equipment used by patients seated in a wheelchair provide a wheelchair space that was at least 36 inches wide. There were no public comments and no MDE Advisory Committee recommendations regarding this requirement. Thus, the final rule retains the 36-inch wheelchair space width requirement. However, the Board added a new exception for wheelchair spaces on raised platforms, as discussed in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces), and discussed briefly below.

In the preamble to the MDE NPRM, the Access Board sought input on whether an exception to the width requirement was needed for wheelchair spaces on raised platforms. Multiple commenters responded to this provision and the MDE Advisory Committee recommended reducing the width requirement for wheelchair spaces on raised platforms. The Access Board has added an exception in the final rule that permits wheelchair spaces on raised platforms to be 32 inches wide minimum with edge protection no higher than 4 inches, measured from the platform surface.

M303.2.3 Depth

The MDE NPRM proposed two wheelchair space depth requirements based on how the wheelchair user enters the space: For spaces entered from the front or rear, 48 inches deep minimum; and for spaces that can only be entered from the side, 60 inches deep minimum. In the preamble in the MDE NPRM, the Access Board noted it was considering increasing the minimum depth for wheelchair spaces entered from the front or rear to 58 inches and sought input in question 29 on whether the Access Board should increase this minimum depth requirement. NPRM, 77 FR at 6928.

The Access Board received eight comments in response to this question. Three commenters (two disability rights organizations and a state agency concerned with accessibility) recommended increasing the depth of front or rear entered spaces to 58 inches. The other five commenters (manufacturers, medical associations and accessibility consultants) recommended retaining the proposed requirement in the MDE NPRM of 48 inches minimum, raising concerns that the size of the rooms in which the diagnostic equipment are located are insufficient to provide additional space. The MDE Advisory Committee did not make recommendations regarding the general requirement for depth for wheelchair spaces, but did make recommendations regarding the depth of wheelchair spaces on raised platforms, which is discussed in above in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces).

First, the Access Board clarifies that this provision is not a clear space requirement for wheelchair approach, but is instead the wheelchair space integral to diagnostic equipment for a patient seated in a wheelchair, such as mammography equipment or wheelchair accessible scales. Second, based on the comments received and the absence of recommendations from the MDE Advisory Committee to change the proposed requirement, the Access Board has retained the MDE NPRM's requirements for a minimum depth of 48 inches for wheelchair spaces entered from the front or rear, and a minimum depth of 60 inches for wheelchair spaces entered from the side. However, the Access Board has reorganized this provision into three separate requirements based on how the wheelchair space is entered, made an editorial change to clarify that front or rear entry is where the wheelchair space entry and exit is provided at only one end, and as discussed in Section IV.C.1. (Significant Changes—Width and Depth of Wheelchair Spaces), added an additional requirement to the depth provision for wheelchair spaces entered from the front or rear to permit a minimum of 40 inches if the wheelchair space provides pass-through from one end to the other.

M303.2.4 Equipment Clearances

The MDE NPRM proposed knee and toe clearance for diagnostic equipment used by patients seated in wheelchairs to allow for components in the wheelchair space which the patient could approach successfully to use for its intended diagnostic purpose. The proposed requirements for equipment clearances paralleled the knee and toe clearance requirements from the 2004 ADA and ABA Accessibility Guidelines. The proposed rule provided one additional requirement for breast platforms on mammography equipment, proposing the knee and toe clearance under a breast platform to be 25 inches deep (proposed M303.2.4). The MDE NPRM preamble sought input with question 34 on whether the dimensions recommended by the Wheeled Mobility Anthropometry Project should be adopted.[10] Three commenters responded. A manufacturer asserted that adopting a different requirement than what is already required under existing accessibility guidelines and standards would cause confusion and increase costs. A medical association asserted that to the best of their knowledge, imaging equipment already meets the Wheeled Mobility Anthropometry Project recommendations. The final commenter, a state agency concerned with accessibility, recommended adopting the new Wheeled Mobility Anthropometry Project recommendations. The MDE Advisory Committee only provided recommendations pertaining to the knee and toe clearance for mammography equipment.

The Access Board has determined that mammography equipment presents a unique challenge. Mammography equipment contains breast platforms which patients seated in wheelchairs must approach, and successfully maneuver their lower body under the platform enough to allow their chest to be flush with the leading edge of the platform. A separate set of equipment clearance requirements is necessary to address the unique positioning at mammography equipment. Therefore, in the final rule the Access Board has separated out the knee and toe clearance requirements into two provisions; breast platforms and other equipment. Breast platform requirements address the knee and toe clearance requirements for mammography equipment which is usable by patients seated in a wheelchair and is discussed in Section IV.C.2. (Significant Changes—Equipment Clearances for Breast Platforms). All other diagnostic equipment used by patients seated in a wheelchair must comply with the other equipment clearances requirements.

For all other equipment, the Access Board has decided to retain the original requirements in the proposed rule for knee and toe clearance. The Access Board is not persuaded to adopt the Wheeled Mobility Anthropometry Project recommendations for knee and toe clearances at this time. These recommendations represent a significant departure from the 2004 ADA and ABA Accessibility Guidelines. Therefore, the Board has elected in the final rule to retain the proposed provisions in the NPRM for knee and toe clearance for other equipment (M303.2.4.2). Due to the reorganization of the equipment clearances provision in the final rule, the knee and toe clearance requirements for the other equipment section have been renamed depth and height and relocated to M303.2.4.2. In addition, the Access Board has made an editorial change to the toe height requirement to clarify that the measurement is taken from the toe end of the wheelchair space.

M303.2.5 Surfaces

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair to provide a wheelchair space with a surface that does not slope more than 1:48 in any direction. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory

[10] The Wheeled Mobility Anthropometry Project recommended a toe clearance that is 5 inches deep maximum at 14 inches above the floor and a knee clearance that is 12 inches deep minimum at 28 inches above the floor.

Committee. There have been no changes made to this provision.

M303.2.6 Edge Protection

The MDE NPRM proposed edge protection on the ramps leading up to the raised platform (proposed M303.3.3.4), but did not require edge protection on the raised platforms themselves. The Access Board received two comments and two recommendations from the MDE Advisory Committee regarding edge protection on raised platforms. As discussed in Section IV.C.5. (Significant Changes—Edge Protection), the final rule requires platforms with wheelchair spaces that are raised more than 1½ inches in height to provide a minimum 2-inch-high edge protection, measured from the surface of the platform, on each side of the platform not providing entry to or exit from the diagnostic equipment.

M303.3 Entry

This is an introductory section.

M303.3.1 Vertical

The MDE NPRM proposed that for equipment with a change in level at the entry to the wheelchair space, level changes of up to ¼ inch high are permitted to be vertical. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M303.3.2 Beveled

The MDE NPRM proposed that for equipment with a change in level at the entry to the wheelchair space, level changes greater than ¼ inch but not greater than ½ inch would be required to be beveled with a slope not steeper than 1:2. This provision is consistent with the 2004 ADA and ABA Accessibility Guidelines. There were no comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M303.3.3 Ramped

The MDE NPRM proposed that for equipment with a change in level at the entry of a wheelchair space, level changes greater than ½ inch high would be required to be ramped and comply with technical requirements for running slope, cross slope, clear width, edge protection, and handrails. The Access Board received one comment on this provision. The commenter, a medical association, concurred with the requirement for handrails on diagnostic equipment with ramps over six inches in height. The MDE Advisory Committee only reviewed and gave recommendations on the portion of the provision addressing running slope. Therefore, the Access Board has retained the proposed requirements for cross slope, clear width, edge protection, and handrails in the final rule.

Regarding running slope, the MDE NPRM proposed that ramp runs have a running slope not steeper than 1:12. There were no comments on this section; however, as discussed in Section IV.C.3. (Significant Changes—Exception to Ramp Running Slope), the MDE Advisory Committee made a three-tiered recommendation for the allowable running slope. After careful consideration of the Advisory Committee's recommendations, the Access Board has retained in the final rule the original requirement for running slope, but has added an exception that permits a running slope not steeper than 1:8 for ramp runs with a maximum height of 2½ inches. See Section IV.C.3. (Significant Changes—Exception to Ramp Running Slope) for a full discussion of the rationale for this exception.

M303.4 Components

The MDE NPRM proposed to require diagnostic equipment used by patients seated in a wheelchair which has components that are used to examine specific body parts, be capable of examining those body parts of the patient while the patient is seated in a wheelchair. For example, an x-ray platform on which a patient places an arm or hand would have to be capable of examining the arm or hand of the patient while seated in a wheelchair. NPRM, 77 FR at 6930. There were no comments on this requirement and it was not addressed by the MDE Advisory Committee. There have been no changes made to this requirement.

M303.4.1 Breast Platform Adjustability

The MDE NPRM proposed a mammography breast platform height range of 30 inches high minimum and 42 inches high maximum above the floor. The Access Board received three comments on this provision, and the MDE Advisory Committee made several recommendations for changes. As discussed above in the Section IV.C.4. (Significant Changes—Breast Platform Adjustability), the Access Board has revised this provision to require the breast platform to be continually adjustable from a low height of 26 inches to a high height of 42 inches above the floor and made an editorial change to the provision title changing it from height to adjustability.

M304 Diagnostic Equipment Used by Patients in Standing Position

M304 in the final rule establishes the technical criteria for diagnostic equipment used by patients in a standing position such as a weight scale or x-ray equipment that is used in a standing position for certain diagnostic procedures.

M304.1 General

This is an introductory section.

M304.2 Standing Surface

The MDE NPRM proposed to require that the standing surface on which patients stand be slip resistant. In preparing the final rule, the Board has determined that as previously drafted this provision unintentionally placed requirements on the facility floor, as opposed to restricting the requirements to the diagnostic equipment itself. While the Access Board may choose to promulgate requirements for the building under its other rulemaking authority at a later date, this type of requirement is outside the scope of the MDE Standards and therefore M304 in the final rule has been restructured. The requirement for slip resistant and standing supports has been moved under this new requirement applying to standing surfaces. This reorganization ensures that only diagnostic equipment used by patients in a standing position that provides a surface for the patient to stand on must be slip resistant (M304.2.1) and provide standing supports (M304.2.2) in the final rule. Both of these requirements are discussed below.

M304.2.1 Slip Resistant

The MDE NPRM proposed to require that the standing surface on which patients stand be slip resistant. One manufacturer commented on this requirement, requesting that the rule provide clarification on how to define or measure a standing surface as ''slip resistant.'' This provision was not addressed by the MDE Advisory Committee. The Access Board has decided to retain the original requirement in the final rule as it is the Board's understanding that various industries employ different testing methods, there is no universally adopted or specified test for slip resistance, and the assessed level varies according to the measuring method used. Other than the change to clarify that the provision applies only to standing surfaces that are part of the

diagnostic equipment, there have been no changes to this provision.

M304.2.2 Standing Supports

The MDE NPRM proposed requiring standing supports on each side of the standing surface of diagnostic equipment used by patients in the standing position, and compliance with the technical requirements for standing supports in proposed M305.3. The Access Board received multiple comments and two recommendations from the MDE Advisory Committee. As discussed above in the Section IV.D.1. (Significant Changes—Standing Supports) and IV.E.2. (Significant Changes—Standing Supports), the final rule retains the general requirement that standing supports be provided on two sides of the standing surface. In addition, the Access Board has added a new exception for diagnostic equipment with entry and exit that permits pass-through from one end to another to provide one standing support provided it complies with the requirements for standing supports in the horizontal position in M305.3 in the final rule.

M305 Supports

M305 in the final rule provides the technical requirements for transfer supports, standing supports, leg supports, and head and back supports. Transfer supports are required for diagnostic equipment complying with M301 and M302 and standing supports are required for diagnostic equipment complying with M304. Leg supports and head and back supports apply, where provided, to diagnostic equipment complying with M301 and M302.

M305.1 General

This is an introductory section.

M305.2 Transfer Supports

This is an introductory section. As discussed above in Section IV.E.1. (Significant Changes—Transfer Supports), the Access Board strengthened the transfer support requirements and added additional requirements in the final rule to ensure that supports are capable of assisting with independent transfer onto and off of the diagnostic equipment. With the changes to the final rule, the Board sought to harmonize as much as possible, these requirements with the 2004 ADA and ABA Accessibility Guidelines for grab bars.

M305.2.1 Location

The MDE NPRM proposed that transfer supports be located within reach of the transfer surface and not obstruct transfer onto or off of the surface when in position (proposed M305.2.1). In the preamble to the MDE NPRM, the Access Board noted it was considering requiring transfer supports to be located no further than 1½ inches from the transfer surface, when measured horizontally, and requiring the transfer support to be located on the side of the transfer surface opposite the transfer side. NPRM, 77 FR at 6925. The Access Board sought public comment with question 19, which asked for input on multiple proposed changes to the transfer support provision, including whether the proposed location of the transfer support, and the requirement that it be located 1½ inches from the transfer surface, would be sufficient to facilitate transfers. *Id.*

Eight commenters responded to question 19, but only six of the commenters addressed the location of transfer supports. Two commenters, a manufacturer and a state agency concerned with accessibility, concurred with the technical requirements proposed in question 19 for the transfer support location. Another commenter, a disability rights organization, stated that transfer supports should be required on both sides of the equipment. A manufacturer noted that if the proposed transfer surface size of 30 inches wide is adopted, then a transfer support opposite the transfer side would be useless as the patient would be unable to reach the support until nearly fully on the diagnostic equipment. This commenter noted that an adjacent transfer support would be more effective, but would conflict with the provider expectations of bed and stretcher side rails. The final two commenters, a manufacturer and a medical association, raised concerns about requiring any transfer supports on imaging equipment, specifically MRI and CT machines, asserting that the supports may interfere with the image quality.

The MDE Advisory Committee made three separate recommendations for the location of transfer supports: A general requirement, a requirement for stretchers, and a requirement for imaging equipment. For the general provision, the MDE Advisory Committee recommended requiring transfer supports on both sides of the transfer surface that can be removed or repositioned during transfer and are located at a maximum distance of 1½ inches from the transfer surface. The Committee explained that ''transfer supports or handholds on adjustable medical equipment facilitate transfers onto a transfer surface by giving the individual something to hold or grab onto while transferring. This recommendation for placement of supports on both sides of the equipment will increase the options during patient transfers.'' MDE Advisory Committee Report, 86, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

For stretchers, the MDE Advisory Committee noted that patients enter from either of the long sides, rather than on one long side and one short side, and this change in orientation necessitated a different location for the transfer supports so that the support would be reachable during transfer. The MDE Advisory Committee recommended locating the transfer support ''along the long side of the transfer surface on the opposite side of the transfer.'' MDE Advisory Committee Report, 87–88, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Additionally, the Committee recommended a horizontal distance from the transfer surface of no more than 3 inches from the edge of the patient support surface, indicating that stretcher transfer supports are part of a rail system that needs to fold and store out of the way and therefore require more space to articulate. *Id.* at 96.

For imaging equipment, the MDE Advisory Committee recommended requiring transfer supports when the transfer surface was 24 inches deep or less, and requiring positioning supports for transfer surface depths of greater than 24 inches. *Id.* at 88–89. The Committee recommended requiring one support on the opposite side of the transfer side regardless of whether it was a transfer support or positioning support. The Committee noted that:

> Because of the size, diversity, and use of diagnostic imaging tables, this support will carry out different functions on different tables . . . This two-part recommendation recognizes the different use of the supports based on the table width. The Committee used a 24-inch dividing point for table width to accommodate the dimensions for the maximum reach range. For transfer surface depths on tables less than 24 inches wide, a transfer support must be available on the side opposite the entry of the transfer surface . . . For transfer surface depths on tables greater than 24 inches wide, a positioning support must be available on the side opposite the entry to the transfer surface. *Id.*

After review of the public comments and the MDE Advisory Committee recommendations, the Access Board has determined that there is a need for two types of transfer supports, based on the orientation of the transfer surface. As

described in Section IV.B.1.b.(Significant Changes—Transfer Surface Location), the Access Board has designated two types of transfer surfaces based on orientation for diagnostic equipment used by patients in the supine, prone, or side-lying position: End and side transfer surfaces, either of which can be employed depending on the configuration and use of the particular equipment. Here, a similar dual approach is warranted for transfer supports. While the MDE Advisory Committee recommended separate requirements based on the type of diagnostic equipment, stretchers and imaging equipment, the Access Board believes that the type of support should be based on where the transfer surface is located on the examination surface. Therefore, the Access Board has separated the location provision into end transfer supports and side transfer supports. End transfer supports cover diagnostic equipment used by patients in the supine, prone, or side-lying position with end transfer surfaces, M301.2.3.1 in the final rule, and all diagnostic equipment with transfer surfaces used by patients in the seated position, M302.2 in the final rule. Side transfer supports cover diagnostic equipment used by patients in the supine, prone, or side-lying position with side transfer surfaces, this includes stretchers and most imaging equipment, M301.2.3.2.

In the final rule the Access Board has decided for end transfer supports to require at least one support located on the long side of the transfer surface, opposite the transfer side. For side transfer supports, the Access Board has decided to require a transfer support which is capable of supporting transfer on each side of the transfer surface. A side transfer surface could contain one transfer support which is capable of being repositioned from one side to the other side depending on which side the patient chooses to transfer or it is acceptable to have two transfer supports, one on each long side, which are both capable of being removed or repositioned on the side the patient chooses to transfer. Additionally, the final rule requires both end and side transfer supports to be located a maximum of 1½ inches measured horizontally from the nearest edge of the transfer surface to the transfer support. In reviewing the MDE Advisory Committee's recommendations, the Access Board agrees that transfer supports that fold, collapse, or articulate need more space, but disagrees with the MDE Advisory Committee that an allowance for more space should apply only to stretchers and imaging equipment. The Access Board finds that other types of diagnostic equipment, such as hospital beds, also have transfer supports that collapse on either side to allow transfer. Therefore, the Access Board has provided an exception to the general provision which permits supports that fold, collapse, or articulate to be located three inches maximum from the nearest edge of the transfer surface to the transfer support. Additionally, as discussed in Section IV.E.1.b (Significant Changes—Positioning Supports), the Access Board has decided not to include positioning supports in the final rule.

M305.2.2 Length

In the MDE NPRM there was no requirement for length of the transfer support; however, the MDE NPRM preamble noted that the Access Board was considering requiring the transfer supports to extend the entire depth of the transfer surface and be a minimum of 15 inches in length. NPRM, 77 FR at 6925. The Access Board specifically sought public input with question 19, asking if the proposed length of the transfer supports would be sufficient to facilitate transfer and maintain position on the diagnostic equipment. *Id.*

Three commenters responded to this issue, two manufacturers and a state agency concerned with accessibility. The state agency concurred with the 15-inch requirement. One commenter did not support a 15-inch length transfer support. This commenter (a manufacturer) stated that a transfer support that is a minimum of 15 inches in length would make it even more difficult to comply with load bearing requirements and recommended that this length requirement be reduced. The second commenter, a manufacturer, recommended revising the proposed provision from requiring the transfer support to extend horizontally the entire depth of the transfer surface, to extend horizontally along the transfer surface to within three inches, to allow for manufacturing tolerances.

The MDE Advisory Committee made three transfer support length recommendations, one for each type of transfer support recommended by the Committee, described above. For the general provision, the MDE Advisory Committee recommended a transfer support with a length of 15 inches minimum, that overlaps the minimum depth of the transfer surface by 80 percent. The Committee explained that the transfer support length provides the gripping surface for the patient to grasp or maintain balance while transferring. MDE Advisory Committee Report, 90, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* For stretchers, the MDE Advisory Committee also recommended 15 inches in length stating that this would provide continuous support for patients and still accommodate the articulation that is necessary for the head and back support on stretchers. *Id.* For imaging equipment with transfer surfaces less than or equal to 24 inches deep, the Committee recommended requiring a transfer support to extend horizontally along the side of the patient table at the designated transfer location for at least the minimum width of the transfer surface, with a minimum length of 28 inches. For transfer surfaces greater than 24 inches deep, the MDE Advisory Committee recommended requiring a positioning support instead of a transfer support, which extends horizontally along the side of the patient table 12 to 16 inches and is located at a position to accommodate clinical use. *Id.* at 91–92.

The Access Board agrees with the MDE Advisory Committee that the addition of a requirement for a transfer support length provision is necessary and has adopted many of the MDE Advisory Committee's recommendations for transfer support length in the final rule. The Board restructured the Committee's recommendations to fit within the end and side transfer supports discussed above. For end transfer supports the Access Board has adopted the general provision recommended by the MDE Advisory Committee and determined that the required length will be 15 inches minimum. Additionally, the Access Board acknowledges that manufacturers need some flexibility with respect to the location of the support to account for clearances with other equipment components that may articulate or move. Therefore, the final rule requires that the 15-inch minimum length transfer support be positioned along 13½ inches minimum of the depth of the transfer surface.

For side transfer supports the Access Board adopted the MDE Advisory Committee recommendation for imaging equipment, that this support be a minimum of 28 inches long positioned along the width of the transfer surface. In addition, the Board has added two exceptions to the requirements for side transfer supports to address the concerns raised by the MDE Advisory Committee. The first exception addresses articulating patient surfaces, primarily stretchers, where a continuous 28-inch transfer support may conflict with other supports or railings as the

equipment is adjusted. In such cases, the support may be reduced to no less than 15 inches in length. The second exception applies to transfer supports on imaging bed surfaces of more than 24 inches in width, such as large x-ray tables, where the support is likely to be used in the latter stages of a transfer from a prone or side-lying position. In these cases, the Access Board finds that permitting the transfer support to be no less than 12 inches long is appropriate. While the exception is based on an Advisory Committee recommendation using the term ''positioning support,'' this is still transfer support, that can assist with transfer onto the transfer surface and will likely be used to reposition in the later stages of a transfer.

In question 19 part (e) the Access Board sought input on whether angled or vertical transfer supports should be permitted. 77 FR at 6925. Three commenters, a manufacturer, an accessibility consultant, and a disability rights organization, responded and all concurred with the proposal. The MDE Advisory Committee did not specifically address this proposal, however, in its recommendations for the length of transfer supports on imaging equipment, it did recommend that the transfer support should extend horizontally along the side of the patient table. MDE Advisory Committee Report, 90–91, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Access Board considered the public comments and the MDE Advisory Committee's recommendation, and has decided not to require that transfer supports be horizontal, allowing manufacturers flexibility to contour supports appropriate for the diagnostic purpose of the equipment.

M305.2.3 Height

In the MDE NPRM there was no specific requirement regarding the height of the transfer support, only that it be ''within reach'' of the patient (proposed M305.2.1). The Access Board sought input from the public in question 20 of the MDE NPRM preamble, on whether a transfer support height requirement of 6 inches minimum and 19 inches maximum above the transfer surface would be usable by patients with disabilities. NPRM, 77 FR at 6925. Six commenters responded to question 20. Four commenters (two manufacturers, one disability rights organization, and a state agency concerned with accessibility) supported the proposed height range. Three commenters (a manufacturer, a medical association, and a disability rights organization) did not support the proposal. The manufacturer opposing the proposed range raised concerns with its ability to attain a 19-inch height on its diagnostic equipment. The medical association asserted that radiography exam tables are not equipped with transfer bars, and if required should retract fully into the surface of the table and the disability rights organization expressed concern that 19 inches was too high to facilitate safe transfer.

The MDE Advisory Committee supported adding a requirement setting the height of transfer supports within the range described in question 20 in the MDE NPRM preamble, of 6 inches minimum and 19 inches maximum. The MDE Advisory Committee explained that the manufacturers on the Committee determined that this recommendation did not conflict with the IEC 60601–2–52, which provides requirements for side rails to prevent entrapment hazards, and would allow the equipment to be designed to provide accessibility and safety from entrapment hazards. MDE Advisory Committee Report, 94, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* Additionally, for transfer surfaces that are greater than 24 inches deep, the MDE Advisory Committee recommended requiring a positioning support instead of a transfer support, with a height of three to six inches above the transfer surface. *Id.*

The Access Board considered the public comments and the MDE Advisory Committee's recommendations, and has decided to include a new provision, M305.2.3 in the final rule, that requires the tops of transfer support gripping surfaces to be located 6 inches minimum and 19 inches maximum higher than the top of the associated uncompressed transfer surface during use. This range allows the manufacturer to choose a height between 6 inches and 19 inches to place their transfer supports; it does not require that the transfer supports be 19 inches high. The transfer support is permitted to be horizontal, angled, curved, or a combination of these as long as the top of any point along the gripping surface is located at or between 6 inches and 19 inches. Thus, the commenter's concern about reaching the 19-inch height is not warranted. Secondly, as discussed above in Section IV.E.1.b (Significant Changes —Positioning Supports), the Access Board has declined to include the MDE Advisory Committee's recommended positioning supports in the final rule; however, the Access Board does concur with the MDE Advisory Committee that for imaging equipment with transfer surfaces that exceed 24 inches in width, a lower transfer support is warranted. Therefore, in the final rule, the Access Board has provided an exception that permits transfer supports to be located three inches minimum and six inches maximum higher than the tops of the transfer surfaces for imagining beds that are greater than 24 inches wide.

M305.2.4 Cross Section

The proposed rule did not provide specific requirements for the cross section of transfer supports. However, in the MDE NPRM preamble, the Access Board noted that it was considering adopting the cross sectional dimensions for grab bars from the 2004 ADA and ABA Accessibility Guidelines for transfer supports. NPRM, 77 FR at 6925–6926. Specifically, the Access Board indicated it was considering requiring circular cross sections to have an outside diameter of 1¼ inches minimum and 2 inches maximum, and transfer supports with non-circular cross sections to have a cross section dimension of 2 inches maximum, and a perimeter dimension of 4 inches minimum and 4.8 inches maximum. *Id.* The Access Board sought input in MDE NPRM preamble question 21, on whether the gripping surfaces of current transfer supports on different types of equipment meet the cross sectional dimensions specified above and whether handholds that meet the above cross section dimensions could be integrated into armrests that are also cushioned to support arms and elbows. *Id.*

Five commenters responded to question 21. Two commenters (one manufacturer and one accessibility consultant) were opposed to permitting non-rounded cross sections, noting concern that harsh edges or angles may not allow users to comfortably and adequately grasp the support. One commenter (a manufacturer) asserted that because currently there are no standards, existing products would likely not meet the proposed provision. Another commenter (a manufacturer) was concerned that the requirement could preclude the use of cushioned arm pads.

The MDE Advisory Committee expressed confidence ''in reliance on the cross section dimensions in the 2010 Standards.'' MDE Advisory Committee Report, 99, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The Committee further opined:

Allowing both noncircular cross sections and circular cross sections gives manufacturers flexibility to employ the best configuration for use of the equipment, hand, grip strength, and power grab functions. While a majority of the Committee members supported a recommendation allowing both noncircular and circular cross sections, some members noted ergonomic considerations support the better functionality of circular cross section gripping surface. *Id.*

After review of the comments and the MDE Advisory Committee's recommendations, the Access Board has decided to apply the 2004 ADA and ABA Accessibility Guidelines for grab bar cross sections to transfer supports in the final rule. Accordingly, the final rule includes a new provision, M305.2.4, requiring transfer supports to have one of two cross sections: circular cross sections, with an outside diameter of 1¼ inches minimum and 2 inches maximum; or non-circular cross sections, a cross section dimension of 2 inches maximum and a perimeter dimension of 4 inches minimum and 4.8 inches maximum.

M305.2.5 Surface Hazards

The proposed rule did not provide any specific restrictions regarding surface hazards around the transfer supports. No public comments were submitted on this issue, but the MDE Advisory Committee voiced concern about surface hazards stating, ''gripping surface configurations must provide an effective and safe surface for patients to hold onto. Sharp edges or abrasive elements may injure and cause the patient to lose their grip during positioning or transfer.'' The MDE Advisory Committee recommended that a provision be added to the final rule requiring ''gripping surfaces to be free of sharp or abrasive elements and have rounded edges.'' The Committee based this recommendation on related provisions in the 2004 ADA and ABA Accessibility Guidelines for handrails and grab bars. MDE Advisory Committee Report, 101, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the MDE Advisory Committee's recommendation and views the proposed provision as beneficial and consistent with the cross section requirements of M305.2.4, above. Therefore, the Access Board has added a new provision to the final rule, M305.2.5 Surface Hazards, to ensure that transfer supports and surfaces adjacent to transfer supports are free of sharp or abrasive components and have eased edges.

M305.2.6 Gripping Surfaces

The proposed rule did not provide any specific requirements regarding gripping surfaces on transfer supports. However, in the MDE NPRM preamble the Access Board repeatedly noted that it was considering applying many of the provisions from the 2004 ABA and ADA Accessibility Guidelines for grab bars and handrails to transfer supports. NPRM, 77 FR at 6924–6926. The MDE Advisory Committee explained that:

[t]ransfer supports may contain elements to provide structural support or prevent patient entrapment. The elements, bars, pickets, spacers, panels, and similar features, connect to the transfer support and may interrupt the gripping surface. At the point of connection, these features impede the ability to grasp completely around the cross section of the gripping surface. MDE Advisory Committee Report, 102, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report. The Committee recommended requiring the bottom of the transfer support to have no obstructions affecting more than 20 percent of the transfer support's length. Id.*

The Access Board concurs with the recommendation of the MDE Advisory Committee and views the proposed provision as beneficial and consistent with the existing accessibility guidelines. Therefore, the Access Board has added this new provision to the final rule, M305.2.6, which ensures that an adequate surface area for gripping is provided to the patient.

M305.2.7 Clearance

In the MDE NPRM, the Access Board did not provide any specific requirements for clearances around the transfer support. However, in the preamble to the MDE NPRM the Access Board noted that it was considering applying the 2004 ADA and ABA Accessibility Guidelines for clearance around grab bars to the transfer support provision in the final rule. NPRM, 77 FR at 6926. Specifically, the Access Board sought input from the public in question 22, on whether transfer supports on diagnostic equipment could provide 1½ inches minimum clearance around the gripping surface. *Id.* Two commenters responded, both manufacturers, and indicated that transfer supports could provide 1½ inches minimum clearance around the transfer support. The MDE Advisory Committee concurred with the commenters and expressed support for the use of the 2010 ADA Standards and International Building Code Requirements (ICC/ANSI A117.1–2009), and recommended adding the requirements to the final rule. MDE Advisory Committee Report, 100, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

Based on public commenter responses and MDE Advisory Committee recommendations, the Access Board has added a new provision to the final rule, M305.2.7, requiring a 1½ inch minimum clearance between the transfer support gripping surface and adjacent surfaces or obstructions.

M305.2.8 Fittings

The MDE NPRM proposed to require that transfer supports not rotate in their fittings (proposed M305.2.3). Five commenters addressed this provision. Four of the commenters disagreed with this requirement and explained the need for transfer supports to be able to rotate in their fittings. Specifically, one commenter (manufacturer) asserted that the technical criteria from the 2004 ADA and ABA Accessibility Guidelines for grab bars in bathrooms should not be applied to exam tables as they would restrict the ability for the transfer supports to be moved out of the way after transfer. Further, this commenter noted that the requirement conflicts with proposed M302.2.3, which allows for temporary obstructions such as armrests, footrests, and side rails that can be repositioned to allow for transfer. Another commenter (manufacturer) pointed out that bed rails, which are common on hospital beds, require a latched position and an unlatched position, which allows them to rotate in their fittings when not latched. A different manufacturer stated that its seated diagnostic equipment uses armrests as transfer supports, which can be pushed back toward the rear of the equipment to allow entry. An accessibility consultant recommended swing-away or removable armrests for chairs to allow for transfer on either side. The only commenter (accessibility consultant) opposed to allowing transfer supports to rotate in their fittings, expressed concern for the potential for injury if transfer supports rotated unexpectedly during transfer.

The MDE Advisory Committee recommended amending this provision to allow transfer supports to rotate in their fittings, but to require that they not rotate when they are locked into place for transfer. The Committee noted that it is advantageous to allow supports to perform the needed movement, but they should not do so when locked. MDE Advisory Committee Report, 102–103, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.*

The Access Board concurs with the majority of the commenters and the MDE Advisory Committee. As noted in proposed M302.2.3, the Access Board intended to allow manufacturers to provide temporary obstructions such as armrests and bedrails that can be repositioned, or rotate in their fittings, and then be locked into place when needed as a transfer support. Therefore, the Access Board has revised this provision in the final rule to require that transfer supports do not rotate in their fittings when in place for transfer (M305.2.8).

M305.3 Standing Supports

M305.3 provides the technical requirements for standing supports which are required on diagnostic equipment covered by M304. This provision has been reorganized in the final rule into requirements for length and height, as opposed to vertical and horizontal.

In the MDE NPRM preamble, the Access Board noted that it was considering adopting the cross section dimensions for grab bars from the 2004 ADA and ABA Accessibility Guidelines and applying them to standing supports. The Access Board sought public input in questions 39 and 40 in the MDE NPRM preamble on whether the cross section dimensions for gripping surfaces should be applied to standing supports and whether standing supports can provide a 1½ inch minimum clearance around the gripping surface. Three commenters responded to question 39 (a medical association, accessibility consultant, and a state agency concerned with accessibility). All three concurred with adding cross section dimension requirements to standing supports. Two commenters responded to question 40 (one medical association and a state agency concerned with accessibility), and both concurred that diagnostic equipment could provide a 1½ inch minimum clearance around the gripping surface of standing supports. The MDE Advisory Committee did not address the cross section and clearance proposal for standing supports. Unlike transfer supports, standing supports can be horizontal or vertical and thus there will be variations in the configuration of standing supports dependent on the equipment configuration. Due to this wide variety of allowable standing supports and the significant difference in the nature of how a standing support is used versus a transfer support, the Access Board has decided not to adopt cross section dimensions or require a minimum clearance around the gripping surface for standing supports in the final rule.

Additionally, one commenter (manufacturer) requested that requirements for structural strength be added to the standing support provision. For the same reasons the Access Board has removed the requirement of structural strength for transfer supports (See Section IV.E.1.a. (Significant Changes—Structural Strength) the Access Board declines to adopt such a requirement for standing supports in the final rule.

M305.3.1 Length

In the MDE NPRM, the Access Board proposed a gripping surface length of four inches minimum for horizontal standing supports. No public comments were submitted on this requirement. The MDE Advisory Committee supported the proposed technical provisions, but recommended adding additional criteria for standing supports on raised platforms with wheelchair spaces. As discussed above in the Section IV.E.2. (Significant Changes—Standing Supports), the final rule requires that horizontal standing supports be positioned horizontally in relation to standing surfaces and retains the proposed requirement of four inches minimum length. The Access Board added a new provision applying to diagnostic equipment containing a wheelchair space that also requires standing supports. This provision, M305.3.1.2 in the final rule, has added two new requirements for this type of equipment. First, for diagnostic equipment containing wheelchair spaces with one entry that also serves as the exit, the length of the gripping surface for horizontal standing supports must be equal to or greater than 80 percent of the overall length of the platform. Second, for diagnostic equipment with wheelchair spaces that permit pass-through from one end to the other, the length of the gripping surface for the horizontal standing support must be at least equal to the length of the platform. In the final rule these requirements are located in M305.3.1.1 Horizontal Position and M305.3.1.2 Diagnostic Equipment Containing a Wheelchair Space.

For vertical standing supports, the MDE NPRM proposed a gripping surface length of 18 inches minimum. There were no public comments submitted on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule, the Access Board retained the original requirement for gripping surface length and clarified that the vertical standing supports must be positioned vertically in relation to the standing surface. Both requirements are included in the new M305.3.1.3 Vertical Position provision in the final rule.

M305.3.2 Height

For horizontal supports, the MDE NPRM proposed a gripping surface height of 34 inches minimum and 38 inches maximum above the standing surface. There were no public comments on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule the Access Board retains the original requirement. This requirement has been relocated to M305.3.2.1 in the final rule.

For vertical supports, the MDE NPRM proposed that the bottom end of the support be 34 inches high minimum and 37 inches high maximum above the standing surface. There were no public comments on this requirement, and the MDE Advisory Committee supported the proposed technical provisions. In the final rule the Access Board retains the original requirement, but made a few minor editorial changes to the text. This requirement has been relocated to M305.3.2.2 in the final rule.

M305.3.3 Fittings

The MDE NPRM proposed to prohibit standing supports from rotating in their fittings. There were no comments on this section and it was not addressed by the MDE Advisory Committee. The Access Board made no changes to this provision.

M305.4 Leg Supports

As discussed above in Section V.C.3.b (Section-by-Section Analysis—M301.3.2) and Section V.C.7.b (Section-by-Section Analysis—M302.3.2), the technical requirements for leg supports from M301 and M302 have been relocated to M305 Supports. The MDE NPRM proposed that where stirrups are provided, they must provide a method to support, position, and secure the patients legs. Four commenters (medical association, accessibility consultant, disability rights organization, and a state agency) agreed with requiring leg supports when stirrups are provided.

The MDE Advisory Committee agreed that, for procedures that use stirrups and require the leg to be stable, there must be a method to support the patient's legs. The Committee referenced ANSI/AAMI HE75 which recommends that ''[f]or patients with limited leg strength and control, instead of stirrups that support only the foot and require active user leg strength, leg supports that support both the foot and the leg should be used to assist patients in keeping their legs in the appropriate position.'' MDE Advisory Committee

Report, 105, available at *https://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report.* The MDE Advisory Committee recommended adding additional language to this provision to clarify that ''where the equipment provides stirrups, it must also provide an alternate method to support, position, and secure the patients legs (specifically including sufficient support of the patient's thigh, knee, and calf to stabilize the leg). This method will either supplement or serve as a substitute for the stirrups.'' *Id.*

After reviewing the MDE Advisory Committee recommendations, the Access Board has decided that the proposed provision is sufficient to require the leg support advocated by the MDE Advisory Committee and has therefore not adopted the MDE Advisory Committee recommendation to require an alternate method of leg supports. However, in the final rule the Access Board has made an editorial change in terminology, from stirrups to leg supports, in response to the MDE Advisory Committee recommendation and to provide consistency with the headings of other support provisions that are based on the body part supported.

M305.4 Head and Back Support

As discussed above in Section V.C.3.c (Section-by-Section Analysis—M301.3.3) and Section V.C.7.c. (Section-by-Section Analysis—M302.3.3), the technical requirements for head and back supports from M301 and M302 have been relocated to M305 Supports. The MDE NPRM proposed to require diagnostic equipment used by patients in the supine, prone, or side-lying position and the seated position that can be adjusted to a reclined position to provide head and back support throughout the entire range of the incline. Three manufacturers commented on this provision. One manufacturer asserted that this requirement was ambiguous and that he had to read it multiple times to understand it; however, this commenter also indicated that the tables it currently manufactures meet the proposed requirement. Another manufacturer noted that existing MRI equipment meets this requirement. The final manufacturer asserted that a reclining backrest necessarily provides head and back support, unless the Access Board intended a different meaning for ''support.'' The MDE Advisory Committee did not review the proposed requirement for head and back support, and thus provided no recommendations on this requirement.

After review of the comments, the Access Board has decided not to make any changes to this provision in the final rule. All of the commenters on this topic agree that current diagnostic equipment meets the proposed requirement and the Access Board believes that this requirement is clearly articulated. Therefore, the final rule requires that where diagnostic equipment can be adjusted to a reclined position, head and back support must be provided.

M306 Communication

M306 in the final rule provides the technical criteria for communication from the diagnostic equipment to the patient.

M306.1 General

The MDE NPRM proposed that, where diagnostic equipment communicates instructions or other information to the patient, the instructions or information must be provided in at least two of the following methods: Audible, visible, or tactile (proposed M306.1). The Access Board sought public input in question 41 in the preamble to the MDE NPRM, on whether diagnostic equipment that communicates instructions or other information to the patient should provide information in all three methods of communication, and what the cost to provide all three methods would be. NPRM, 77 FR at 6931. Seven commenters responded. Three commenters (a manufacturer, a medical association, and a state agency concerned with accessibility) concurred with the proposed requirement to provide two methods of communication. Three commenters (two disability rights organizations and one medical association) supported requiring all three modes of communication, and the final commenter (a manufacturer) recommended requiring one mode of communication if the medical provider is present and three modes of communication for home use devices. The MDE Advisory Committee did not address this provision.

The Access Board carefully considered the public comments; however, it has decided to retain the provision from the proposed rule, requiring diagnostic equipment that communicates instructions or other information to the patient to provide the communication in two methods. The commenters were split in their support of two or three methods of communication and the commenters supporting the increase to three methods of communication provided no additional information to warrant the increase. The commenter that recommended different requirements for home-use equipment is not dispositive as this rule does not cover any home use equipment. The Access Board has concluded that providing two means of communication will serve the majority of people and that there was not enough information provided to warrant an increase in this requirement in the final rule.

M307 Operable Parts

M307 in the final rule provides the technical criteria for operable parts used by patients to activate, deactivate, or adjust the diagnostic equipment. For example, equipment used for an auditory examination may require the patient to press a button when sounds are heard. M307 does not apply to controls used only by health care personnel or others who are not patients. There were no comments received on the proposed provisions, and as discussed below, the provisions from the proposed rule have been retained in the final rule.

The Access Board did receive comments in response to question 43, which sought public input on whether the final rule should include reach range requirements such as those in the 2004 ADA and ABA Accessibility Guidelines for an unobstructed forward reach or side reach for the operable parts provision. Five commenters responded, one commenter (state agency concerned with accessibility) recommended adopting the reach ranges and four commenters (one medical association, one academic, and two disability rights organizations) recommended against adding reach ranges for operable parts to the final rule. One of these commenters (disability rights organization) explained that the 2004 ADA and ABA requirements are not appropriate for application to operable parts of medical diagnostic equipment. The MDE Advisory Committee did not address this provision. Based on the majority of the commenters response, the Access Board has decided not to add reach ranges to the operable parts section at this time.

M307.1 General

This is an introductory section.

M307.2 Tactilely Discernible

The MDE NPRM proposed that operable parts intended for patient use be tactilely discernible without activation. Patients who are blind or have low vision have difficulty

distinguishing a flat membrane button or similar control unless it is tactilely discernible from the surrounding surface and any adjacent controls. The most common method to ensure that buttons and similar controls are tactilely discernible is to raise part or all of the control surface above the surrounding surface and at a distance from any adjacent controls such that a relief of each individual control can be determined by touch. There were no public comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M307.3 Operation

The MDE NPRM proposed to require operable parts to be operable with one hand and not require tight grasping, pinching, or twisting of the wrist. There were no public comments on this section and it was not addressed by the MDE Advisory Committee. There have been no changes made to this provision.

M307.4 Operating Force

The MDE NPRM proposed to restrict the force required to activate operable parts to 5 pounds. The Access Board sought public input on this provision in question 42 on whether the operating force should be reduced to 2 pounds. NPRM, 77 FR at 6932. One commenter, a state agency concerned with accessibility, responded and concurred with the suggested reduction. The MDE Advisory Committee did not address this requirement. Although the Access Board initially considered a reduction in the force required to activate operable parts, upon further consideration, the Board found no reason to deviate from the long-established maximum of 5 pounds in the 2004 ADA and ABA Accessibility Guidelines. 36 CFR part 1191, App. D 309.4. Therefore, there have been no changes made to this provision.

VI. Regulatory Process Matters

A. Final Regulatory Assessment (E.O. 13563 and E.O. 12866)

Executive Orders 13563 and 12866 direct agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Important goals of regulatory analysis are to (1) establish whether federal regulation is necessary and justified to achieve a market failure or other social goal and (2) demonstrate that a range of reasonably feasible regulatory alternatives have been considered and that the most efficient and effective alternative has been selected. Executive Order 13563 also recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively those values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The final rule, which sets forth the MDE Standards, is a significant regulatory action within the meaning of Executive Order 12866. *See* E.O. 12866 § 3(f)(4), 58 FR 51735 (Oct. 4, 1993) (defining ''significant regulatory action'' as, among other things, regulatory action that raises novel legal or policy issues). Accordingly, we prepared a final regulatory assessment (Final RA) to accompany the MDE Standards. The Final RA is available on the Access Board's Web site (*www.access-board.gov*), as well the federal government's online rulemaking portal (*www.regulations.gov*). Summarized below are some of the key findings of this regulatory assessment.

Section 510 of the Rehabilitation Act, as amended by the Patient Protection and Affordable Care Act, requires the Access Board, in coordination with the Food and Drug Administration, to issue accessibility standards that contain minimum technical criteria to ensure that medical diagnostic equipment is accessible to and usable by patients with disabilities. Examples of such diagnostic equipment include examination tables and chairs, weight scales, mammography equipment, and other imaging equipment. The Access Board is now issuing the final rule pursuant to this authority.

The MDE Standards set forth minimum technical criteria for medical diagnostic equipment to facilitate access and use of medical diagnostic equipment by persons with disabilities, most particularly those with mobility- or communication-related impairments. However, under Section 510, the Access Board is statutorily tasked only with promulgation (and revision) of these Standards. Although the MDE Standards do not have legal effect until adopted (in whole or in part) by an enforcing authority, they can advance accessibility to medical services for persons with disabilities by providing specific guidance concerning accessible medical diagnostic equipment that can be used by service providers in a voluntary manner.

At this point, the Board does not know whether enforcing authorities will adopt the MDE Standards, nor (if they do) to what extent health care practices or particular types of medical diagnostic equipment will be required to comply with the Standards' technical requirements. For this reason, the Board cannot estimate the incremental monetary or quantitative impacts of the final rule.

Nevertheless, the Board is able to characterize qualitatively some of the potential impacts of these Standards. If enforcing agencies adopt the MDE Standards as mandatory for entities regulated under their jurisdiction, the Standards could affect health care providers, medical device manufacturers, and individuals with disabilities. Once health care providers and facilities are required to acquire accessible medical equipment, they could incur compliance costs, to the extent that their equipment is not already accessible. Medical device manufacturers would then decide whether to incur incremental costs to meet the demand for accessible equipment, and some or many manufacturers may have an economic incentive to produce accessible equipment. Finally, given the many barriers to health care that patients with disabilities encounter due to inaccessible medical diagnostic equipment, individuals with mobility and communication disabilities will benefit from access to and use of diagnostic equipment meeting the MDE Standards. Consequently, they may be able to receive health care comparable to that received by their non-disabled counterparts.

In addition, the Standards could yield some immediate benefits, even before any adoption by implementing agencies in formal rulemaking. First, the technical specifications for accessible MDE incorporated in the Standards will benefit enforcing agencies that are considering similar accessibility requirements for entities under their jurisdiction. Although enforcing agencies have full authority over whether to adopt the Access Board's final rule (in whole or in part), the technical specifications in the MDE Standards reflects the input from a diverse set of stakeholders and provide solid groundwork for any future rulemaking pertaining to the accessibility of medical diagnostic equipment. Second, the Standards will serve as a best-practice document for the medical device industry and for health care providers and facilities. While the MDE Standards are non-binding, health care providers can use this final rule as

guidance on how to provide equitable access to medical diagnostic equipment for people with mobility and communication disabilities. Manufacturers can also use the MDE Standards as they target their research and development efforts at producing diagnostic equipment that can be used by a larger segment of population—one that includes more people with disabilities and older adults.

The Board thus concludes that the potential benefits of the MDE Standards justify the potential costs; that the MDE Standards will impose the least burden on society, consistent with achieving the regulatory objectives; and that the regulatory approach selected will maximize net benefits.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires federal agencies to analyze the impact of regulatory actions on small entities, unless an agency certifies that the rule will not have a significant impact on a substantial number of small entities. 5 U.S.C. 604, 605(b). The MDE Standards do not impose any mandatory requirements on any entity, including small entities. Therefore, we did not prepare a final regulatory flexibility analysis for the final rule.

C. Executive Order 13132: Federalism

The MDE Standards do not impose any mandatory requirements on state and local governments. The MDE Standards do not have any direct effects on the state governments, the relationship between the national government and state governments, or the distribution of power and responsibilities among the various levels of government. The MDE Standards do not preempt state law. Therefore, the consultation and other requirements of Executive Order 13132 (Federalism) do not apply.

D. Unfunded Mandates Reform Act

The proposed standards do not impose any mandatory requirements on state, local, or tribal governments or the private sector. Therefore, the Unfunded Mandates Reform Act does not apply.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA), federal agencies are generally prohibited from conducting or sponsoring a ''collection of information'' as defined by the PRA, absent OMB approval. *See* 44 U.S.C. 3507 *et seq.* The MDE Standards do not impose any new or revised collections of information within the meaning of the PRA.

List of Subjects in 36 CFR Part 1195

Health care, Individuals with disabilities, Medical devices.

Approved by vote of the Board on September 14, 2016.

David M. Capozzi,

Executive Director.

■ For the reasons stated in the preamble, the Access Board adds part 1195 to title 36 of the Code of Federal Regulations to read as follows:

PART 1195—STANDARDS FOR ACCESSIBILE MEDICAL DIAGNOSTIC EQUIPMENT

Sec.
1195.1 Standards.
Appendix to Part 1195—Standards for Accessible Medical Diagnostic Equipment

Authority: 29 U.S.C. 794f.

§ 1195.1 Standards.

The standards for accessible medical diagnostic equipment are set forth in the appendix to this part. Other agencies, referred to as an enforcing authority in the standards, may adopt the standards as mandatory requirements for entities subject to their jurisdiction. Advisory sections and figures that illustrate the technical requirements in the appendix to part 1195 are available on the Internet at: *www.access-board.gov.* These advisory materials provide guidance only and do not contain mandatory requirements.

Appendix to Part 1195—Standards for Accessible Medical Diagnostic Equipment

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Chapter 1: Application and Administration

M101 General

M101.1 Purpose. These Standards (MDE Standards) contain scoping and technical requirements for medical diagnostic equipment (diagnostic equipment) to ensure accessibility to, and usability of the diagnostic equipment by patients with disabilities. The MDE Standards provide for independent access to, and use of, diagnostic equipment by patients with disabilities to the maximum extent possible.

M101.2 Application. Sections M301 through M304 shall be applied to diagnostic equipment, based on the patient positions that the equipment supports, during patient transfer and diagnostic use. Sections M306 and M307 shall be applied to diagnostic equipment where communication features or operable parts are provided for patient use.

M101.3 Existing Diagnostic Equipment. The MDE Standards do not address the applicability of scoping or technical requirements to existing diagnostic equipment. Enforcing authorities, such as the Department of Justice or the Department of Health and Human Services, have authority over the accessibility of existing equipment and any regulation of that equipment will be effective only to the extent required by such enforcing authorities.

M101.4 Equivalent Facilitation. The use of alternative designs or technologies that result in substantially equivalent or greater accessibility and usability than specified in the MDE Standards is permitted.

M101.5 Dimensions. The MDE Standards are based on adult dimensions and anthropometrics. Dimensions that are not stated as ''maximum'' or ''minimum'' are absolute.

M101.6 Dimensional Tolerances. Dimensions are subject to conventional industry tolerances for manufacturing processes, material properties, and field conditions.

M101.7 Units of Measurement. Measurements are stated in U.S. customary and metric units. The values stated in each system (U.S. customary and metric units) may not be exact equivalents, and each system shall be used independently of the other.

M102 Definitions

M102.1 Defined Terms. For the purpose of the MDE Standards, the following terms have the indicated meaning:

End Transfer Surface. A transfer surface located at one end of an examination surface that allows patient transfer at the end and one adjoining side of the examination surface.

Enforcing Authority. An agency or other governmental entity that adopts the MDE Standards as mandatory requirements for entities subject to its jurisdiction. Enforcing authorities may include, but are not limited to the United States Departments of Justice and Health and Human Services.

Examination Chair. Diagnostic equipment with a seat in which a patient typically is positioned with buttocks approximately parallel to the ground and shins approximately perpendicular to the ground. Examination chairs typically have back support and may recline to properly position the patient during examination. Such chairs may also have footrests or stirrups. Examination chairs include, but are not limited to, equipment used for dental, ophthalmic, podiatric, gynecological,

urological, and ear, nose, and throat examinations.

Imaging bed. A component of diagnostic scanning equipment that accommodates patients in supine, prone, or side-lying positions.

Imaging equipment with bores. Diagnostic scanning equipment using magnets, x-rays, or detectors into which a patient and the table on which the patient lies is inserted into the equipment through a cylindrical opening (bore) in order to achieve the positioning accuracy needed during the scan. Such equipment includes, but is not limited to, computerized axial tomography (CT or CAT), positron emission tomography (PET), and nuclear medicine (NM) scanning equipment or a combination thereof.

Medical Diagnostic Equipment (Diagnostic Equipment). Equipment used in, or in conjunction with, medical settings by health care providers for diagnostic purposes.

Operable Parts. Components of diagnostic equipment that are used by the patient to activate, deactivate, or adjust the equipment.

Side Transfer Surface. A transfer surface located within the length of the examination surface that allows patient transfer on two opposing sides of the examination surface.

Transfer Surface. Part of diagnostic equipment onto which patients who use mobility devices or aids transfer when moving onto and off of the equipment.

Wheelchair Space. Space for a single wheelchair and its occupant.

M102.2 Undefined Terms. Terms not defined in M102.1 or in regulations or policies issued by an enforcing authority shall be given their ordinarily accepted meaning in the sense that the context implies.

M102.3 Interchangeability. Words, terms, and phrases used in the singular include the plural and those used in the plural include the singular.

Chapter 2: Scoping

M201 General

M201.1 Application by Enforcing Authority. The enforcing authority shall specify the number and type of diagnostic equipment that are required to comply with the MDE Standards.

M201.2 General Exception. Medical diagnostic equipment shall not be required to comply with one or more applicable requirements in the MDE Standards in the rare circumstances where compliance would alter diagnostically required structural or operational characteristics of the equipment and would prevent the use of the equipment for its intended diagnostic purpose. Diagnostic equipment subject to M201.2 shall comply to the maximum extent practicable.

Chapter 3: Technical Requirements

M301 Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position

M301.1 General. Diagnostic equipment that supports patients in a supine, prone, or side-lying position shall comply with M301.

Exception: Examination chairs complying with M302 that recline to facilitate diagnosis after patients transfer onto the chair shall not be required to comply with M301.

M301.2 Transfer Surface. A transfer surface shall be provided and shall comply with M301.2.

M301.2.1 Adjustability. Transfer surfaces shall be adjustable in height measured from the floor to the top of the uncompressed transfer surface and shall provide the following:

A. A low transfer position at a height of 17 inches (430 mm) minimum and 19 inches (485 mm) maximum;

B. A high transfer position at 25 inches (635 mm); and

C. At least 4 additional transfer positions located between the low and high transfer positions and separated by 1 inch (25 mm) minimum.

M301.2.2 Sunset. The low transfer position height, Item A of M301.2.1, shall cease to have effect on January 10, 2022.

M301.2.3 Size. The size of the transfer surface shall comply with M301.2.3.1 or M301.2.3.2. The size of transfer surfaces shall be measured from center points of their opposing sides.

M301.2.3.1 End Transfer Surface. End transfer surfaces shall be 28 inches (710 mm) wide minimum and 17 inches (430 mm) long minimum.

Exception: Transfer surfaces for imaging equipment with bores shall be permitted to be 21 inches (535 mm) wide minimum but shall not be permitted to be less than the full width of the examination surface provided for the patient.

M301.2.3.2 Side Transfer Surface. Side transfer surfaces shall be 28 inches (710 mm) wide minimum and 28 inches (710 mm) long minimum.

Exception: Transfer surfaces for imaging equipment with bores shall be permitted to be 21 inches (535 mm) wide minimum but shall not be permitted to be less than the full width of the examination surface provided for the patient.

M301.2.4 Unobstructed Transfer. Each transfer surface shall provide two unobstructed sides for patient transfer.

Exceptions: 1. Obstructions no more than 3 inches (75 mm) deep shall be permitted to extend beyond transfer sides of transfer surfaces provided that such obstructions do not protrude above the tops of transfer surfaces.

2. Temporary obstructions shall be permitted provided that they can be repositioned during transfer to comply with M301.2.4, including Exception 1.

M301.3 Supports. Transfer supports, leg supports, and reclining surfaces shall comply with M301.3.

M301.3.1 Transfer Supports. Transfer surfaces required by M301.2 shall provide transfer supports and shall comply with M305.2.

M301.3.2 Leg Supports. Where stirrups are provided, leg supports shall also be provided and shall comply with M305.4.

M301.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided and shall comply with M305.5.

M301.4 Lift Compatibility. Diagnostic equipment shall be usable with portable patient lifts and, when in use with such lifts, shall comply with M301.4.1 or M301.4.2.

Exception: Where fixed overhead patient lifts are provided, and when their use with diagnostic equipment is permitted by an enforcing authority, diagnostic equipment shall not be required to meet the lift compatibility requirements of this section provided that such equipment is clearly labeled as not compatible with portable floor lifts.

M301.4.1 Clearance in Base. The base of diagnostic equipment shall provide a clearance 39 inches (990 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of examination surfaces is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment. Components of diagnostic equipment are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

M301.4.2 Clearance Around Base. The base of diagnostic equipment shall provide a clearance 6 inches (150 mm) high minimum measured from the floor and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance shall be 26 inches (660 mm) wide maximum at the edge of the examination surface and shall be permitted to increase at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth.

M302 Diagnostic Equipment Used by Patients in Seated Position

M302.1 General. Diagnostic equipment that supports patients in a seated position shall comply with M302.

Exception: Where weight scales contain wheelchair spaces complying with M303 and also provide a seat integral to the equipment, the scales shall not be required to comply with M302.

M302.2 Transfer Surface. A transfer surface shall be provided and shall comply with M302.2.

M302.2.1 Adjustability. Transfer surfaces shall be adjustable in height measured from the floor to the top of the uncompressed transfer surface and shall provide the following:

A. A low transfer position at a height of 17 inches (430 mm) minimum and 19 inches (485 mm) maximum;

B. A high transfer position at 25 inches (635 mm); and

C. At least 4 additional transfer positions located between the low and high transfer positions and separated by 1 inch (25 mm) minimum.

M302.2.2 Sunset. The low transfer position height, Item A of M302.2.1, shall cease to have effect on January 10, 2022.

M302.2.3 Size. Transfer surfaces shall be 21 inches (610 mm) wide minimum and 17 inches (430 mm) deep minimum. The size of transfer surfaces shall be measured from center points of their opposing sides.

M302.2.4 Transfer Sides. Options to transfer from a mobility device shall be provided on two adjoining sides of transfer surfaces.

Exception: Options to transfer to or from a mobility device onto opposing sides of

transfer surfaces shall be permitted where the transfer surface is obstructed by fixed footrests.

M302.2.5 Unobstructed Transfer. Each transfer side complying with M302.2.4 shall provide unobstructed access to transfer surfaces.

Exceptions: 1. Obstructions no more than 3 inches (75 mm) deep shall be permitted to extend beyond transfer sides of transfer surfaces provided that such obstructions do not protrude above the tops of transfer surfaces.

2. Temporary obstructions shall be permitted provided that they can be repositioned during transfer to comply with M302.2.5, including Exception 1.

M302.3 Supports. Transfer supports, leg supports and reclining surfaces shall comply with M302.3.

M302.3.1 Transfer Supports. Transfer supports shall be provided for use with transfer sides required by M302.2.4 and shall comply with M305.2.1.1, M305.2.2.1, and M305.2.3 through M305.2.8.

M302.3.2 Leg Supports. Where stirrups are provided, leg supports shall also be provided and comply with M305.4.

M302.3.3 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided and shall comply with M305.5.

M302.4 Lift Compatibility. Diagnostic equipment shall be usable with portable patient lifts and, when in use with such lifts, shall comply with M302.4.1 or M302.4.2.

Exception: Where fixed overhead patient lifts are provided, and when their use with diagnostic equipment is permitted by an enforcing authority, diagnostic equipment shall not be required to meet the lift compatibility requirements of this section provided that such equipment is clearly labeled as not compatible with portable floor lifts.

M302.4.1 Clearance in Base. The base of the diagnostic equipment shall provide a clearance 39 inches (990 mm) wide minimum, 6 inches (150 mm) high minimum measured from the floor, and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. Where the width of the examination surface is less than 36 inches (915 mm), the clearance depth shall extend the full width of the equipment. Equipment components are permitted to be located within 8 inches (205 mm) maximum of the centerline of the clearance width.

M302.4.2 Clearance Around Base. The base of the diagnostic equipment shall provide a clearance 6 inches (150 mm) high minimum measured from the floor and 36 inches (915 mm) deep minimum measured from the edge of the examination surface. The width of the base permitted within this clearance shall be 26 inches (660 mm) wide maximum at the edge of the examination surface and shall be permitted to increase at a rate of 1 inch (25 mm) in width for each 3 inches (75 mm) in depth.

M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

M303.1 General. Diagnostic equipment used by patients seated in a wheelchair shall comply with M303.

M303.2 Wheelchair Spaces. Wheelchair spaces complying with M303.2 shall be provided at diagnostic equipment.

M303.2.1 Orientation. Wheelchair spaces shall be designed so that a patient seated in a wheelchair orients in the same direction that a patient not seated in a wheelchair orients when the diagnostic equipment is in use.

M303.2.2 Width. Wheelchair spaces shall be 36 inches (915 mm) wide minimum.

Exception: Wheelchair spaces located on raised platforms shall be permitted to be 32 inches (815 mm) wide minimum to a height of 4 inches (100 mm) measured from the platform surface.

M303.2.3 Depth. The depth of wheelchair spaces shall comply with M303.2.3.

M303.2.3.1 Front or Rear Entry. Where wheelchair space entry and exit is provided at only one end (front or rear) the wheelchair space shall be 48 inches (1220 mm) deep minimum.

M303.2.3.2 Pass Through Entry. Where wheelchair space entry and exit permits pass through from one end to the other, the wheelchair space shall be 40 inches deep (1015 mm) minimum.

M303.2.3.3 Side Entry. Where wheelchair space entry is only from the side, the wheelchair space shall be 60 inches (1525 mm) deep minimum.

M303.2.4 Equipment Clearances. Where wheelchair spaces are entered from the rear and includes space beneath components, wheelchair spaces shall include knee and toe clearances complying with M303.2.4.1 for breast platforms and M303.2.4.2 for all other equipment.

M303.2.4.1 Breast Platforms. Wheelchair spaces beneath breast platforms shall comply with M303.2.4.1.

M303.2.4.1.1 Depth. Wheelchair spaces shall include knee and toe clearance 25 inches (635 mm) deep minimum and 28 inches (710 mm) deep maximum.

M303.2.4.1.2 Height. Wheelchair spaces shall include toe clearance 9 inches (230 mm) high minimum above the floor measured to a depth of 6 inches (150 mm) maximum from the toe end of the wheelchair space. Knee clearance shall be provided at a depth of 19 inches (485 mm) minimum and 22 inches (560 mm) maximum at 9 inches (230 mm) above the floor and at a depth of 16 inches (405 mm) minimum at 27 inches (685 mm) above the floor measured from the leading edge of the breast platform. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to reduce at a rate of 1 inch (25 mm) in depth for every 6 inches (150 mm) in height.

Exception: Components shall be permitted to extend into the wheelchair space at a height of 1½ inches (38 mm) maximum between 17 inches (430 mm) minimum and 25 inches (635 mm) maximum in depth measured from the leading edge of the breast platform. From 25 inches (635 mm) to 28 inches (710 mm) in depth the height of a component above 1½ inches (38 mm) shall be beveled at a rate of 2.5:3 maximum.

M303.2.4.2 Other Equipment. Wheelchair spaces beneath diagnostic equipment other than breast platforms shall comply with M303.2.4.2.

M303.2.4.2.1 Depth. Wheelchair spaces shall include knee and toe clearance 17 inches (430 mm) deep minimum and 25 inches (635 mm) deep maximum.

M303.2.4.2.2 Height. Wheelchair spaces shall include toe clearance 9 inches (230 mm) high minimum above the floor measured to a depth of 6 inches (150 mm) maximum measured from the toe end of the wheelchair space. Knee clearance shall be provided at a depth of 11 inches (280 mm) minimum and 25 inches (635 mm) maximum at 9 inches (230 mm) above the floor and at a depth of 8 inches (205 mm) minimum at 27 inches (685 mm) above the floor measured from the leading edge of the equipment. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to reduce at a rate of 1 inch (25 mm) in depth for every 6 inches (150 mm) in height.

M303.2.5 Surfaces. Wheelchair space surfaces shall not slope more than 1:48 in any direction.

M303.2.6 Edge Protection. Where wheelchair spaces are provided on a platform raised more than 1½ inches (38 mm) in height, edge protection 2 inches (51 mm) high minimum measured from the surface of the platform shall be provided on each side not providing entry to or exit from the equipment.

M303.3 Entry. Where there is a change in level at the entry to wheelchair spaces, the change in level shall comply with M303.3.

M303.3.1 Vertical. Changes in level of ¼ inch (6.4 mm) high maximum shall be permitted to be vertical.

M303.3.2 Beveled. Changes in level between ¼ inch (6.4 mm) high and ½ inch (13 mm) high maximum shall be beveled with a slope not steeper than 1:2.

M303.3.3 Ramped. Changes in level greater than ½ inch (13 mm) high shall be ramped and shall comply with M303.3.3.

M303.3.3.1 Running Slope. Ramp runs shall have a running slope not steeper than 1:12.

Exception: A running slope not steeper than 1:8 shall be permitted for ramp runs with a maximum height of 2½ inches (64 mm).

M303.3.3.2 Cross Slope. The cross slope of ramp runs shall not be steeper than 1:48.

M303.3.3.3 Clear Width. The clear width of ramp runs shall be 36 inches (915 mm) minimum.

M303.3.3.4 Edge Protection. Ramps with drop offs ½ inch (13 mm) or greater shall provide edge protection 2 inches (50 mm) high minimum on each side with a drop off.

M303.3.3.5 Handrails. Ramps with a rise greater than 6 inches (150 mm) shall provide handrails on both sides.

M303.4 Components. Where components of diagnostic equipment are used to examine specific body parts, the components shall be capable of examining the body parts of a patient seated in a wheelchair. Breast platforms shall comply with M303.4.1.

M303.4.1 Breast Platform Adjustability. Breast platforms shall be continuously adjustable from a low height of 26 inches (660 mm) to a high height of 42 inches (1065 mm) above the floor.

M304 Diagnostic Equipment Used by Patients in Standing Position

M304.1 General. Diagnostic equipment used by patients in a standing position shall comply with M304.

M304.2 Standing Surface. Equipment surfaces on which patients stand must comply with M304.2

M304.2.1 Slip Resistant. The surface on which the patient stands shall be slip resistant.

M304.2.2 Standing Supports. Standing supports shall be provided on two sides of the standing surface and shall comply with M305.3.

Exception: Diagnostic equipment with entry and exit permitting pass-through from one end to the other shall be permitted to provide one standing support on one side of the standing surface provided that the standing support complies with the requirements for standing supports in a horizontal position in M305.3.

M305 Supports

M305.1 General. Supports shall comply with M305.

M305.2 Transfer Supports. Transfer supports shall comply with M305.2.

M305.2.1 Location. Transfer supports shall comply with M305.2.1.1 or M305.2.1.2 and shall be located 1½ inches (38 mm) maximum measured horizontally from the plane defined by the nearest edge of the transfer surface.

Exception: Where the support folds, collapses, or articulates, the transfer support shall be permitted to be located 3 inches (75 mm) maximum from the plane defined by the nearest edge of the transfer surface.

M305.2.1.1 End Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.1 and M302.2 shall be located on the short side (length) opposite the transfer side.

M305.2.1.2 Side Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.2 shall be capable of supporting transfer on each side of the transfer surface.

M305.2.2 Length. The length of transfer supports shall comply with M305.2.2.1 or M305.2.2.2.

M305.2.2.1 End Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.1 and M305.2.2.1 shall be 15 inches (380 mm) long minimum. Transfer supports shall be positioned along 13½ inches (345 mm) minimum of the depth of the transfer surface.

M305.2.2.2 Side Transfer Supports. Transfer supports for transfer surfaces complying with M301.2.3.2 shall be 28 inches (710 mm) long minimum and shall be positioned along the width of transfer surfaces.

Exceptions: 1. Where transfer surfaces are part of an articulating surface, the support shall be permitted to be 15 inches (380 mm) long minimum.

2. Where the width of an imaging bed is more than 24 inches (533 mm), transfer supports shall be permitted to be 12 inches (305 mm) long minimum.

M305.2.3 Height. During use, the tops of transfer support gripping surfaces shall be 6 inches (150 mm) minimum and 19 inches (485 mm) maximum higher than the top of the associated uncompressed transfer surface.

Exception: Where the width of the transfer surface for imaging beds exceed 24 inches (610 mm), the tops of the gripping surfaces shall be permitted to be 3 inches (75 mm) minimum and 6 inches (150 mm) maximum higher than the top of the associated uncompressed transfer surface.

M305.2.4 Cross Section. Transfer supports shall have a cross section complying with 305.2.4.1 or 305.2.4.2.

M305.2.4.1 Circular Cross Section. Transfer supports with circular cross sections shall have an outside diameter of 1¼ inches (32 mm) minimum and 2 inches (51 mm) maximum.

M305.2.4.2 Non-Circular Cross Section. Transfer supports with non-circular cross sections shall have a cross-section dimension of 2 inches (51 mm) maximum and a perimeter dimension of 4 inches (100 mm) minimum and 4.8 inches (120 mm) maximum.

M305.2.5 Surface Hazards. Transfer supports and surfaces adjacent to transfer supports shall be free of sharp or abrasive components and shall have eased edges.

M305.2.6 Gripping Surface. Transfer support gripping surfaces shall be continuous along their length and shall not be obstructed along their tops or sides. The bottoms of transfer support gripping surfaces shall not be obstructed for more than 20 percent of their length.

M305.2.7 Clearance. Clearance between the transfer support gripping surface and adjacent surfaces or obstructions shall be 1½ inches (38 mm) minimum.

M305.2.8 Fittings. Transfer supports shall not rotate within their fittings when in place for transfer.

M305.3 Standing Supports. Standing supports shall provide continuous support throughout use of the diagnostic equipment and shall comply with M305.3.

M305.3.1 Length. The length of gripping surfaces for standing supports shall be based on the position of the standing supports in relation to the standing surfaces they serve. Horizontal standing support gripping surfaces shall comply with M305.3.1.1, horizontal standing support gripping surfaces on diagnostic equipment containing a wheelchair space shall comply with M305.3.1.2 and, vertical standing support gripping surfaces shall comply with M305.3.1.3.

M305.3.1.1 Horizontal Position. The length of gripping surfaces on horizontal standing supports shall be 4 inches (100 mm) minimum except for diagnostic equipment containing a wheelchair space which shall comply with M305.3.1.2.

M305.3.1.2 Diagnostic Equipment Containing a Wheelchair Space. On diagnostic equipment containing wheelchair spaces with one entry that also serves as the exit, the length of the gripping surface of horizontal standing supports shall be equal to or greater than 80 percent of the overall length of the platform. On diagnostic equipment containing a wheelchair space and permitting pass-through from one end to the other, the length of the gripping surface on horizontal standing supports shall be at least equal to the length of the platform.

M305.3.1.3 Vertical Position. The length of the gripping surface on vertical standing supports shall be 18 inches (455 mm) minimum.

M305.3.2 Height. The height of gripping surfaces for standing supports shall be based on the position of the standing supports in relation to the standing surfaces they serve. Horizontal standing support gripping surfaces shall comply with M305.3.2.1 and vertical standing support gripping surfaces shall comply with M305.3.2.2.

M305.3.2.1 Horizontal Position. The height of the top of the gripping surface on horizontal standing supports shall be 34 inches (865 mm) minimum and 38 inches (965 mm) maximum above the standing surface.

M305.3.2.2 Vertical Position. The height of the lowest end of the gripping surface on vertical standing supports shall be 34 inches (865 mm) minimum and 37 inches (940 mm) maximum above the standing surface.

M305.3.3 Fittings. Standing supports shall not rotate within their fittings.

M305.4 Leg Supports. Leg supports shall provide a method of supporting, positioning, and securing the patient's legs.

M305.5 Head and Back Support. Where the diagnostic equipment is used in a reclined position, head and back support shall be provided. Where the incline of the back support can be modified while in use, head and back support shall be provided throughout the entire range of the incline.

M306 Communication

M306.1 General. Where instructions or other information necessary for performance of the diagnostic procedure is communicated to the patient through the diagnostic equipment, the instructions and other information shall be provided in at least two of the following methods: Audible, visible, or tactile.

M307 Operable Parts

M307.1 General. Operable parts for patient use shall comply with M307.

M307.2 Tactilely Discernible. Operable parts shall be tactilely discernible without activation.

M307.3 Operation. Operable parts shall be operable with one hand and shall not require tight grasping, pinching, or twisting of the wrist.

M307.4 Operating Force. The force required to activate operable parts shall be 5 pounds (22.2 N) maximum.

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