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Federal Register

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

5 CFR Part 7501

[Docket No. FR–5722–F–01]

RIN 2501–AD61

Supplemental Standards of Ethical Conduct for Employees of the Department of Housing and Urban Development; Correction to Standards Governing Prohibited Financial Interests

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: HUD (or Department), with the concurrence of the Office of Government Ethics (OGE), amends its Supplemental Standards of Ethical Conduct, which are regulations for HUD officers and employees that supplement the Standards of Ethical Conduct for Employees of the Executive Branch (Standards) issued by OGE. In its final rule published on August 6, 2012, HUD did not comprehensively describe an exception to the provision that prohibits Department employees from directly or indirectly receiving, acquiring, or owning certain financial interests that may be subsidized by the Department. This final rule corrects this omission and establishes that HUD employees may not hold a financial interest in any grant, loan, cooperative agreement, or other form of assistance provided by the Department, including the insurance or guarantee of a loan, except to the extent that such interest represents assistance on the employee's principal residence. This final rule codifies current policy and practice.

DATES: *Effective Date:* October 15, 2013.

FOR FURTHER INFORMATION CONTACT: Robert H. Golden, Assistant General Counsel, Ethics and Appeals Division, telephone number 202–402–6334, or Peter J. Constantine, Associate General Counsel for Ethics Appeals and Personnel Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone number 202–402–2377. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: On August 6, 2012 (77 FR 46601), HUD published a final rule revising its Supplemental Standards of Ethical Conduct regulation. HUD revised its Supplemental Standards of Ethical Conduct regulation to ensure that its ethics program reflected the significant statutory changes to HUD's programs and operations enacted subsequent to 1996, the year that HUD issued its original Supplemental Standards of Ethical Conduct regulation. In this regard, HUD stated that the Housing and Economic Recovery Act of 2008 (HERA) (Pub. L. 110–289, approved July 20, 2008) transferred regulatory authority over the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively known as Government-Sponsored Enterprises or GSEs) from HUD to the Federal Housing Finance Agency. Based on this transfer of regulatory authority, HUD removed provisions of its Supplemental Standards of Ethical Conduct that prohibited all HUD employees from owning financial interests issued by the GSEs. HUD also removed a provision that limited employees whose official duties included the regulation or oversight of the GSEs from owning financial interests in certain mortgage institutions. HUD also issued its August 6, 2012, final rule to clarify and streamline several sections of its Supplemental Standards of Ethical Conduct.

One section that HUD revised in the August 6, 2012, final rule was § 7501.104, entitled ''Prohibited financial interests.'' Specifically, HUD revised this section to remove reference to covered employees under § 7501.106 and to remove paragraphs (a)(1) and (a)(2) of this section, that, respectively, prohibited HUD employees from directly or indirectly receiving, acquiring, or owning securities issued by Fannie Mae or Freddie Mac. HUD removed these provisions consistent with the transfer of regulatory authority over Fannie Mae and Freddie Mac under HERA.

HUD also revised and reorganized what was § 7501.104(a)(4) for clarity. This section prohibited employees, their spouses, or minor children, from directly or indirectly receiving, acquiring, or owning stock or another financial interest in a multifamily project or single-family dwelling, cooperative unit, or condominium unit which is owned or subsidized by the Department or which is subject to a note or mortgage or other security interest insured by the Department, except to the extent that the stock or other interest represents the employee's principal residence.

Specifically, HUD's August 6, 2012, final rule revised § 7501.104(a)(4) by redesignating it as § 7501.104(a)(2). HUD also removed the phrase, ''in a multifamily project or single family dwelling, cooperative unit or condominium unit'' and substituted the term ''project.'' HUD intended that this change would cover all HUD projects that exist or that may come into existence in the future. In revising this section, however, HUD did not retain in the redesignated paragraph the language that establishes an exception to the prohibition; specifically, ''to the extent that the stock or other interest represents the employee's principal residence.''

To correct this omission, HUD is revising, in this rule, its Supplemental Standards of Ethical Conduct regulation by defining ''Subsidized by the Department'' in § 7501.102. Specifically, HUD is defining this term to mean ''any grant, loan, cooperative agreement, or other form of assistance provided by the Department, including the insurance or guarantee of a loan.'' This definition is intended to ensure that HUD's Supplemental Standards of Conduct regulation comprehensively covers all HUD programs. In addition, this rule revises § 7501.104(a)(2) by restoring the exception to the prohibition that HUD employees, their spouses, or minor children may not receive, acquire, or own financial interests in projects, including any single-family dwelling or unit that is subsidized by the Department, ''except to the extent that such subsidy represents assistance on the employee's principal residence.''

Providing an exception that permits HUD employees to hold a financial interest in a project, including a single-family dwelling or unit, that is subsidized by the Department to the extent that such interest assists the employee's principal residence is not new. As noted in this preamble, such an exception existed since 1996, when HUD issued its original Supplemental Standards of Ethical Conduct. This long-standing exception recognizes that HUD employees remain subject to ethical requirements that ensure the public's confidence in the impartiality and objectivity with which HUD programs are administered. These requirements include 18 U.S.C. 208, a federal criminal statute, which prohibits employees from participating personally and substantially in any particular matters that will have a direct and predictable effect on the employee's financial interests, and 5 CFR 2635.502, which provides that an employee should not participate in a particular matter when the employee or the agency designee determines that the circumstances may cause a reasonable person with knowledge of the relevant facts to question his or her impartiality in the matter. Additionally, HUD employees must also adhere to the procedures established by the HUD Assistant Secretary with responsibility for the program in order to participate in the program.

Justification for Final Rulemaking

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with HUD's regulations on rulemaking at 24 CFR part 10. Part 10, however, provides, in § 10.1, for exceptions from that general rule when HUD finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when the prior public procedure is ''impracticable, unnecessary, or contrary to the public interest.''

HUD finds that good cause exists to publish this rule for effect without soliciting public comment, on the basis that public procedure is unnecessary. This rule does not substantively change HUD's Supplemental Standards of Ethical Conduct regulation but is technical in nature, reflecting long-standing policy and practice and correcting an omission in HUD's August 6, 2012, final rule. Specifically, it restores to HUD's Supplemental Standards of Ethical Conduct regulation the language that establishes that HUD employees may not hold a financial interest in any grant, loan, cooperative agreement, or other form of assistance provided by the Department, including the insurance or guarantee of a loan, except to the extent that such interest represents assistance on the employee's principal residence. To this extent, it relates solely to agency organization, procedure, and practices and is exempt from the provision of the Administrative Procedure Act (5 U.S.C. 551 et seq.) requiring notice and opportunity for public comment.

Matters of Regulatory Procedure

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. Because this rule relates solely to the internal operations of HUD, this rule was determined to be not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was not reviewed by the Office of Management and Budget (OMB).

Information Collection Requirements

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) does not apply to this regulation because it does not contain information collection requirements subject to the approval of OMB.

Environmental Impact

In accordance with 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.20(k) of HUD regulations, the policies and procedures contained in this rule relate only to internal administrative procedures whose content does not constitute a development decision nor affect the physical condition of project areas or building sites, and therefore, are categorically excluded from the requirements of the National Environmental Policy Act.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute or preempts state law, unless the relevant requirements of section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. Since it is only directed toward HUD employees, this rule would not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects in 5 CFR Part 7501

Conflicts of interests.

Accordingly, for the reasons described in the preamble, HUD, with the concurrence of OGE, amends 5 CFR part 7501, as follows:

PART 7501—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

■ 1. The authority citation for part 7501 continues to read as follows:

Authority: 5 U.S.C. 301, 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203(a), 2635.403(a), 2635.803, 2635.807.

■ 2. In § 7501.102, add in alphabetical order a definition of ''Subsidized by the Department'' to read as follows:

§ 7501.102 Definitions.

* * * * *

Subsidized by the Department means any grant, loan, cooperative agreement, or other form of assistance provided by the Department, including the insurance or guarantee of a loan.

* * * * *

■ 3. In § 7501.104, revise paragraph (a)(2) to read as follows:

§ 7501.104 Prohibited financial interests.

(a) * * *

(2) A financial interest in a project, including any single family dwelling or unit, which is subsidized by the Department, except to the extent such subsidy represents assistance on the employee's principal residence. The definition of ''financial interest'' is found at 5 CFR 2635.403(c);

* * * * *

Dated: September 9, 2013.

Shaun Donovan,

Secretary.

Walter M. Shaub, Jr.,

Director, Office of Government Ethics.

[FR Doc. 2013–22214 Filed 9–11–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 318

[Docket No. APHIS–2012–0008]

RIN 0579–AD70

Interstate Movement of Sharwil Avocados From Hawaii

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Hawaii quarantine regulations to allow the interstate movement of untreated Sharwil avocados from Hawaii into the continental United States. As a condition of movement, Sharwil avocados from Hawaii will have to be produced in accordance with a systems approach that includes requirements for registration and monitoring of places of production and packinghouses, an orchard trapping program, grove sanitation, limits on harvest periods and distribution areas, and harvesting and packing requirements to ensure that only intact fruit that have been protected against infestation are shipped. This action will allow for the interstate movement of Sharwil avocados from Hawaii into other States while continuing to provide protection against the introduction of quarantine pests.

DATES: *Effective Date:* October 15, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. David Lamb, Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2103.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in 7 CFR part 318, ''State of Hawaii and Territories Quarantine Notices'' (referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or the Department) prohibits or restricts the interstate movement of fruits, vegetables, and other products from Hawaii, Puerto Rico, the U.S. Virgin Islands, and Guam to the continental United States to prevent the spread of plant pests that occur in Hawaii and the territories.

Among other things, the regulations allow interstate movement of Sharwil avocados from Hawaii to the continental United States only if the avocados undergo fumigation, or combined fumigation and cold treatment for fruit flies. The treatments currently required for the movement of Sharwil avocados can have unacceptable adverse effects on the quality of the fruit.

On February 7, 2013, we published in the **Federal Register** (78 FR 8987–8992, Docket No. APHIS–2012–0008) a proposal [1] to amend the regulations to allow the interstate movement of untreated Sharwil avocados from Hawaii into the continental United States under a systems approach. The proposed conditions included that Sharwil avocados from Hawaii would have to be produced in accordance with a systems approach that includes requirements for registration and monitoring of places of production and packinghouses, an orchard trapping program, grove sanitation, limits on harvest periods and distribution areas, and harvesting and packing requirements to ensure that only intact fruit that have been protected against infestation are shipped.

We solicited comments concerning the proposed rule for 60 days ending April 8, 2013, and received 30 comments by that date. They were from avocado growers and grower associations, researchers, members of Congress, a State plant regulatory agency, and an organization representing State plant regulatory agencies. These comments are discussed below by topic.

Support for the Proposed Rule

Many commenters stated that they were confident that Sharwil avocados could safely move to the mainland in accordance with the requirements of the proposed rule and that the strengthened mitigation measures would prevent shipment of any fruit with viable fruit fly larvae. Many commenters also stated that the proposed rule would benefit Hawaii avocado growers, the economy of Hawaii, and consumers on the mainland.

Trapping in Production Areas

Two commenters addressed actions to be taken if traps find *Bactrocera dorsalis,* the Oriental fruit fly, in the production area. The proposed rule states ''Consistent with the recommendations of the RMD [risk management document], the compliance agreement would initially require bait sprays approved by APHIS to be used to control fruit flies in the orchard if *B. dorsalis* is detected by the trapping at a rate above 0.4 flies per trap per day.'' One commenter stated that a detection rate of 0.1 flies/trap/day should be used as the trigger for bait spray in place of the proposed 0.4 flies/trap/day.

We are not making any change in response to this comment. *B. dorsalis* is known to exist in Hawaii's agricultural areas, and the purpose of the trapping requirement is only to demonstrate a low level of prevalence in the immediate vicinity of the Sharwil orchards. The suggested trapping rate of 0.1 flies/trap/day (based on the minimum of 2 traps we proposed to require for small orchards) would trigger action if 2 or more flies are caught in a week. This trigger level is more suitable to pest free areas than to low prevalence areas. We believe the proposed trigger of 0.4 flies/trap/day, which equates to 6 flies/week for small orchards, is a more realistic and practical trigger. The Sharwil avocado is considered an extremely poor host to *B. dorsalis,* and demonstrating that places of production have a low prevalence of *B. dorsalis* is an effective mitigation.

This commenter also suggested that Mediterranean fruit fly (Medfly) population size should also be monitored through trapping, with the same bait spray triggers in place as for *B. dorsalis.* We are not making any change based on this comment. As noted in the proposed rule and the pest risk assessment, Sharwil avocado is not a host for Medfly and movement of Sharwil avocados is not a pathway for introduction of Medfly. Therefore, we have determined that restrictions associated with Medfly in this case are not necessary.

Another commenter stated that, in addition to trapping and bait spray requirements for orchards, these requirements should also apply to surrounding buffer areas outside the orchard. The commenter also stated that, if trapping triggers a bait spray response, shipping from the orchard should be discontinued for 30 days and resume only after bait spray completion and subsequent negative trapping results.

We are not making changes in response to these comments for the following reasons. Buffer zones are necessary in cases where articles are grown in a pest-free area, or when

[1] To view the proposed rule, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0008.*

articles are a good host to a pest prevalent in the area (such as late-season citrus grown in areas infested with Caribbean fruit fly). Neither of these conditions applies in the case of Hawaii Sharwil avocados. Establishing buffer zones would also be impractical because many Sharwil orchards are small properties where the growers do not own the immediately surrounding land. With regard to actions to be taken when trapping results exceed the threshold, the proposal deliberately provided APHIS with discretion in this matter in § 318.13–20(c)(2), which states ''If *B. dorsalis* is detected by the trapping at an actionable rate as specified in the compliance agreement, control actions required by the compliance agreement or ordered by an inspector must be taken.'' This would allow for a variety of responses depending on the situation at the particular orchard, including such actions as increased trapping or increasing the size of the biometric sample of cut and inspected fruit. If infested fruit are ever found, shipping from that orchard would be suspended not just for 30 days, but until APHIS conducts an investigation and appropriate remedial actions have been implemented.

Movement of Avocados From Place of Production to Packinghouse

One commenter expressed concern that the proposed requirement that avocados ''must be safeguarded by an insect-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing'' would not prevent infestation during that movement. Another commenter stated that the proposed requirement that avocados must be moved to a packinghouse within 12 hours of harvest allowed the avocados to sit in the harvest area for too long.

A search of relevant data and journal articles revealed no instance where fruit awaiting packing was attacked and infested by fruit flies; however, APHIS is aware that this is a remote possibility, as evidenced by the proposed requirements. In response to these comments, we reviewed the practices in other relevant programs and are changing the allowed postharvest time period to 3 hours to be consistent with them. We are not changing the proposed requirement that avocados ''must be safeguarded by an insect-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing,'' which is also the standard in the other programs and appears to be a clear and effective standard.

Fruit Box Labeling

One commenter addressed the proposed labeling requirement, that fruit boxes must be marked ''Distribution limited to the following States: CO, CT, DE, DC, ID, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MO, MT, NE, NH, NJ, NY, ND, OH, PA, RI, SD, UT, VT, VA, WA, WV, WI, and WY.'' He suggested that the marking should also state ''NOT FOR DISTRIBUTION TO [*list of States that prohibit entry*]'' to insure that the product is not moved into fruit fly habitat States such as Florida.

APHIS believes that it would be redundant and possibly confusing to mark every box with a list of States where distribution is allowed and another list consisting of all remaining States. However, we agree that further emphasizing the importance of limited distribution may help with program implementation. Therefore, we have amended the relevant requirement in § 318.13–20(e) to read: ''Fruit boxes must be clearly marked 'Distribution limited to the following States: CO, CT, DE, DC, ID, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MO, MT, NE, NH, NJ, NY, ND, OH, PA, RI, SD, UT, VT, VA, WA, WV, WI, and WY; DISTRIBUTION TO OTHER STATES PROHIBITED' and each consignment must be identified in accordance with the requirements of § 318.13–3(g).''

Transit Shipments and Layovers

Two commenters asked what the proposed rule would allow in terms of transit movement or layovers for shipments of Sharwil avocado to the mainland. For example, a plane carrying Sharwil avocados could stop in California first before making its way to Connecticut.

APHIS agrees that such situations are not clearly addressed in the proposed rule. Therefore, we have amended the relevant requirement in § 318.13–20(g) to read as follows: ''No Sharwil avocados moved under this program may be shipped to or distributed in locations in the continental United States other than Colorado, Connecticut, Delaware, District of Columbia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. If the means of conveyance carrying a shipment stops en route in any other State, the Sharwil avocados may not be unloaded in that State.''

Technical Corrections to Pest Risk Analysis

We are making minor corrections to the pest risk assessment and risk management document that were suggested by commenters. In one case we are rewording a sentence that referred to water stress and nutritional deficiencies as factors in host status to clarify that the magnitude of these factors was not actually measured. We are also correcting an error in the citation to an article on systems approaches that supports the basis of the rule. These changes do not affect the proposed systems approach.

Comments Outside the Scope of the Proposal

One commenter noted that the current regulations allow Sharwil avocados to be moved to the continental United States if they are subject to fumigation, or to combined fumigation and cold treatment. This commenter suggested that a cold treatment alone may be sufficient to eliminate pests of concern, suggested time-temperature combinations for such a treatment, and also suggested that heat shock pretreatment may improve fruit quality when such a treatment is used. APHIS did not make any changes in response to this comment because neither the proposed rule nor the requests that initiated it suggested allowing Sharwil avocados to be moved under such conditions, and we are not aware of industry interest in such movement.

Two commenters suggested that the scope of the proposed rule be extended to apply to other thick-skinned varieties of avocado in addition to the Sharwil variety. We are taking no action on this comment because the request from the Hawaii Department of Agriculture that initiated this rule was specifically limited to Sharwil variety avocados.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Miscellaneous Changes

We are also correcting two minor errors in § 318.13–26, in which the word ''melon'' was omitted from the section heading and the Office of Management and Budget control number was omitted from the section.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of

Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities.

This rule will allow the interstate movement of untreated Sharwil avocados from Hawaii into the continental United States if the avocados are produced in accordance with a systems approach to prevent the spread of *B. dorsalis* and other pests.

The 2007 Census of Agriculture reported that there were a total of 8,245 avocado farms in the United States, with about 76 percent in California, 13 percent in Hawaii, and 11 percent in Florida. Average gross receipts for California avocado producers for the 2007–08 season was about $52,700, compared to average receipts of about $12,700 for Florida's growers and about $750 for Hawaii's growers. The Small Business Administration's small-entity standard for avocado farms is annual receipts of not more than $750,000. While nearly all U.S. avocado operations are small entities, it is evident that there is significant variation among the three States in average farm size.

We anticipate that Sharwil avocado consignments from Hawaii to the mainland will total about 180 metric tons per year, equivalent to about one-half of 1 percent of the U.S. supply of non-Hass avocados and to less than one-twentieth of 1 percent of the U.S. supply of all avocado varieties. They will be shipped between November and March, supplementing winter supplies.

Hawaii avocado production is estimated at 1.0 million pounds for the 2008–09 season, and 660,000 pounds for the 2009–10 season. The decline appears to be associated with adverse weather conditions.

Avocado production in the United States largely takes place in California, where nearly all of the fruit grown is of the small, dark-colored, rough-skinned Hass variety. In Florida and Hawaii, varieties like the Sharwil, which is much larger and bright green in color, are predominant. Most avocado imports and exports by the United States are Hass. Given our limited understanding of the strength of consumers' preferences for the various avocado varieties (that is, their degree of substitutability), we consider potential effects of the rule for producers of non-Hass varieties as well as for all U.S. avocado farmers.

While the rule should benefit Hawaii's avocado producers by allowing them to use a systems approach to mitigate pest risk, making the sale of Sharwil avocados to the continental United States more economically feasible, the quantity that is expected to be shipped would not significantly affect the mainland avocado market overall or the more limited market for non-Hass varieties. With imports providing one-third of the U.S. supply of non-Hass avocados and two-thirds of the U.S. supply of all avocados, any effects of the rule for U.S. mainland producers would be further muted. Moreover, the Sharwil avocados from Hawaii would be shipped between November and March, when there is increased reliance on foreign suppliers. Any market effects of the rule could be expected to be borne proportionately by avocados supplied from abroad during the winter months.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579–0403, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

Lists of Subjects in 7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

Accordingly, we are amending 7 CFR part 318 as follows:

PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

■ 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

■ 2. A new § 318.13–20 is added to read as follows:

§ 318.13–20 Sharwil avocados from Hawaii to the continental United States.

Commercial shipments of Sharwil avocados may be moved interstate from Hawaii to the continental United States without treatment under the following conditions:

(a) *Registration.* Persons wishing to move Sharwil avocados in accordance with this section must register the avocados' place of production and the packinghouse that packs the avocados. A registration form may be obtained from local APHIS offices in Hawaii. Persons registering places of production or packinghouses must agree to allow inspectors access to the places of production and packinghouses as necessary to monitor compliance with this section.

(b) *Grove sanitation.* Avocado fruit that has fallen from the trees must be removed from each place of production at least once every 7 days and in compliance with any schedule specified in the compliance agreement required in paragraph (h) of this section. Fallen avocado fruit may not be included in field containers of fruit brought to the packinghouse to be packed for interstate movement.

(c) *Trapping and orchard control.* (1) Beginning at least 1 month before harvest, the place of production of the avocados must have a trapping system in place for *B. dorsalis* that complies with all conditions specified in the compliance agreement required in paragraph (h) of this section. APHIS-approved traps and APHIS-approved lures must be used, and the place of production or the packinghouse must retain, for at least 1 year, data regarding the number and location of the traps, as well as any fruit flies that have been caught, and make this information available to APHIS upon request.

(2) If *B. dorsalis* is detected by the trapping at an actionable rate as specified in the compliance agreement,

control actions required by the compliance agreement or ordered by an inspector must be taken.

(d) *Harvesting requirements.* Avocados may only be harvested between November 1 and March 31. Avocados must be hard ripe fruit at the mature green stage with stems attached. Fruit must not indent with moderate finger pressure and no part of the fruit shall be soft. The fruit must be moved to a registered packinghouse within 3 hours of harvest or must be protected from fruit fly infestation until moved. The fruit must be safeguarded by an insect-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing.

(e) *Packinghouse requirements.* During the time registered packinghouses are in use for packing avocados for movement to the continental United States, the packinghouses may only accept avocados that are from registered places of production and that are produced in accordance with the requirements of this section and of the compliance agreement required in paragraph (h) of this section.

(1) Avocados must be packed within 24 hours of harvest in an insect-exclusionary packinghouse. All openings to the outside of the packinghouse must be covered by screening with openings of not more than 1.6 mm or by some other barrier that prevents pests from entering.

(2) Fruit must be packed in insect-proof packaging, or covered with insect-proof mesh or a plastic tarpaulin, for transport to the continental United States. These safeguards must remain intact until arrival in the continental United States.

(3) Fruit boxes must be clearly marked ''Distribution limited to the following States: CO, CT, DE, DC, ID, IL, IN, IA, KS, KY, ME, MD, MA, MI, MN, MO, MT, NE, NH, NJ, NY, ND, OH, PA, RI, SD, UT, VT, VA, WA, WV, WI, and WY; DISTRIBUTION TO OTHER STATES PROHIBITED'' and each consignment must be identified in accordance with the requirements of § 318.13–3(g).

(f) *Inspection.* A biometric sample of a size determined by APHIS will be visually inspected for quarantine pests by an inspector, and a portion of the fruit will be cut open to detect internal pests, including *B. dorsalis.* If any quarantine pests are found, the entire consignment of avocados will be prohibited from interstate movement unless it is treated with an approved quarantine treatment monitored by APHIS. If any *B. dorsalis* are found, the entire consignment of avocados will be prohibited from interstate movement, and the place of production producing that fruit will be suspended from the interstate shipment program until APHIS conducts an investigation and appropriate remedial actions have been implemented.

(g) *Limited distribution.* No Sharwil avocados moved under this program may be shipped to or distributed in locations in the continental United States other than Colorado, Connecticut, Delaware, District of Columbia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. If the means of conveyance carrying a shipment stops en route in any other State, the Sharwil avocados may not be unloaded in that State.

(h) *Compliance agreement.* Persons wishing to move avocados in accordance with this section must sign a compliance agreement in accordance with § 318.13–3(d) in which he or she agrees to comply with such conditions as may be required by the inspector in each specific case to prevent infestation.

(Approved by the Office of Management and Budget under control number 0579–0403)

■ 3. In § 318.13–26, the section heading is revised and the OMB citation is added to the end of the section to read as follows:

§ 318.13–26 Breadfruit, jackfruit, fresh pods of cowpea, dragon fruit, mangosteen, melon, and moringa pods from Hawaii.

* * * * *

(Approved by the Office of Management and Budget under control number 0579–0331)

Done in Washington, DC, this 5th day of September 2013.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013–22205 Filed 9–11–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 712

RIN 1992–AA44

Human Reliability Program: Technical Amendments

AGENCY: Department of Energy.

ACTION: Final rule; technical amendment.

SUMMARY: The Department of Energy (DOE) is amending its Human Reliability Program (HRP) regulations to eliminate references to obsolete provisions and to update part 712 to reflect organizational changes within the DOE. Today's regulatory amendments do not alter substantive rights or obligations under current law.

DATES: *Effective Date:* This rule is effective on September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Regina G. Cano, Office of Security, Office of Health, Safety and Security, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; *Regina.Cano@hq.doe.gov;* 301–903–3473.

SUPPLEMENTARY INFORMATION:

I. Introduction

DOE's HRP, is designed to ensure that individuals who occupy positions affording unescorted access to certain nuclear materials, nuclear explosive devices, programs, and facilities where (among other activities) nuclear explosives are tested produced, disassembled and transported, meet the highest standards of reliability, as well as physical and mental suitability, through a system of continuous evaluation of those individuals. The purpose of this continuous evaluation is to identify, in a timely manner, individuals whose judgment may be impaired by physical or mental/personality disorders; the use of illegal drugs or the abuse of legal drugs or other substances; the abuse of alcohol; or any other condition or circumstance that may represent a reliability, safety, or security concern.

A. Accelerated Access Authorization Program

The HRP requires that all individuals who work in positions affording unescorted access to certain materials, facilities, and program be certified as meeting the highest standards of reliability and physical and mental/personality suitability before such access may be granted. As promulgated in 2004 (69 FR 3213; January 23, 2004), the part 712 rule requires in § 712.11(a)(1) that each individual applying for or in an HRP position must have a DOE ''Q'' access authorization based on a background investigation, ''except for security police officers who have been granted an interim ''Q'' through the Accelerated Access Authorization Program (AAAP).'' The AAAP is defined in the current rule as ''*the DOE program for granting interim access to classified matter and special nuclear material based on a drug test,*

a National Agency Check, a psychological assessment, a counterintelligence-scope polygraph examination in accordance with 10 CFR part 709, and a review of the applicant's completed ''Questionnaire for National Security Positions'' (Standard Form 86).''

In 2007, however, the Chief Health, Safety and Security Officer directed the termination of the AAAP as no longer necessary to meet DOE's access authorization needs. This elimination of the AAAP from the process for granting interim access authorizations was formalized on July 21, 2011 by DOE Order 472.2, *Personnel Security.* DOE is amending the part 712 rule now to eliminate any reference to the obsolete AAAP.

B. Questionnaire for National Security Positions (QNSP), Part 2

One of the four components of the annual HRP recertification process involves a review of an HRP incumbent's personnel security file by the DOE office responsible for the ''Q'' access authorization held by that individual. As part of this review, the current HRP rule requires the annual submission of the ''*SF–86, OMB Control No. 3206–0007, Questionnaire for National Security Positions* [QNSP], *Part 2''* (emphasis added) by each HRP incumbent. Under the current rule, the submission of the QNSP Part 2 (1995 QNSP) requires an HRP incumbent to report sensitive personal information the DOE deems relevant for determining continued eligibility for a ''Q'' access authorization.

In July 2008, however, OPM revised the QNSP, both structurally and substantively, and the new QNSP (2008 QNSP) was issued a new OMB control number. Specifically, in addition to eliminating the former two-part structure of the 1995 version, the 2008 QNSP differs from the 1995 version as to what is reportable. Based on these substantive differences and the change to the OMB control number, DOE no longer collects information from the public using the version of the QNSP referenced in the current rule. Therefore, DOE is amending the rule to eliminate the requirement for submission of the SF–86, OMB Control No. *3206–0007,* QNSP Part 2.

C. Internal Agency Responsibilities

DOE is amending part 712 to reflect recent organizational changes within DOE. Under current regulations, the Director, Office of Policy, within the Office of Health, Safety and Security (HSS) is responsible for HRP policy. The Chief Health, Safety and Security Officer has transferred the responsibility for HRP policy to the Director, Office of Security within HSS. Therefore, this amendment replaces all references to the former ''*Director, Office of Policy''* with ''*Director, Office of Security, or designee.''*

In addition, the definition of ''*Manager''* in the current rule does not reflect recent changes within DOE's organizational structure. Part 712 defines ''Manager'' to mean ''*the Manager of the Chicago, Idaho, Oak Ridge, Richland, and Savannah River Operations Offices; Manager of the Pittsburgh Naval Reactors Office and the Schenectady Naval Reactors Office; Site Office Managers for Livermore, Los Alamos, Sandia, Y–12, Nevada, Pantex, Kansas City, and Savannah River; Director of the Service Center, Albuquerque; Assistant Deputy Administrator for the Office of Secure Transportation, Albuquerque; and for the Washington, DC area, the Deputy Chief for Operations, Office of HSS.''* At this time, the Managers of the Chicago Operations Office; the Pittsburgh and Schenectady Naval Reactors Offices; Site Office Managers for the National Nuclear Security Administration (NNSA) Savannah River, Y–12 and Pantex sites; the Director of the NNSA Service Center; and the Deputy Chief for Operations no longer have HRP management responsibilities under part 712 or the named offices have been eliminated as a result of reorganization. In addition, a number of site-level DOE or NNSA line-management officials have been assigned HRP ''Manager'' authorities, but are not listed in the definition of ''Manager.''

DOE has decided to substitute the following definition of ''*Manager''* for the current listing in § 712.3: ''*Manager* means the senior Federal line manager at a departmental site or Federal office with HRP-designated positions.'' This revised definition in no way changes the actual HRP authorities of the senior Federal line management officials, who otherwise would be listed if the current paradigm were continued. On the other hand, such a functional definition should eliminate the need in future for technical amendments that merely reflect changed nomenclature or the removal of any HRP responsibilities at a site or within a program management office.

II. Procedural Requirements

A. Review Under Executive Orders 12866 and 13563

Today's regulatory action has been determined not to be ''a significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the OMB Office of Information and Regulatory Affairs.

DOE has also reviewed this rule pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281 (Jan. 21, 2011)). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. DOE believes that today's rule is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies to ensure that the potential impacts of its draft rules on small entities are properly considered during the rulemaking process (68 FR 7990, February 19, 2003), and has made them available on the Office of the General Counsel's Web site: *http://www.gc.doe.gov.*

The regulatory changes in this notice of final rulemaking are technical amendments to remove references to a program that no longer exists and to a form that is no longer in use, and to conform references to position descriptions that relate solely to internal agency organization, management or personnel, and as such, are not subject to the requirement for a general notice of proposed rulemaking under the Administrative Procedure Act (5 U.S.C. 553). Consequently, this rulemaking is exempt from the requirements of the Regulatory Flexibility Act.

C. Review Under the Paperwork Reduction Act

This final rule does not impose a collection of information requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

D. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, this rule amends existing regulations without changing the environmental effect of the regulations being amended, and, therefore, is covered under the Categorical Exclusion in paragraph A5 of Appendix A to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined today's rule and has determined that it does not preempt State law and does not have 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. No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to assess the effects of a Federal regulatory action on State, local, and tribal governments, and the private sector. DOE has determined that today's regulatory action does not impose a Federal mandate on State, local or tribal governments or on the private sector.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's rulemaking under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that

promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Today's regulatory action is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

K. Administrative Procedure Act

The regulatory changes in this notice of final rulemaking consist of technical amendments to remove references a program that no longer exists and to a form that is no longer in use, and to conform references to position descriptions that relate solely to internal agency organization, management or personnel. As such, pursuant to 5 U.S.C. 553(a)(2), this rule is not subject to the rulemaking requirements of the Administrative Procedure Act, including the requirements to provide prior notice and an opportunity for public comment and a 30-day delay in effective date.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of today's final rule prior to the effective date set forth at the outset of this notice. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 801(2).

List of Subjects in 10 CFR Part 712

Administrative practice and procedure, Alcohol abuse, Classified information, Drug abuse, Government contracts, Government employees, Health, Occupational safety and health, Radiation protection, Security measures.

Issued in Washington, DC on August 29, 2013.

Glenn Podonsky,

Chief Health, Safety and Security Officer.

For the reasons set forth in the preamble, DOE amends part 712 of chapter III, title 10, Code of Federal Regulations, as set forth below:

PART 712—HUMAN RELIABILITY PROGRAM

■ 1. The authority citation for part 712 continues to read as follows:

Authority: 42 U.S.C. 2165; 42 U.S.C. 2201; 42 U.S.C. 5814–5815; 42 U.S.C. 7101 et seq.; 50 U.S.C. 2401 et seq.; E.O. 10450, 3 CFR 1949–1953 Comp., p. 936, as amended; E.O. 10865, 3 CFR 1959–1963 Comp., p. 398, as amended; 3 CFR Chap. IV.

■ 2. Section 712.3 is amended by:

■ a. Removing the definition of ''*Accelerated Access Authorization Program.*''

■ b. Revising the definition of ''*Manager*'' to read as follows:

§ 712.3 Definitions.

* * * * *

Manager means the senior Federal line manager at a departmental site or Federal office with HRP-designated positions.

* * * * *

■ 3. Revise § 712.11(a)(1) and (2) to read as follows:

§ 712.11 General requirements for HRP certification.

(a) * * *

(1) A DOE ''Q'' access authorization based on a background investigation;

(2) An annual review of the personnel security file;

* * * * *

§ 712.12 [Amended]

■ 4. Sections 712.12(e) and 712.12(f)(1) are amended by removing ''Policy'' after ''Office of'' and adding in its place ''Security, or designee.''

[FR Doc. 2013–22231 Filed 9–11–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 16

[Docket No.: FAA–2012–0176; Amendment No. 16–1]

RIN 2120–AJ97

Rules of Practice for Federally-Assisted Airport Enforcement Proceedings (Retrospective Regulatory Review)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action updates, simplifies, and streamlines rules of practice and procedure for filing and adjudicating complaints against federally-assisted airports. It improves efficiency by enabling parties to file submissions with the Federal Aviation Administration (FAA) electronically, and by incorporating modern business practices into how the FAA handles complaints. This amendment is necessary to reflect changes in applicable laws and regulations, and to apply lessons learned since the existing rules were implemented in 1996.

DATES: Effective November 12, 2013.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How to Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical or legal questions concerning this action, contact Jessie Di Gregory, Federal Aviation Administration, Office of the Chief Counsel, Airport Law Branch (AGC–610), 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3199; fax (202) 267–5769; email: *Jessie.DiGregory@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Sections 46101, ''Complaint and Investigations'' and 46104, ''Evidence,'' and Part B, Section 47122, ''Administrative.'' Under these sections, Congress provided for the FAA to prescribe regulations for practices, methods, and procedures to hear complaints concerning compliance by federally-assisted airports and carry out investigations and conduct proceedings in a way conducive to justice and the proper dispatch of business. This rulemaking is within the scope of that authority because it would amend rules necessary to investigate, hear, and provide rulings on matters related to federally-assisted airport conduct.

I. Overview of Final Rule

The FAA is required by statute to adjudicate complaints on matters within the agency's authority (49 U.S.C. 46014). Title 14 CFR part 16, Rules of Practice for Federally-Assisted Airport Enforcement Proceedings (Part 16), provides a process for investigating and adjudicating complaints against

sponsors for violation of federal obligations. For this final rule, a sponsor is a recipient of federal assistance, usually an airport operator. This final rule improves the efficiency of Part 16 proceedings by providing an electronic filing alternative, opportunities for sponsors to seek early disposition of complaints in certain cases, and clarification of processes already described in the rule. It affects those parties involved in filing and responding to formal complaints. It also affects the FAA offices involved in investigating and adjudicating those complaints.

The FAA, sponsors, aeronautical users, and other stakeholders have 17 years of experience with Part 16 as implemented in 1996.[1] In general, Part 16 has been a useful process for resolving complaints regarding sponsor compliance. The FAA does not intend to change the basic features of the process. Rather, the FAA has identified updates to Part 16 that could improve the process and reduce time required to address certain cases, based on agency and stakeholder lessons learned.

The FAA has determined that the agency, sponsors, aeronautical users, and other stakeholders in Part 16 proceedings will benefit from adding the following to the rule:

- Procedures for concluding the investigation by ''summary judgment'' or dismissal without an answer by the sponsor.
- Termination of complainant standing in certain cases where the FAA finds the sponsor in noncompliance on all issues raised in the complaint.
- Optional electronic filing procedures.
- Procedures for filing complaints under Title 49 CFR part 23, Participation of Disadvantaged Business Enterprises (DBEs) in Airport Concessions, and 49 CFR part 26, Participation by DBEs in Department of Transportation (DOT) Financial Assistance Programs.

In addition, the FAA has determined it will be helpful to clarify existing language in Part 16 that addresses [2]—

- Intervention and other participation.
- The process for ordering corrective action for noncompliant sponsors.
- Processes involving the Director, including procedures for seeking rehearing of Director's Determinations upon a showing of good cause.
- Standard of Proof and Burden of Proof requirements.
- Standards for raising new issues on appeal to the Associate Administrator.
- Consent Orders.
- Requests for testimony of agency employees.
- Processes involving the Associate Administrator, including procedures for seeking rehearing of Final Agency Decisions upon a showing of good cause.
- Transfer of responsibility for decision-making for civil rights cases.
- Availability of judicial review.
- Extension of the time period for filing pleadings by mail.

Finally, the FAA is making minor updates to terminology and organization within Part 16 as part of its revision. These changes streamline the rule and reflect current practices.

The FAA expects benefits of these changes to include a decrease in both time spent and volume of paper documents required to process Part 16 complaints.

II. Background

A. Statement of the Problem

Part 16 has not been updated since its original implementation in 1996. As described earlier in this preamble and in the NPRM, existing Part 16 processes have worked well but are in need of revision based on agency and stakeholder experience during the past 15 years. The FAA is adding new processes and revising existing processes to clarify Part 16 and apply lessons learned to provide for more efficient use of agency and stakeholder time and resources during complaint proceedings.

B. Summary of the NPRM

The FAA proposed to update, simplify, and streamline rules of practice and procedure for filing and adjudicating complaints against federally-assisted airports found in 14 CFR part 16 (Part 16) with an NPRM published in the **Federal Register** on March 5, 2012.[3] The NPRM provided a 60-day period for the public to file comments on the proposal.

On May 17, 2012, the FAA re-opened the comment period with a Notice published in the **Federal Register** in response to a request from the Airports Council International-North America (ACI–NA), an association representing the local, regional and state governing bodies that own and operate the principal airports served by scheduled air carriers in North America.[4] ACI–NA sought additional time to complete its review and coordinate comments received from members that would be impacted by the proposed changes. The re-opened comment period closed on June 7, 2012.[5]

C. General Overview of Comments

The FAA received five comments. Two groups representing airports (the Airports Council International-North America (ACI–NA) and the American Association of Airport Executives (AAAE) provided supportive comments with suggestions to improve the rule, as did the Port Authority of New York and New Jersey. All three of these commenters have experience with responding to complaints filed under Part 16. In addition, an individual who represents complainants in Part 16 complaints also indicated support while offering specific suggestions. One private citizen commented as well, indicating general support for the FAA's effort to revise and streamline the rule.

Commenters raised eleven issues regarding the proposal, from concerns and suggestions to improve new options for motions to dismiss and motions for summary judgment to minor editorial corrections.

III. Discussion of Public Comments and Final Rule

A. Motions to Dismiss and Motions for Summary Judgment (§§ 16.25 and 16.26)

The Port Authority of New York and New Jersey (Port Authority) and ACI–NA commented on the new options for motions to dismiss and motions for summary judgment proposed in §§ 16.25 and 16.26. ACI–NA encouraged the FAA to carefully scrutinize complaints and not docket complaints in accordance with § 16.25 that fall outside of the FAA's jurisdiction, fail to state a claim that warrants investigation, or where the complainant lacks standing. ACI–NA then pointed out that the new provisions for motions are meant to reduce paperwork for respondents and the FAA, and not increase it by requiring respondents to submit motions to dismiss in response to complaints that should not have been docketed in the first place. ACI–NA indicated that the FAA should ''be more vigilant'' in assessing complaints at the docketing stage. Finally, ACI–NA pointed out that as proposed in the NPRM, § 16.26 draws no distinction between motions to dismiss and motions for summary judgment. Since there are differences between the two motions, ACI–NA recommended that to avoid confusion, the FAA should

[1] 61 FR 53998, October 16, 1996.

[2] This list is one of general introductions. It is not intended to explain each issue in detail.

[3] 77 FR 13027.

[4] 77 FR 29250.

[5] *Id.*

distinguish between these dispositive motions in the rule and proposed specific language. ACI–NA also urged the FAA to distinguish between these two kinds of motions so that this rule would be consistent with the Federal Rules of Civil Procedure.

ACI–NA suggested substituting the word ''dockets'' for the word ''receives'' in proposed § 16.26(a) for greater consistency with deadlines throughout the rule.

The Port Authority and ACI–NA expressed concern that these sections would require the filing of motions before the docketing of a complaint. The Port Authority further stated that the provisions of § 16.26 are not consistent with the stated intent of relieving respondents of unnecessary effort in drafting an answer and compiling supporting documents, and achieving consistency with the Federal Rules of Civil Procedure. The Port Authority indicated its concern that there is a possibility under the current proposal that a respondent might be required to file an answer prior to the FAA's determination on the motion to dismiss or motion for summary judgment. The Port Authority proposed that the FAA delete § 16.26(f) to make the rule consistent with the Federal Rules of Civil Procedure, which stay the time for filing and service of an answer during deliberations on the motion.

The Port Authority and ACI–NA also recommended that the rules for dispositive motions be located in a new § 16.28 since both §§ 16.25 and 16.27 address actions to be taken by the FAA before docketing a complaint.

The FAA continues to closely scrutinize incoming Part 16 complaints to make certain that they are in compliance with the rule. The FAA routinely returns Part 16 complaints prior to the official docketing (so that no answer is due from the respondent) when one or more requirements in the rule are not met. In a May 24, 2011 partial dismissal order, the FAA dismissed the city of New York as a party since it was not a ''respondent'' within the meaning of Part 16.[6] The U.S. Court of Appeals for the Second Circuit upheld the FAA's order on June 12, 2012.[7]

The FAA is aware of the fact that parties to a Part 16 proceeding often have differing levels of legal expertise and familiarity with the rule. The FAA also recognizes that some of those who file complaints under Part 16 do so pro se, that is, without the benefit of legal counsel. While the FAA closely scrutinizes complaints filed under Part 16, it will docket complaints that have any basis for filing under the rule. If a respondent feels that a complaint contains frivolous or extraneous issues, it can avail itself of the motions described in § 16.26. The FAA believes that these new provisions for motions will help to reduce paperwork for respondents and the agency.

The FAA agrees with ACI–NA's suggestion to more clearly differentiate between motions to dismiss and motions for summary judgment. The FAA is including the provisions on motions to dismiss under § 16.26(b). The FAA is including the provisions addressing motions for summary judgment under § 16.26(c). Sections 16.26(e) and 16.26(f), as proposed in the NPRM, are renumbered as §§ 16.26(b)(4) and (5) and 16.26(c)(4) and (5), respectively. Additionally, the FAA has restructured § 16.26(c) to streamline it. The FAA also has added language in renumbered § 16.26(c)(4) for clarification.

The FAA is modifying section headings, organization, and introductory language to make clear that motions to dismiss are addressed in § 16.26(b), and motions for summary judgment are addressed in § 16.26(c). As a result, motions to dismiss and motions for summary judgment continue to have the same effect on filings, deadlines, and orders.

The FAA agrees with ACI–NA's suggestion to change § 16.26(a) by substituting language similar to that used in § 16.23(d). However, the FAA notes that § 16.23(d) requires an answer to be filed ''within 20 days of the date of service of the FAA notification [of docketing].'' This differs from ACI–NA's assertion in their comment that § 16.23(d) requires an answer to be filed within 20 days of the FAA docketing a complaint.

B. Method of Filing (§§ 16.13 and 16.17)

Two commenters recommended improvements to the provisions regarding electronic filing and postal submissions. AAAE encouraged the FAA to improve its technological capabilities so that parties might upload and access documents through an electronic docket.

The Port Authority noted that the term ''post office address'' (§ 16.13(f)) is no longer accurate. It also suggested that one day be added to a prescribed period for a right or requirement to perform an act after service of a document if the document is served by overnight express delivery.

The FAA partially agrees with these comments. The FAA believes that the changes proposed to § 16.13 in the NPRM address AAAE's interest in modernizing the filing process. Anyone may access all documents regarding a particular complaint via the electronic docket on *http://www.regulations.gov.* AAAE correctly stated that parties may not upload documents to regulations.gov. The FAA does not find it necessary for parties to be able to do so. Proposed § 16.13 gives parties an opportunity to email their pleadings to the Docket Clerk, who will then send the pleadings to the DOT Docket Staff for submission to *http://www.regulations.gov.*

The FAA agrees with the Port Authority's suggestion to replace the term ''post office address'' with the term ''physical address'' in § 16.13(f). However, the FAA finds it unnecessary to add a day to deadlines when parties choose overnight, express delivery.

C. Complaints Related to Civil Rights and Disadvantaged Business Enterprises Filed Under 49 CFR 26.105(c) (§§ 16.3 and 16.21)

The Port Authority questioned the proposal to permit someone who is not ''directly and substantially affected'' by a sponsor's alleged violations to file a Part 16 complaint. The Port Authority also objected to the exemption of persons filing complaints under 49 CFR 26.105(c) from good faith efforts at informal resolution required of other Part 16 complainants. ACI–NA expressed support for these comments by reference.

The FAA notes that the provisions of 49 CFR part 26 are outside the scope of this rulemaking. Participation of Disadvantaged Business Enterprises (DBEs) in the Airport Improvement Program (AIP) is governed by 49 CFR part 26. Under this regulation, complainants are not required to be directly and substantially affected by the sponsor's alleged violations and ''[a]ny person who knows of a violation of this part by a recipient of FAA funds may file a complaint.''[8] Additionally, 49 CFR § 26.105 does not mandate informal dispute resolution before filing a complaint under Part 16.

D. Oral Argument Before the Associate Administrator and Availability of a Hearing (§§ 16.33 and 16.241)

Three commenters expressed confusion over the role of oral arguments and hearings in the Part 16

[6] *Paskar, et al.* v. *City of New York and Port Authority of New York and New Jersey,* FAA Docket No. 16–11–04.

[7] *Paskar and Friends of LaGuardia Airport* v. *FAA,* No. 11–2720–ag, 478 Fed.Appx. 707.

[8] 49 CFR 26.105(c).

process. The Port Authority, and ACI–NA by reference, suggested allowing oral argument before the Associate Administrator on appeal from a Director's Determination in certain circumstances to provide assistance to the Associate Administrator. AAAE complained that it was unclear when a sponsor may request a hearing to appeal the Director's Determination and to challenge the Director's orders.

The FAA notes that oral argument for all complaints appealed to the Associate Administrator is not required by law. A hearing, with oral argument, is required for either withholding approval or payment of grants as stated in 49 U.S.C. 47106(d), 49 U.S.C. 47111, and 47114(c) and (e). Title 49 of the United States Code, 47114(d), does not require the FAA to provide a hearing for withholding discretionary grant funds from general aviation airports.

Moreover, the FAA believes that allowing oral argument for all appeals of Director's Determinations would cause undue delay. When not required by statute, the FAA finds oral argument unnecessary for a fair, just, and complete process.

E. Timing of Pleadings, Director's Determinations, and Final Agency Decisions

ACI, AAAE, and a private citizen contended that the deadlines in the current rule are unrealistic and suggested extending them throughout the process. AAAE encouraged the FAA to do so while maintaining the expedited nature of the process. The private citizen made general suggestions for further revision of procedures.

The FAA did not propose changes to the timing for pleadings, Director's Determinations, or Final Agency Decisions in the NPRM because the existing process allows flexibility as needed for all parties involved. Therefore, any changes to the time periods for steps in the Part 16 complaint process are outside the scope of the NPRM.[9]

The FAA notes that deadlines for service of pleadings in §§ 16.19 and 16.23 are subject to parties' petitions for extension under current § 16.11. Parties are able to determine if they can meet the deadlines, and can request extensions if they feel more time is necessary to complete the process fairly.

The FAA's intent has been to make the Part 16 process both expedited and complete since it originally proposed the rule in 1994. The 1994 NPRM stated that a Director's Determination should be issued within six months of the FAA's receipt of a complaint, reflecting intent ''to expedite substantially the handling and disposition of airport-related complaints'' (in comparison to the 49 CFR part 13 process used prior to 1996).[10] Part 16 was also designed to ensure a final and complete resolution of disputes because the Part 13 process did ''not provide a structure that regularly facilitates the final administrative disposition of airports-related cases within prescribed time limits.'' [11]

F. Burden of Proof Versus Burden of Persuasion (§ 16.23)

The Port Authority noted that proposed § 16.23(k) does not distinguish the legal concept of burden of proof from that of burden of persuasion. The commenter suggested that proposed § 16.23(k) be separated out into a new § 16.24.

The FAA notes, in response, that the Parties entering the Part 16 process have varying levels of legal expertise and familiarity with the rule. While those with legal training likely understand the difference between burden of proof and burden of persuasion, others may not. Rather than adhering to the legal definitions of these terms, the FAA has chosen the term ''burden of proof'' to cover both concepts to make Part 16 more accessible to all participants. The FAA finds that since burden of proof applies to all pleadings, the provision addressing it is best left as proposed in § 16.23.

G. Form of Complaints and Other Pleadings (§§ 16.23 and 16.3)

ACI–NA sought consistent application of the requirement that a complainant show ''how the complainant was 'directly and substantially affected''' by the respondent's actions, especially regarding ripeness. It also recommended more rigorous formatting requirements for complaints. The Port Authority suggested that all pleadings be submitted according to the standards established in Federal Rule of Civil Procedure 10.

The FAA must balance reliance on the Federal Rules of Civil Procedure with its obligation to provide a fair, just, and complete process to all parties. Many complainants and some respondents file without the benefit of general or specialized legal counsel. The FAA believes that adherence to strict formatting requirements for a Part 16 complaint would place an unnecessary burden on those parties.

Part 16 was designed with the Federal Rules of Civil Procedure in mind, but it was not intended to replicate the Federal Rules of Civil Procedure. Part 16 was designed for administrative adjudication that relies on flexibility.

H. Content of Pleadings (§§ 16.23 and 16.3)

Two commenters made suggestions regarding the content of pleadings received by the FAA during the Part 16 process. ACI–NA recommended that the FAA define ''affirmative defense'' in § 16.3 for clarity and restrict acceptance of supplemental pleadings to expedite the process. A private citizen suggested that the rules specify that a complainant may raise whatever issues and submit whatever documents it felt proper to respond to any matter raised in an answer, and that the FAA permit both parties to raise new issues at any time to ensure a full and fair Part 16 process.

The FAA notes that the term ''affirmative defense,'' while a legal term of art, is self-explanatory. The FAA finds it unnecessary to define this term in the Part 16 regulation. Various federal court decisions have relied upon the definition of ''affirmative defense'' in Black's Law Dictionary.[12]

The FAA has two concerns regarding the suggestion that complainants be able to bring new information to the Director prior to the issuance of the Director's Determination (i.e., during the investigatory phase). First, it would be difficult, if not impossible, to finalize the investigation and draft the decision document where new information was able to be routinely submitted to the docket. In a sense, the docket would never close in some cases, and investigations might have to be re-started leading to significant inefficiencies and delay.

Second, § 16.19 currently allows parties to submit motions at any time, and for the opposing party to respond. So, there is a mechanism in place now that would permit new information to be submitted if the complainant believed that it was necessary for the FAA to consider this information. This provision allows flexibility in supplementing the record with relevant information while allowing the Director to exercise discretion to expedite the process.

Concerning the suggestion that complainants should be able to bring new information to the attention of the

[9] 77 FR 13027, March 7, 2012.

[10] 59 FR 29880, 29882, June 9, 1994.

[11] ID. at 29881.

[12] See Black's Law Dictionary, 9th ed. 2009, See also, e.g., *National Union Fire Insurance Co. of Pittsburgh* v. *City Savings FSB,* 28 F.3d 376, 393 (3d Cir. 1994), and *Starnes Family Office, LLC* v. *McCullar,* 765 F.Supp.2d 1036, 1048 (W.D. Tenn., 2011).

Associate Administrator during the Director's Determination appeal process, the FAA notes that new § 16.33(f) expressly provides that new issues or evidence may be brought before the Associate Administrator if certain requirements are met. If a complainant were not able to meet these requirements, he or she would be free to file a new complaint to address the new information.

Concerning the suggestion that the FAA should state specifically that a complainant may raise any issue and submit any document necessary or desirable to respond to any denial or affirmative defense raised in the Answer, the FAA does believe that such clarification is necessary in the rule.

I. Processes Involving the Director (§§ 16.31 and 16.109)

Three commenters were concerned with clarity of language and improper extension of the Director's authority. ACI–NA commented that the language in proposed § 16.109, addressing orders terminating grants, cease and desist orders, and compliance orders, is unclear in relation to that of § 16.31, addressing Director's Determinations after investigations. AAAE suggested that the proposed changes in the Director's authority exceed legal limits and fail to clearly describe what orders the Director could issue. The Port Authority proposed that a definition of ''Corrective Action Plan'' be added to § 16.3.

The FAA finds that neither the provisions in proposed §§ 16.31(c) nor 16.109(c) exceed the scope of the FAA's authority. Under 49 U.S.C. 47107(a–e), the FAA is required to seek specific commitments from sponsors before giving those sponsors grants. Other provisions, such as 49 U.S.C. 47111, give the FAA authority to withhold grants from sponsors when those conditions are not met. By requiring corrective action, the FAA helps the sponsor take steps necessary to retain grant eligibility. Orders to this effect are within the scope of the Director's authority. As stated in the NPRM, proposed §§ 16.31(c) and 16.109(c) allow both flexibility and finality in the process.[13]

The FAA also finds it beneficial to both the agency and respondents to leave ''Corrective Action Plan'' undefined. These plans for bringing an airport sponsor into compliance with its federal obligations are dependent on the specific facts of each Part 16 proceeding. Defining this term could limit the FAA's flexibility in ensuring sponsor compliance and a fair outcome for the parties.

The FAA has added language to § 16.34(a) and (c) to clarify the Director's authority to determine whether or not to issue a consent order where parties propose to dispose of a case through the issuance of that order.

J. Deposition of FAA Employees (§ 16.215(e))

AAAE objected to the breadth of the provision allowing parties to depose agency employees only with written permission of the Chief Counsel. It suggested adding an exception to this rule.

The FAA finds an exception is unnecessary. As proposed in the NPRM, § 16.215(e) is consistent with the provisions of 49 CFR part 9, Testimony of Employees of the Department and Production of Records in Legal Proceedings.

K. Third Party Participation in Part 16 Hearings (§ 16.207)

The Port Authority believes that participation in Part 16 proceedings should be limited to third parties whose interests are sufficient to give them standing equal to that of a complainant or respondent.

The FAA believes that new provisions on third party participation are sufficiently restrictive to prevent the involvement of uninterested third parties. The current rule does not limit third party participation to the hearing stage, nor does it require a written motion to intervene. Changes proposed in the NPRM further restrict third party participation. The FAA is changing these provisions while maintaining the discretion of the hearing officer to admit parties necessary to ensure a fair, just, and complete process.

L. Miscellaneous Issues (§§ 16.13, 16.17, 16.19, 16.26, 16.33, 16.109, 16.111, and 16.245)

Several commenters noted typographical errors, omissions, and inconsistencies throughout the proposed regulatory text.

The FAA is addressing the following typographical errors, omissions, and inconsistencies identified by commenters:

- Removing ''A facsimile neither constitutes an executed original nor one of the three copies required directly above'' from § 16.13(c) (Port Authority and ACI);
- Replacing reference to paragraph (a) in § 16.33(c) with a reference to paragraph (b) (ACI); and
- Replacing ''appeal'' with ''seek judicial review of'' in § 16.245(d) for clarity and consistency with § 16.245(g) (Port Authority).

However, the FAA notes that the following suggested changes would not improve clarity, and is not implementing these recommendations:

- § 16.17(d)—The Port Authority noted that proposed § 16.17(d) contained confusing language and suggested changes;
- §§ 16.19 (e) and 16.17—The Port Authority suggested repeating § 16.19(e) as § 16.17(e) to improve clarity;
- § 16.26(d)—The Port Authority (and ACI–NA by reference) suggested replacing the words ''A reply to'' with ''a brief answering'';
- § 16.109—The Port Authority suggested moving § 16.109 (c)–(g) to § 16.111 (a)–(e); and
- § 16.245(e)—The Port Authority suggested adding new language.

IV. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995).

A. Regulatory Evaluation

DOT Order 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for

[13] 77 FR 13032.

this final rule. The reasoning for this determination follows:

The FAA's Office of Airport Compliance and Management Analysis handles complaints made against federally-assisted airports. Part 16 provides a process for investigating and adjudicating complaints against airport operators for violation of federal obligations. This final rule clarifies and improves the efficiency of the current part 16 regulations for adjudicating complaints on matters within the agency's authority. These changes will be cost-beneficial because they decrease time spent and volume of paper documents required to process part 16 complaints. The new electronic filing process available to the government, complainants, and respondents will produce resource savings. Additionally, allowing a respondent to file a motion to dismiss, or a motion for summary judgment, will also produce resource savings.

The expected outcome will be a minimal impact with positive net benefits, and therefore a full regulatory evaluation was not prepared. The FAA requested comments regarding this determination in the NPRM. Because no comments were received on this determination, the FAA believes the expected outcome is correct. The FAA has therefore determined that this final rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures.

Additionally, this action fulfills the principles of Executive Order 13563, specifically those relating to retrospective analyses of existing rules. This rule is being issued as a result of the reviews of existing regulations that the FAA periodically conducts. The FAA is streamlining its regulations to reflect changes in applicable law and regulations, and to apply lessons learned since the original rule was published in 1996.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As noted above, the proposed changes to Part 16 are cost-relieving. Accordingly, the final rule will not have a significant economic impact on a substantial number of small entities. The FAA certified in the NPRM that the proposed rule would not have a significant economic impact on a substantial number of small entities. The FAA requested comments regarding this determination in the NPRM. Specifically, the FAA requested comments on whether the proposed rule would create any specific compliance costs unique to small entities and requested any respondents to provide detailed economic analysis to support any cost claims. The FAA received no response to its request for comments.

Therefore, as the FAA Administrator, I certify that this final rule will not have a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA assessed the potential effect of this proposed rule in the NPRM and determined that it would have only a domestic impact and therefore create no obstacles to the foreign commerce of the United States. The FAA received no comments on this determination. Therefore, the FAA determines that this final rule will have only a domestic impact and therefore create no obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a 'significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million. The NPRM found that the proposed rule did not contain such a mandate; and, therefore, the requirements of Title II of the Act did not apply. The FAA received no comments on this finding. Therefore, the FAA finds that this final rule does not contain such a mandate; and, therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this final rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

G. Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances.

The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312d of the Order and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

VI. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal (*http://www.regulations.gov*);
2. Visit the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/* or
3. Access the Government Printing Office's Web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 16

Administrative practice and procedure, Airports, Investigations.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 16—RULES OF PRACTICE FOR FEDERALLY-ASSISTED AIRPORT ENFORCEMENT PROCEEDINGS

■ 1. The authority citation for part 16 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 322, 1110, 1111, 1115, 1116, 1718(a) and (b), 1719, 1723, 1726, 1727, 40103(e), 40113, 40116, 44502(b), 46101, 46104, 46110, 47104, 47106(e), 47107, 47108, 47111(d), 47122, 47123–47125, 47133, 47151–47153, 48103.

■ 2. Amend § 16.1 by revising paragraphs (a) introductory text and (a)(3) through (6) to read as follows:

§ 16.1 Applicability and description of part.

(a) *General.* The provisions of this part govern all Federal Aviation Administration (FAA) proceedings involving Federally-assisted airports, except for complaints or requests for determination filed with the Secretary under 14 CFR part 302, whether the proceedings are instituted by order of the FAA or by filing a complaint with the FAA under the following authorities:

* * * * *

(3) The assurances and other Federal obligations contained in grant-in-aid agreements issued under the Federal Airport Act of 1946, 49 U.S.C. 1101 *et seq.* (repealed 1970).

(4) The assurances and other Federal obligations contained in grant-in-aid agreements issued under the Airport and Airway Development Act of 1970, as amended, 49 U.S.C. 1701 *et seq.*

(5) The assurances and other Federal obligations contained in grant-in-aid agreements issued under the Airport and Airway Improvement Act of 1982 (AAIA), as amended and recodified, 49 U.S.C. 47101 *et seq.,* specifically section 511(a), 49 U.S.C. 47107, and 49 U.S.C. 47133.

(6) Section 505(d) of the Airport and Airway Improvement Act of 1982, and the requirements concerning civil rights and/or Disadvantaged Business Enterprise (DBE) issues contained in 49 U.S.C. 47107(e) and 49 U.S.C. 47113; 49 U.S.C. 47123; 49 U.S.C. 322, as amended; 49 CFR parts 23 and/or 26; and/or grant assurance 30 and/or grant assurance 37.

* * * * *

■ 3. Amend § 16.3 as follows:

■ a. Remove the definitions of *Director's determination, File,* and *Final decision and order;*

■ b. Revise the definitions of *Agency employee, Associate Administrator, Complaint, Director, Hearing officer, Mail,* and *Personal delivery;* and

■ c. Add definitions for *Administrator, Agency, Decisional employee, Electronic filing, Ex parte communication,* and *Writing or written* in alphabetical order.

The revisions and additions read as follows:

§ 16.3 Definitions.

* * * * *

Administrator means the Administrator of the FAA.

Agency means the FAA.

* * * * *

Agency employee means any employee of the FAA.

Associate Administrator means the FAA Associate Administrator for Airports or a designee. For the purposes of this part only, Associate Administrator also means the Assistant Administrator for Civil Rights or a designee for complaints that the FAA Associate Administrator for Airports transfers to the Assistant Administrator for Civil Rights.

* * * * *

Complaint means a written document meeting the requirements of this part and filed under this part:

(1) By a person directly and substantially affected by anything allegedly done or omitted to be done by any person in contravention of any provision of any Act, as defined in this section, as to matters within the jurisdiction of the Administrator, or

(2) By a person under 49 CFR 26.105(c) against a recipient of FAA funds alleged to have violated a provision of 49 CFR parts 23 and/or 26.

Decisional employee means the Administrator, Deputy Administrator,

Associate Administrator, Director, hearing officer, or other FAA employee who is or who may reasonably be expected to be involved in the decisional process of the proceeding.

Director means the Director of the FAA Office of Airport Compliance and Management Analysis, or a designee. For the purposes of this part only, Director also means the Deputy Assistant Administrator for Civil Rights for complaints that the Director of the FAA Office of Airport Compliance and Management Analysis transfers to the Deputy Assistant Administrator for Civil Rights or designee.

Electronic filing means the process of sending electronic mail (email) to the FAA Part 16 Docket Clerk, with scanned documents attached, as a Portable Document Format (PDF) file.

Ex parte communication means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this part, or communications between FAA employees who participate as parties to a hearing pursuant to 16.203(b) of this part and other parties to a hearing.

Hearing officer means an attorney designated by the Deputy Chief Counsel in a hearing order to serve as a hearing officer in a hearing under this part. The following are not designated as hearing officers: the Chief Counsel and Deputy Chief Counsel; the Regional or Center Counsel and attorneys in the FAA region or center in which the noncompliance has allegedly occurred or is occurring; the Assistant Chief Counsel and attorneys in the Airports and Environmental Law Division of the FAA Office of the Chief Counsel; and the Assistant Chief Counsel and attorneys in the Litigation Division of the FAA Office of Chief Counsel.

* * * * *

Mail means U.S. first class mail; U.S. certified mail; and U.S. express mail. Unless otherwise noted, mail also means electronic mail containing PDF copies of pleadings or documents required herein.

* * * * *

Personal delivery means same-day hand delivery or overnight express delivery service.

* * * * *

Writing or written includes paper documents that are filed and/or served by mail, personal delivery, facsimile, or email (as attached PDF files).

■ 4. Amend § 16.11 by revising the section heading and paragraphs (a) and (b) introductory text, and adding paragraphs (c) and (d) to read as follows:

§ 16.11 General processes.

(a) Under the authority of 49 U.S.C. 40113 and 47121, the Director may conduct investigations, issue orders, and take such other actions as are necessary to fulfill the purposes of this part. This includes the extension of any time period prescribed, where necessary or appropriate for a fair and complete consideration of matters before the agency, prior to issuance of the Director's Determination.

(b) Notwithstanding any other provision of this part, upon finding that circumstances require expedited handling of a particular case or controversy, the Director may issue an order directing any of the following prior to the issuance of the Director's Determination:

* * * * *

(c) Other than those matters concerning a Corrective Action Plan, the jurisdiction of the Director terminates upon the issuance of the Director's Determination. All matters arising during the appeal period, such as requests for extension of time to make an appeal, will be addressed by the Associate Administrator.

(d) The Director may transfer to the FAA Deputy Assistant Administrator for Civil Rights or Office of Civil Rights designee the authority to prepare and issue Director's Determinations pursuant to § 16.31 for complaints alleging violations of section 505(d) of the Airport and Airway Improvement Act of 1982, and the requirements concerning civil rights and/or Disadvantaged Business Enterprise (DBE) issues contained in 49 U.S.C. 47107(e) and 49 U.S.C. 47113; 49 U.S.C. 47123; 49 U.S.C. 322, as amended; 49 CFR parts 23 and/or 26; and/or grant assurance 30 and/or grant assurance 37.

■ 5. Amend § 16.13 by revising paragraphs (a), (b), (c), (d), and (f) and adding paragraphs (h) and (i) to read as follows:

§ 16.13 Filing of documents.

* * * * *

(a) *Filing address.* Documents filed under this Part shall be filed with the Office of the Chief Counsel, Attention: FAA Part 16 Docket Clerk, AGC–600, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591. Documents to be filed with a hearing officer shall be filed at the address and in the manner stated in the hearing order.

(b) *Date and method of filing.* Filing of any document shall be by personal delivery or mail as defined in this part, by facsimile (when confirmed by filing on the same date by one of the foregoing methods), or electronically as set forth in paragraph (h) of this section. Unless the date is shown to be inaccurate, documents filed with the FAA shall be deemed to be filed on the date of personal delivery, on the mailing date shown on the certificate of service, on the date shown on the postmark if there is no certificate of service, on the send date shown on the facsimile (provided filing has been confirmed through one of the foregoing methods), or on the mailing date shown by other evidence if there is no certificate of service and no postmark. Unless the date is shown to be inaccurate, documents filed electronically shall be deemed to be filed on the date shown on the certificate of service or, if none, the date of electronic transmission to the last party required to be served.

(c) *Number of copies.* With the exception of electronic filing or unless otherwise specified, an executed original and three copies of each document shall be filed with the FAA Part 16 Docket Clerk. One of the three copies shall not be stapled, bound or hole-punched. Copies need not be signed, but the name of the person signing the original shall be shown. If a hearing order has been issued in the case, one of the three copies shall be filed with the hearing officer unless otherwise prescribed by the hearing officer.

(d) *Form.* Documents filed under this part shall:

(1) Be typewritten or legibly printed;

(2) Include, in the case of docketed proceedings, the docket number of the proceeding on the front page; and

(3) Be marked to identify personal, privileged or proprietary information. Decisions for the publication and release of these documents will be made in accordance with 5 U.S.C. 552 and 49 CFR part 7.

* * * * *

(f) *Designation of person to receive service.* The initial document filed by any person shall state on the first page the name, physical address, telephone number, facsimile number, if any, and email address, if filing electronically, of the person(s) to be served with documents in the proceeding. If any of these items change during the proceeding, the person shall promptly file notice of the change with the FAA Part 16 Docket Clerk and the hearing officer and shall serve the notice on all parties.

* * * * *

(h) *Electronic filing.* (1) The initial complaint may be served electronically

upon the respondent only if the respondent has previously agreed with the complainant in writing to participate in electronic filing. Documents may be filed under this Part electronically by sending an email containing (an) attachment(s) of (a) PDF file(s) of the required pleading to the FAA Docket Clerk, and the person designated in paragraph (h)(3) of this section.

(2) The subject line of the email must contain the names of the complainant and respondent, and must contain the FAA docket number (if assigned). The size of each email must be less than 10 MB. Email attachments containing executable files (e.g., .exe and .vbs files) will not be accepted.

(3) The email address at which the parties may file the documents described in this section is *9-AWA-AGC-Part-16@faa.gov*. No acknowledgement or receipt will be provided by the FAA to parties using this method. A party filing electronically as described in this section must provide to the FAA Part 16 Docket Clerk and the opposing party an email address of the person designated by the party to receive pleadings.

(4) By filing a pleading or document electronically as described in this section, a party waives the rights under this part for service by the opposing party and the FAA by methods other than email. If a party subsequently decides to ''opt-out'' of electronic filing, that party must so notify the FAA Part 16 Docket Clerk and the other party in writing, from which time the FAA and the parties will begin serving the opting-out party in accordance with §§ 16.13 and 16.15. This subsection only exempts the parties from the filing and service requirements in § 16.13(a) (with the exception that ''Documents to be filed with a hearing officer shall be filed at the address and in the manner stated in the hearing order.''), the method of filing requirements in § 16.13(b), and the number of documents requirements in § 16.13(c).

(i) *Internet accessibility of documents filed in the Hearing Docket.* (1) Unless protected from public disclosure, all documents filed in the Hearing Docket are accessible through the Federal Docket Management System (FDMS): *http://www.regulations.gov*. To access a particular case file, use the FDMS number assigned to the case.

(2) Determinations issued by the Director and Associate Administrator in Part 16 cases, indexes of decisions, contact information for the FAA Hearing Docket, the rules of practice, and other information are available on the FAA Office of Airports' Web site at: *http://part16.airports.faa.gov/index.cfm*.

■ 6. Amend § 16.15 by revising paragraphs (a), (b), (d)(1) and (d)(2), and adding paragraph (d)(3) to read as follows:

§ 16.15 Service of documents on the parties and the agency.

* * * * *

(a) *Whom must be served.* Copies of all documents filed with the FAA Part 16 Docket Clerk shall be served by the persons filing them on all parties to the proceeding. A certificate of service shall accompany all documents when they are tendered for filing and shall certify concurrent service on the FAA and all parties. Certificates of service shall be in substantially the following form:

I hereby certify that I have this day served the foregoing [name of document] on the following persons at the following addresses, facsimile numbers (if also served by facsimile), or email address (if served electronically in accordance with § 16.13(h)), by [specify method of service]:

[list persons, addresses, facsimile numbers, email addresses (as applicable)]

Dated this __day of __, 20__.

[signature], for [party]

(b) Method of service. Except as otherwise agreed by the parties and, if applicable, the hearing officer, the method of service is the same as set forth in § 16.13(b) for filing documents.

* * * * *

(d) * * *

(1) When acknowledgment of receipt is by a person who customarily or in the ordinary course of business receives mail at the address of the party or of the person designated under § 16.13(f);

(2) When a properly addressed envelope, sent to the most current address submitted under § 16.13(f), has been returned as undeliverable, unclaimed, or refused; or

(3) When the party serving the document electronically has a confirmation statement demonstrating that the email was properly sent to a party correctly addressed.

* * * * *

■ 7. Amend § 16.17 by revising paragraph (c) to read as follows:

§ 16.17 Computation of time.

* * * * *

(c) Whenever a party has the right or is required to do some act within a prescribed period after service of a document upon the party, and the document is served on the party by first class mail or certified mail, 5 days shall be added to the prescribed period.

■ 8. Amend § 16.19 by adding paragraphs (d) and (e) to read as follows:

§ 16.19 Motions.

* * * * *

(d) *Deferred actions on motions.* A ruling on a motion made before the time set for the issuance of the Director's Determination may be deferred to and included with the Director's Determination.

(e) *Extension by motion.* A party shall file a written motion for an extension of time not later than 3 business days before the document is due unless good cause for the late filing is shown. A party filing a motion for extension should attempt to obtain the concurrence of the opposing party. A party filing a written motion for an extension of time shall file the motion as required under § 16.13, and serve a copy of the motion on all parties and the docket clerk as required under § 16.15.

■ 9. Revise § 16.21 to read as follows:

§ 16.21 Pre-complaint resolution.

(a) Except for those persons filing under 49 CFR 26.105(c), prior to filing a complaint under this part, a person directly and substantially affected by the alleged noncompliance shall initiate and engage in good faith efforts to resolve the disputed matter informally with those individuals or entities believed responsible for the noncompliance. These efforts at informal resolution may include, without limitation, at the parties' expense, mediation, arbitration, or the use of a dispute resolution board, or other form of third party assistance. The FAA Airports District Office, FAA Airports Field Office, FAA Regional Airports Division responsible for administering financial assistance to the sponsor, or the FAA Office of Civil Rights will be available upon request to assist the parties with informal resolution.

(b) Except for complaints filed under 49 CFR 26.105(c), a complaint will be dismissed under § 16.27 unless the person or authorized representative filing the complaint certifies that:

(1) The complainant has made substantial and reasonable good faith efforts to resolve the disputed matter informally prior to filing the complaint; and

(2) There is no reasonable prospect for practical and timely resolution of the dispute.

(c) The certification required under paragraph (b) of this section, shall include a brief description of the party's efforts to obtain informal resolution but

shall not include information on monetary or other settlement offers made but not agreed upon in writing by all parties. Such efforts to resolve informally should be relatively recent and be demonstrated by pertinent documentation. There is no required form or process for informal resolution, but in each case the requirements to resolve the matter informally must meet the requirements of this paragraph.

■ 10. Amend § 16.23 by revising the section heading; revising paragraphs (a), (b)(2), (b)(4), (c), (d), and (j); and adding paragraphs (k) and (l) to read as follows:

§ 16.23 Pleadings.

(a) A person directly and substantially affected by any alleged noncompliance or a person qualified under 49 CFR 26.105(c) may file a complaint under this part. A person doing business with an airport and paying fees or rentals to the airport shall be considered directly and substantially affected by alleged revenue diversion as defined in 49 U.S.C. 47107(b).

(b) * * *

(2) Include all documents then available in the exercise of reasonable diligence, to be offered in support of the complaint, and to be served upon all persons named in the complaint as persons responsible for the alleged action(s) or omission(s) upon which the complaint is based;

* * * * *

(4) Except for complaints filed under 49 CFR 26.105(c), describe how the complainant was directly and substantially affected by the things done or omitted to be done by the respondents.

(c) Unless the complaint is dismissed pursuant to § 16.25 or § 16.27, the FAA notifies the complainant and respondent in writing within 20 days after the date the FAA receives the complaint that the complaint has been docketed.

(d) The respondent shall file an answer within 20 days of the date of service of the FAA notification or, if a motion is filed under § 16.26, within 20 days of the date of service of an FAA order denying all or part of that motion.

* * * * *

(j) Amendments or supplements to the pleadings described in this section will not be allowed without showing good cause through a motion and supporting documents.

(k) *Burden of proof.* Except as used in subpart F of this part,

(1) The burden of proof is on the complainant to show noncompliance with an Act or any regulation, order, agreement or document of conveyance issued under the authority of an Act.

(2) Except as otherwise provided by statute or rule, the proponent of a motion, request, or order has the burden of proof.

(3) A party who has asserted an affirmative defense has the burden of proving the affirmative defense.

(l) Except for good cause shown through motion and supporting documents, discovery is not permitted except as provided in §§ 16.213 and 16.215.

■ 11. Revise § 16.25 to read as follows:

§ 16.25 Dismissals.

(a) Within 20 days after the receipt of the complaint, unless a motion has been filed under § 16.26, the Director will dismiss a complaint, or any claim made in a complaint, with prejudice if:

(1) It appears on its face to be outside the jurisdiction of the Administrator under the Acts listed in § 16.1;

(2) On its face it does not state a claim that warrants an investigation or further action by the FAA; or

(3) The complainant lacks standing to file a complaint under §§ 16.3 and 16.23.

(b) A dismissal under this section will include the reasons for the dismissal.

■ 12. Add § 16.26 to read as follows:

§ 16.26 Motions to dismiss and motions for summary judgment.

(a) In lieu of an answer, the respondent may file a motion to dismiss the complaint or a motion for summary judgment on the complaint. The respondent may move for dismissal of the entire complaint or move for dismissal of particular issues from adjudication. The motion must be filed within 20 days after the date of service of the FAA notification of docketing.

(b) *Motions to dismiss.* (1) A motion to dismiss shall be accompanied by a concise statement of the reasons for seeking dismissal. The respondent must show that the complaint should be dismissed, with prejudice, if:

(i) It appears on its face to be outside the jurisdiction of the Administrator under the Acts listed in § 16.1;

(ii) On its face it does not state a claim that warrants an investigation or further action by the FAA; or

(iii) The complainant lacks standing to file a complaint under §§ 16.3 and 16.23.

(2) A motion to dismiss may seek dismissal of the entire complaint or the dismissal of specified claims in the complaint. A motion to dismiss shall be accompanied by a supporting memorandum of points and authorities.

(3) A complainant may file an answer to the motion to dismiss within 10 days of the date the motion is served on the complainant, or within any other period set by the Director. The answer shall be accompanied by a concise statement of reasons for opposing dismissal, and may be accompanied by affidavits and other documentary evidence in support of that contention.

(4) Within 30 days of the date an answer to a motion to dismiss is due under this section, the Director may issue an order disposing of the motion. If the Director denies the motion to dismiss in whole or in part, or grants the motion in part, then within 20 days of when the order is served on the respondent, the respondent shall file an answer to the complaint.

(5) If the Director does not act on the motion to dismiss within 30 days of the date an answer to a motion is due under this section, the respondent shall file an answer to the complaint within the next 20 days.

(c) *Motions for summary judgment.* (1) A motion for summary judgment may be based upon the ground that there is no genuine issue of material fact for adjudication and that the complaint, when viewed in the light most favorable to the complainant, should be summarily adjudicated in favor of the respondent as a matter of law. A motion for summary judgment may seek dismissal of the entire complaint or dismissal of specified claims or issues in the complaint.

(2) The motion for summary judgment shall be accompanied by a concise statement of the material facts as to which the respondent contends there is no genuine issue of material fact. The motion may include affidavits and documentary evidence in support of the contention that there is no genuine issue of material fact in dispute.

(3) A complainant may file an answer to the motion for summary judgment within 10 days of the date the motion is served on the complainant, or within any other period set by the Director. The answer shall be accompanied by a concise statement of the material facts as to which the complainant contends there is a genuine issue, and may be accompanied by affidavits and other documentary evidence in support of that contention.

(4) Within 30 days of the date an answer to a motion for summary judgment is due under this section, the Director may issue an order disposing of the motion. If the Director denies the motion in whole or in part, or grants the motion in part, then within 20 days of when the order is served on the respondent, the respondent shall file an answer to the complaint.

(5) If the Director does not act on the motion for summary judgment within

30 days of the date an answer to a motion is due under this section, the respondent shall file an answer to the complaint within the next 20 days.

■ 13. Revise § 16.27 to read as follows:

§ 16.27 Incomplete complaints.

(a) If a complaint is not dismissed pursuant to § 16.25, but is deficient as to one or more of the requirements set forth in § 16.21 or § 16.23(b), the Director will dismiss the complaint within 20 days after receiving it. Dismissal will be without prejudice to the refiling of the complaint after amendment to correct the deficiencies. The Director's dismissal will include the reasons for the dismissal.

(b) Dismissals under this section are not initial determinations, and appeals from decisions under this section will not be permitted.

■ 14. In § 16.29, revise the first sentence of paragraph (b)(2) to read as follows:

§ 16.29 Investigations.

* * * * *

(b) * * *

(2) Obtaining additional oral and documentary evidence by use of the agency's authority to compel production of such evidence under 49 U.S.C. 40113 and 46104, and 49 U.S.C. 47122. * * *

* * * * *

■ 15. Revise § 16.31 to read as follows:

§ 16.31 Director's Determinations after investigations.

(a) After consideration of the pleadings and other information obtained by the FAA after investigation, the Director will render an initial determination and serve it upon each party within 120 days of the date the last pleading specified in § 16.23 was due.

(b)(1) The Director's Determination shall include findings of fact and conclusions of law, accompanied by explanations and based upon all material issues of fact, credibility of the evidence, law and discretion presented on the record, together with a statement of the reasons therefor.

(2) The Director shall issue a determination or rule in a party's favor only if the determination or ruling is in accordance with law and supported by a preponderance of the reliable, probative, and substantial evidence contained in the record.

(c) A party adversely affected by the Director's Determination may appeal the initial determination as provided in § 16.33. However, if the Director's Determination that is appealed contains a Corrective Action Plan, the Director has the discretion to suspend the Corrective Action Plan until the appeal is resolved.

(d) If the Director's Determination finds the respondent in noncompliance and proposes the issuance of a compliance order, the initial determination will include notice of opportunity for a hearing under subpart F of this part if a hearing is required by statute or otherwise provided by the FAA. A hearing may be required by statute if the FAA determination would terminate eligibility for grants under 49 U.S.C. 47114(c) or (e), or terminate payments on a grant agreement under 49 U.S.C. subchapter 471. The respondent may elect or waive a hearing, as provided in subpart E of this part.

(e) The Director will not consider requests for rehearing, reargument, reconsideration, or modification of a Director's Determination without a finding of good cause.

■ 16. Revise § 16.33 to read as follows:

§ 16.33 Final decisions without hearing.

(a) The Associate Administrator may transfer to the FAA Assistant Administrator for Civil Rights the responsibility to prepare and issue Final Agency Decisions pursuant to this section for appeals with issues concerning civil rights.

(b) The Associate Administrator will issue a final decision on appeal from the Director's Determination, without a hearing, where—

(1) The complaint is dismissed after investigation;

(2) A hearing is not required by statute and is not otherwise made available by the FAA; or

(3) The FAA provides opportunity for a hearing to the respondent and the respondent waives the opportunity for a hearing as provided in subpart E of this part.

(c) In the cases described in paragraph (b) of this section, within 30 days after the date of service of the initial determination, a party adversely affected by the Director's Determination may file in accordance with § 16.13 and serve in accordance with § 16.15 a simultaneous Notice of Appeal and Brief.

(d) A reply to an appeal brief may be filed within 20 days after the date of service of the appeal.

(e) On appeal, the Associate Administrator will consider the issues addressed in any order on a motion to dismiss or motion for summary judgment and any issues accepted in the Director's Determination using the following analysis:

(1) Are the findings of fact each supported by a preponderance of reliable, probative, and substantial evidence contained in the record?

(2) Are conclusions made in accordance with law, precedent and policy?

(3) Are the questions on appeal substantial?

(4) Have any prejudicial errors occurred?

(f) Any new issues or evidence presented in an appeal or reply will not be considered unless accompanied by a petition and good cause found as to why the new issue or evidence was not presented to the Director. Such a petition must:

(1) Set forth the new matter;

(2) Contain affidavits of prospective witnesses, authenticated documents, or both, or an explanation of why such substantiation is unavailable; and

(3) Contain a statement explaining why such new issue or evidence could not have been discovered in the exercise of due diligence prior to the date on which the evidentiary record closed.

(g) The Associate Administrator will issue a final decision and order within 60 days after the due date of the reply.

(h) If no appeal is filed within the time period specified in paragraph (c) of this section, the Director's Determination becomes the final decision and order of the FAA without further action. A Director's Determination that becomes final, because there is no administrative appeal, is not judicially reviewable.

(i) No requests for rehearing, reargument, reconsideration, or modification of a final order will be considered without a finding of good cause.

■ 17. Add § 16.34 to subpart C to read as follows:

§ 16.34 Consent orders.

(a) The parties may agree at any time before the issuance of a final agency decision to dispose of the case by proposing a consent order. Good faith efforts to resolve a complaint through issuance of a consent order may continue throughout the administrative process. However, except as provided in § 16.11(a), such efforts may not serve as the basis for extensions of the times set forth in this part.

(b) A proposal for a consent order, specified in paragraph (a) of this section, shall include:

(1) A proposed consent order;

(2) An admission of all jurisdictional facts; and

(3) An express waiver of the right to further procedural steps and of all rights of judicial review.

(c) If the parties agree to dispose of a case by issuance of a consent order

before the FAA issues a Director's Determination, the proposal for a consent order is submitted jointly by the parties to the Director, together with a request to adopt the consent order and dismiss the case. The Director may issue the consent order as an order of the FAA and terminate the proceeding.

§ 16.105 [Amended]

■ 18. Amend § 16.105 by removing ''determination'' and adding ''Determination'' in its place.

■ 19. Revise § 16.109 to read as follows:

§ 16.109 Orders terminating eligibility for grants, cease and desist orders, and other compliance orders.

(a) The agency will provide the opportunity for a hearing if, in the Director's determination, the agency issues or proposes to issue an order terminating eligibility for grants pursuant to 49 U.S.C. 47106(d), an order suspending the payment of grant funds pursuant to 49 U.S.C. 47111(d); an order withholding approval of any new application to impose a passenger facility charge pursuant to 49 U.S.C. 47111(e); a cease and desist order; an order directing the refund of fees unlawfully collected; or any other compliance order issued by the Administrator to carry out the provisions of the Acts, and required to be issued after notice and opportunity for a hearing. In cases in which a hearing is not required by statute, the FAA may provide opportunity for a hearing at its discretion.

(b) In a case in which the agency provides the opportunity for a hearing, the Director's Determination issued under § 16.31 will include a statement of the availability of a hearing under subpart F of this part.

(1) Within 20 days after service of a Director's Determination under § 16.31 that provides an opportunity for a hearing a person subject to the proposed compliance order may—

(i) Request a hearing under subpart F of this part;

(ii) Waive hearing and appeal the Director's Determination in writing, as provided in § 16.33;

(iii) File, jointly with a complainant, a motion to withdraw the complaint and to dismiss the proposed compliance action; or

(iv) Submit, jointly with the agency, a proposed consent order under § 16.34(c).

(2) If the respondent fails to file an appeal in writing within the time periods provided in paragraph (c) of this section, the Director's Determination becomes final.

(c) The Director may either direct the respondent to submit a Corrective Action Plan or initiate proceedings to revoke and/or deny the respondent's application for Airport Improvement Program discretionary grants under 49 U.S.C. 47115 and general aviation airport grants under 49 U.S.C. 47114(d) when a Director's Determination finds a respondent in noncompliance and does not provide for a hearing.

(d) In the event that the respondent fails to submit, in accordance with a Director's Determination, a Corrective Action Plan acceptable to the FAA within the time provided, unless extended by the FAA for good cause, and/or if the respondent fails to complete the Corrective Action Plan as specified therein, the Director may initiate action to revoke and/or deny applications for Airport Improvement Program discretionary grants under 49 U.S.C. 47115 and general aviation airport grants under 49 U.S.C. 47114(d).

(e) For those violations that cannot be remedied through corrective action, the Director may initiate action to revoke and/or deny the respondent's applications for Airport Improvement Program discretionary grants under 49 U.S.C. 47115 and general aviation airport grants under 49 U.S.C. 47114(d).

(f) When the Director concludes that the respondent has fully complied with the Corrective Action Plan and/or when the Director determines that the respondent has corrected the areas of noncompliance, the Director will terminate the proceeding.

(g) A complainant's standing terminates upon the issuance of a Director's Determination that finds a respondent in noncompliance on all identified issues. The complainant may not appeal the Director's Determination if the Director finds noncompliance on all identified issues.

■ 20. Amend § 16.201 by revising paragraph (b) to read as follows:

§ 16.201 Notice and order of hearing.

* * * * *

(b) Where there are no genuine issues of material fact requiring oral examination of witnesses, the hearing order may contain a direction to the hearing officer to conduct a hearing by submission of briefs and oral argument without the presentation of testimony or other evidence.

■ 21. Amend § 16.203 by revising paragraphs (a)(1), (b)(1), and (b)(2) to read as follows:

§ 16.203 Appearances, parties, and rights of parties.

(a) * * *

(1) Any party may be accompanied, represented, or advised by an attorney licensed by a State, the District of Columbia, or a territory of the United States to practice law or appear before the courts of that State or territory, or by another person authorized by the hearing officer to be the party's representative.

* * * * *

(b) * * *

(1) The parties to the hearing are the complainant(s) and respondent(s) named in the hearing order, and the agency. The style of any pleadings filed under this Subpart shall name the respondent as the Appellant, and the Federal Aviation Administration as the Agency.

(2) Unless otherwise specified in the hearing order, the agency attorney will serve as prosecutor for the agency from the date of issuance of the Director's Determination providing an opportunity for hearing.

■ 22. Revise § 16.207 to read as follows:

§ 16.207 Intervention and other participation.

(a) Intervention and participation by other persons are permitted only at the hearing stage of the complaint process and with the written approval of the hearing officer.

(b) A person may submit a written motion for leave to intervene as a party. Except for good cause shown, a motion for leave to intervene shall be submitted not later than 10 days after the notice of hearing and hearing order.

(c) If the hearing officer finds that intervention will not unduly broaden the issues or delay the proceedings and, if the person has an interest that will benefit the proceedings, the hearing officer may grant a motion for leave to intervene. The hearing officer may determine the extent to which an intervenor may participate in the proceedings.

(d) Other persons may petition the hearing officer for leave to participate in the hearing. Participation is limited to the filing of a posthearing brief and reply to the hearing officer and the Associate Administrator. Such a brief shall be filed and served on all parties in the same manner as the parties' posthearing briefs are filed.

(e) Participation under this section is at the discretion of the hearing officer, and no decision permitting participation shall be deemed to constitute an expression that the participant has such a substantial interest in the proceeding as would entitle it to judicial review of such decision.

■ 23. In § 16.211, revise the last sentence in paragraph (c) to read as follows:

§ 16.211 Prehearing conference.

* * * * *

(c) * * * In addition, the hearing officer establishes the schedule, which shall provide for the issuance of an initial decision not later than 110 days after issuance of the Director's Determination order unless otherwise provided in the hearing order.

■ 24. Amend § 16.215 by adding paragraph (e) to read as follows:

§ 16.215 Depositions.

* * * * *

(e) *Depositions of agency employees.* (1) Depositions of Agency Employees will not be allowed except under the provisions of 49 CFR part 9.

(2) Such depositions will be allowed only with the specific written permission of the Chief Counsel or his or her designee.

■ 25. Revise § 16.227 to read as follows:

§ 16.227 Standard of proof.

The hearing officer shall issue an initial decision or rule in a party's favor only if the decision or ruling is in accordance with law and supported by a preponderance of the reliable, probative, and substantial evidence contained in the record.

■ 26. Amend § 16.229 by adding introductory text to read as follows:

§ 16.229 Burden of proof.

As used in this subpart, the burden of proof is as follows:

* * * * *

■ 27. Revise § 16.233 to read as follows:

§ 16.233 Record.

(a) *Exclusive record.* The transcript of all testimony in the hearing, all exhibits received into evidence, all motions, applications requests and rulings, all documents included in the hearing record and the Director's Determination shall constitute the exclusive record for decision in the proceedings and the basis for the issuance of any orders.

(b) *Examination and copy of record.* A copy of the record will be filed by the FAA Part 16 Docket Clerk in the Federal Docket Management System (FDMS). Any person desiring to review the record may then do so at *http://www.regulations.gov*.

■ 28. Amend § 16.235 by revising paragraph (b) to read as follows:

§ 16.235 Argument before the hearing officer.

* * * * *

(b) *Posthearing briefs.* The hearing officer may request or permit the parties to submit posthearing briefs. The hearing officer may provide for the filing of simultaneous reply briefs as well, if such filing will not unduly delay the issuance of the hearing officer's initial decision. Posthearing briefs shall include proposed findings of fact and conclusions of law; exceptions to rulings of the hearing officer; references to the record in support of the findings of fact; and supporting arguments for the proposed findings, proposed conclusions, and exceptions.

§§ 16.241 and 16.243 [Transferred to Subpart F]

■ 29. Sections 16.241 and 16.243 are transferred from subpart G to subpart F.

Subpart G—[Removed and Reserved]

■ 30. Remove and reserve subpart G.

■ 31. Amend § 16.241 by revising paragraphs (a) and (c) and removing paragraph (f).

The revisions read as follows:

§ 16.241 Initial decisions, order, and appeals.

(a) The hearing officer shall issue an initial decision based on the record developed during the proceeding and shall send the initial decision to the parties not later than 110 days after the Director's Determination unless otherwise provided in the hearing order.

* * * * *

(c) If an appeal is filed, the Associate Administrator reviews the entire record and issues a final agency decision and order within 60 days of the due date of the reply. If no appeal is filed, the Associate Administrator may take review of the case on his or her own motion. If the Associate Administrator finds that the respondent is not in compliance with any Act or any regulation, agreement, or document of conveyance issued or made under such Act, the final agency order includes, in accordance with § 16.245(d), a statement of corrective action, if appropriate, and identifies sanctions for continued noncompliance.

* * * * *

■ 32. Add § 16.245 to subpart F to read as follows:

§ 16.245 Associate Administrator review after a hearing.

(a) The Associate Administrator may transfer to the FAA Assistant Administrator for Civil Rights the authority to prepare and issue Final Agency Decisions pursuant to § 16.241 for appeals from a hearing concerning civil rights issues.

(b) After a hearing is held, and, after considering the issues as set forth in § 16.245(e), if the Associate Administrator determines that the hearing officer's initial decision or order should be changed, the Associate Administrator may:

(1) Make any necessary findings and issue an order in lieu of the hearing officer's initial decision or order, or

(2) Remand the proceeding for any such purpose as the Associate Administrator may deem necessary.

(c) If the Associate Administrator takes review of the hearing officer's initial decision on the Associate Administrator's own motion, the Associate Administrator will issue a notice of review within 20 days of the actual date the initial decision is issued.

(1) The notice sets forth the specific findings of fact and conclusions of law in the initial decision that are subject to review by the Associate Administrator.

(2) Parties may file one brief on review to the Associate Administrator or rely on their posthearing brief to the hearing officer. A brief on review shall be filed not later than 10 days after service of the notice of review. Filing and service of a brief on review shall be by personal delivery.

(3) The Associate Administrator issues a final agency decision and order within 30 days of the due date of the brief. If the Associate Administrator finds that the respondent is not in compliance with any Act or any regulation, agreement or document of conveyance issued under such Act, the final agency order includes a statement of corrective action, if appropriate.

(d) When the final agency decision finds a respondent in noncompliance, and where a respondent fails to properly seek judicial review of the final agency decision as set forth in subpart G of this part, the Associate Administrator will issue an order remanding the case to the Director for the following action:

(1) In the event that the respondent fails to submit, in accordance with the final agency decision, a Corrective Action Plan acceptable to the FAA within the time provided, unless extended by the FAA for good cause, and/or if the respondent fails to complete the Corrective Action Plan as specified therein, the Director may initiate action to revoke and/or deny applications for Airport Improvement Program grants issued under 49 U.S.C. 47114(c)–(e) and 47115. When the Director concludes that the respondent has fully complied with the Corrective Action Plan, the Director will issue an Order terminating the proceeding.

(2) For those violations that cannot be remedied through corrective action, the

Director may initiate action to revoke and/or deny the respondent's applications for Airport Improvement Program grants issued under 49 U.S.C. 47114(c)–(e) and 47115.

(e) On appeal from a hearing officer's initial decision, the Associate Administrator will consider the following questions:

(1) Are the findings of fact each supported by a preponderance of reliable, probative and substantial evidence?

(2) Are conclusions made in accordance with law, precedent and policy?

(3) Are the questions on appeal substantial?

(4) Have any prejudicial errors occurred?

(f) Any new issues or evidence presented in an appeal or reply will not be allowed unless accompanied by a certified petition and good cause found as to why the new matter was not presented to the Director. Such a petition must:

(1) Set forth the new issues or evidence;

(2) Contain affidavits of prospective witnesses, authenticated documents, or both, or an explanation of why such substantiation is unavailable; and

(3) Contain a statement explaining why such new matter could not have been discovered in the exercise of due diligence prior to the date on which the evidentiary record closed.

(g) A Final Agency Decision may be appealed in accordance with subpart G of this part.

Subparts H and I [Redesignated as Subparts G and H]

■ 33. Redesignate subpart H, consisting of § 16.247, and subpart I, consisting of §§ 16.301, 16.303, 16.305, and 16.307, as subparts G and H, respectively.

■ 34. In § 16.247, revise paragraphs (a), (b)(2), and (b)(4) to read as follows:

§ 16.247 Judicial review of a final decision and order.

(a) A person may seek judicial review, in a United States Court of Appeals, of a final decision and order of the Associate Administrator, and of an order of dismissal with prejudice issued by the Director, as provided in 49 U.S.C. 46110 or 49 U.S.C. 47106(d) and 47111(d). A party seeking judicial review shall file a petition for review with the Court not later than 60 days after the order has been served on the party or within 60 days after the entry of an order under 49 U.S.C. 46110.

(b) * * *

(2) A Director's Determination;

* * * * *

(4) A Director's Determination or an initial decision of a hearing officer becomes the final decision of the Associate Administrator because it was not appealed within the applicable time periods provided under §§ 16.33(c) and 16.241(b).

§ 16.301 [Removed]

■ 35. Remove § 16.301 from newly redesignated subpart H.

§§ 16.303, 16.305, and 16.307 [Redesignated as §§ 16.301, 16.303, and 16.305]

■ 36. In newly redesignated subpart H, redesignate §§ 16.303, 16.305, and 16.307 as §§ 16.301, 16.303, and 16.305, respectively.

Issued under authority provided by 49 U.S.C. 106(f), 46101, 46104, and 47122 in Washington, DC, on August 23, 2013.

Michael P. Huerta,

Administrator.

[FR Doc. 2013–22130 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0400; Directorate Identifier 2009–SW–48–AD; Amendment 39–17579; AD 2013–18–06]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited (Bell) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Bell Model 206A, 206B, 206L, 206L–1, 206L–3, 206L–4, 222, 222B, 222U, 230, 407, 427, and 430 helicopters. This AD requires inspecting each bearing to determine if it has been properly staked and replacing the bearing or assembly if it has not been properly staked. This AD was prompted by bearings not being properly staked and migrating out of their proper position, which may limit the functionality of the affected part. The actions of this AD are intended to prevent failure of a bearing and the assembly in which it is installed and subsequent loss of control of the helicopter.

DATES: This AD is effective October 17, 2013.

ADDRESSES: For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272, or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the foreign authority's AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sharon Miles, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *sharon.y.miles@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On May 13, 2013, at 78 FR 27869, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to Bell Model 206A, 206B, 206L, 206L–1, 206L–3, 206L–4, 222, 222B, 222U, 230, 407, 427, and 430 helicopters. The NPRM proposed using a 10X or higher power magnifying glass or a boroscope to inspect each bearing in each affected part to determine if each bearing had been properly staked. For a part that could not be accessed to determine if the bearing is properly staked, the NPRM proposed removing the part from the helicopter to inspect it. The NPRM proposed replacing the bearing or assembly if it was not properly staked. The proposed requirements were intended to prevent failure of a bearing and the assembly in which it is installed and subsequent loss of control of the helicopter.

The NPRM was prompted by AD No. CF–2009–32, dated July 24, 2009, issued by Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, to correct an unsafe condition for the specified Bell model

helicopters. TCCA advises that some bearings may not have been staked as required, which may limit the proper functioning of the affected part. Bell, the helicopter manufacturer, received two reports stating that a bearing migrated out of a flight control lever. Investigation revealed that, although the inspection witness mark was applied to the part, the bearing had not been staked during manufacturing. Affected parts were associated with a single Bell supplier. Review of the supplier's manufacturing and quality process indicates inspection of additional parts is necessary.

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM (78 FR 27869, May 13, 2013).

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, TCCA has notified us of the unsafe condition described in its AD. We are issuing this AD because we evaluated all information provided by TCCA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

Bell has issued Alert Service Bulletin (ASB) No. 206–09–122 for Model 206A/B series; No. 206L–09–156 for Model 206L series; No. 222–09–107 for Model 222 and 222B; No. 222U–09–78 for Model 222U; No. 230–09–39 for Model 230; No. 407–09–88 for Model 407; No. 427–09–25 for Model 427; and No. 430–09–42, for Model 430, all dated April 7, 2009. The ASBs specify inspecting for parts that contain bearings that have not been staked.

Costs of Compliance

We estimate that this AD will affect 2,601 helicopters of U.S. registry. Based on an average labor rate of $85 per work-hour, we estimate that operators may incur the following costs in order to comply with this AD. It will take about 1 to 5 work-hours per helicopter, depending on the model, to inspect for properly staked bearings. Replacing a bearing will require about 2 work-hours and will cost $3,306 for required parts. Based on an average inspection time of 2 work-hours, we estimate the cost of this AD to inspect the helicopters will be $170 per helicopter and $442,170 for the U.S. operator fleet. Replacing a bearing will cost $3,476 per helicopter.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on helicopters identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2013–18–06 Bell Helicopter Textron Canada Limited: Amendment 39–17579; Docket No. FAA–2013–0400; Directorate Identifier 2009–SW–48–AD.

(a) Applicability

This AD applies to Model 206A, 206B, 206L, 206L–1, 206L–3, 206L–4, 222, 222B, 222U, 230, 407, 427, and 430 helicopters as follows, certificated in any category.

(1) Model 206A, Model 206B helicopters converted from Model 206A, and Model 206B with Bellcrank Assembly, part-number (P/N) 206–001–526–001 or 206–001–538–009; Idler Link Assembly, P/N 206–010–336–109; or Link Assembly, P/N 206–031–589–001, installed.

(2) Model 206L, Model 206L–1, Model 206L–3, and Model 206L–4 with Idler Assembly, P/N 206–001–549–101; Bellcrank Assembly, P/N 206–001–552–001; or Link Assembly, P/N 206–010–336–109, installed.

(3) Model 222 and Model 222B with

(i) Cyclic Link Assembly, P/N 222–010–419–110; or

(ii) Bellcrank Assembly Directional Controls, P/N 222–001–734–001 or 222–001–736–005, installed.

(4) Model 222U with

(i) Cyclic Link Assembly, P/N 222–010–419–110; or

(ii) Bellcrank Assembly Directional Controls, P/N 222–001–734–001 or 222–001–736–005, installed.

(5) Model 230 with

(i) Fitting Assembly Engine Bipod Mount, P/N 230–060–113–101, 230–060–113–102, 230–060–114–101, or 230–060–114–102; Cyclic Link Assembly P/N 222–010–419–110; or

(ii) Bellcrank Assembly Directional Controls, P/N 222–001–734–001, or 222–001–736–005, installed.

(6) Model 407 with

(i) Bearing and Liner Assembly, P/N 406–010–417–101; Cyclic Mixer Follower Assembly, P/N 407–001–325–101; Bellcrank Assembly, P/N 407–001–524–105, 407–001–524–109, 407–001–526–105, 407–001–526–109, 407–001–528–101, or 407–001–528–105; or

(ii) Beam Assembly, P/N 407–001–723–101, installed.

(7) Model 427 with Swashplate Lateral Link Assembly (upper and lower bearing), P/N 427–001–021–101; Swashplate Longitudinal Link Assembly (upper and lower bearing), P/N 427–001–022–101; Transmission Mounted Longitudinal Bellcrank Assembly (pivot bearing), P/N 427–001–521–105/–109; Transmission Mounted Lateral Bellcrank Assembly (pivot bearing), P/N 427–001–520–109/–113; or Bearing and

Liner (lower drive link bearing), P/N 406–010–417–109, installed.

(8) Model 427 with Tail Rotor Actuator Output Idler, P/N 427–001–723–101, installed.

(9) Model 430 with

(i) Fitting Assembly Engine Bipod Mount, P/N 230–060–113–101, 230–060–113–102, 230–060–114–101, or 230–060–114–102; Bearing Assembly M/R Rotating Controls, P/N 430–010–449–101; Rod End Assembly Lift link, P/N 430–010–204–101 or 430–010–204–103, or

(ii) Bellcrank Assembly Directional Controls, P/N 222–001–734–001, or 222–001–736–005, installed.

(b) Unsafe Condition

This AD defines the unsafe condition as bearings that may not have been staked as required and may migrate out of their proper position and limit the functionality of the affected part. This condition could result in failure of a bearing and the lever assembly in which it is installed and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective October 17, 2013.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Perform each action required by this AD within the compliance time for each part listed in the applicability paragraph of this AD as follows: (a)(1), (a)(2), (a)(6)(i), (a)(7), and (a)(8), within 10 hours time-in-service (TIS) or 30 days, whichever occurs first; (a)(3)(i), (a)(4)(i), (a)(5)(i), and (a)(9)(i), within 5 hours TIS or 30 days, whichever occurs first; (a)(3)(ii), (a)(4)(ii), (a)(5)(ii), and (a)(9)(ii) within 150 hours TIS or 12 months, whichever occurs first; and (a)(6)(ii) within 300 hours TIS or 12 months, whichever occurs first.

(2) Using a 10X or higher power magnifying glass or using a boroscope, inspect each bearing and determine if the bearing has been properly staked for each part that contains a part serial number with a prefix of either ''TI'' or ''TIFS.''

(i) If a part does not contain a serial number, inspect the bearing of that part even if that part contains a supplier marking.

(ii) If you cannot access the bearing while the part is installed on the helicopter to make a determination as to whether the bearing in the part is properly staked, remove the part and inspect the bearing using a 10X or higher power magnifying glass or using a boroscope.

(iii) If you find a part that is not properly staked, replace the bearing or the assembly with an airworthy bearing or assembly before further flight.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to Sharon Miles, ASW–111, Aviation Safety Engineer, Rotorcraft Directorate, Regulations and Guidance Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5110, email *sharon.y.miles@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) Bell Alert Service Bulletin (ASB) No. 206–09–122 for Models 206A and 206B; No. 206L–09–156 for Models 206L, 206L–1, 206L–3, and 206L–4; No. 222–09–107 for Models 222 and 222B; No. 222U–09–78 for Model 222U; No. 230–09–39 for Model 230; No. 407–09–88 for Model 407; No. 427–09–25 for Model 427; and No. 430–09–42 for Model 430, all dated April 7, 2009, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272, or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in Transport Canada Civil Aviation AD No. CF–2009–32, dated July 24, 2009, which may be reviewed in the AD docket on the Internet at *http://www.regulations.gov.*

(h) Subject

Joint Aircraft System/Component (JASC) Code: 6700 Rotorcraft Flight Controls and 6710 Main Rotor Control.

Issued in Fort Worth, Texas, on August 27, 2013.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–21716 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0535; Directorate Identifier 2013–CE–018–AD; Amendment 39–17489; AD 2013–13–01]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that published in the **Federal Register**. AD 2013–13–01 applies to certain Piper Aircraft, Inc. Models PA–46–310P, PA–46–350P, PA–46R–350T, and PA–46–500TP airplanes. There is an incorrect reference to a paragraph designation, four instances of an incorrect reference to the paragraph in the service bulletin that references an airworthiness limitation, and an incomplete email address for the person to contact in the Related Information section. This document corrects those errors. In all other respects, the original document remains the same.

DATES: This final rule is effective September 12, 2013. The effective date for AD 2013–13–01 (78 FR 41277, July 10, 2013) remains July 10, 2013.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Gary Wechsler, Aerospace Engineer, Atlanta Aircraft Certification Office, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474–5575; fax: (404) 474–5606; email: *gary.wechsler@faa.gov.*

SUPPLEMENTARY INFORMATION: Airworthiness Directive 2013–13–01, Amendment 39–17489 (78 FR 41277, July 10, 2013), currently requires inspecting the fuel vent valves to identify if the nitrile parts are installed and modifying and eventually replacing the fuel vent valves if the nitrile parts are installed for certain Piper Aircraft, Inc. Models PA–46–310P, PA–46–350P, PA–46R–350T, and PA–46–500TP airplanes.

As published, there is an incomplete email address in the For Further Information Contact section of the preamble. There is an incorrect reference to a paragraph designation, four instances of an incorrect reference to the paragraph in the service bulletin that references an airworthiness limitation, and an incomplete email address for the person to contact in the regulatory information.

No other part of the preamble or regulatory information has been changed; therefore, only the changed portion of the final rule is being published in the **Federal Register**.

The effective date of this AD remains July 10, 2013.

Correction of Non-Regulatory Text

In the **Federal Register** of July 10, 2013, AD 2013–13–01; Amendment 39–17489 is corrected as follows:

On page 41278, in the first column, on line 6 under **FOR FURTHER INFORMATION CONTACT:**, change the email address from ''*gary.wechsler@faa*'' to ''*gary.wechsler@faa.gov*.''

Correction of Regulatory Text

§ 39.13 [Corrected]

In the **Federal Register** of July 10, 2013, on page 41279, in the third column, the last sentence of paragraph (g)(3) of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . A copy of the limitations from paragraph 4 of Part II of Piper Aircraft, Inc. Mandatory Service Bulletin No. 1258, dated June 15, 2013, must be inserted in the pilot's operating handbook.

* * * * *

In the **Federal Register** of July 10, 2013, on page 41280, in the first column, the text in line 7 of subparagraph (h)(1) of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . paragraph (g)(4) of this AD, replace the nitrile . . . .

* * * * *

In the **Federal Register** of July 10, 2013, on page 41280, in the first column, the last sentence of subparagraph (h)(1) of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . This would include removing the limitations requirement in paragraph 4 of Part II of the service bulletin.

* * * * *

In the **Federal Register** of July 10, 2013, on page 41280, in the first column, the last sentence of subparagraph (h)(2) of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . This would include removing the limitations requirement in paragraph 4 of Part II of the service bulletin.

* * * * *

In the **Federal Register** of July 10, 2013, on page 41280, in the first column, the text in line 10 of paragraph (i) of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . the limitations from paragraph 4 of . . . .

* * * * *

In the **Federal Register** of July 10, 2013, on page 41280, in the second column, the email address in line 6 of paragraph (k), heading Related Information, of AD 2013–13–01 is corrected to read as follows:

* * * * *

. . . *gary.wechsler@faa.gov*.

* * * * *

Issued in Kansas City, Missouri, on September 3, 2013.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–22184 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0755]

RIN 1625–AA00

Safety Zone, North Atlantic Ocean; Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the navigable waters of the North Atlantic Ocean in Virginia Beach, VA to support the Virginia Symphony Orchestra fireworks display. This action is intended to restrict vessel traffic movement in the designated area in order to protect the life and property of the maritime public and spectators from the hazards associated with fireworks displays.

DATES: This rule will be effective from 9:20 p.m. to 10:10 p.m. on September 12, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2013–0755]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Hector Cintron, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone (757) 668–5581, email *Hector.L.Cintron@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard received the application for a marine event well short of the 135 day window required for a new marine event application. As such, it is impracticable to provide a full comment period due to lack of time. Any delay encountered in this regulation's effective date to provide for a comment period would be contrary to the public interest as immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The Coast Guard will provide advance notifications to users of the affected waterways of the safety zone via marine information broadcasts and/or local notice to mariners.

B. Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

On September 12, 2013 the City of Virginia Beach will host a fireworks display offshore between 17th and 31st Streets of Virginia Beach, VA. The fireworks debris fallout area will extend over the navigable waters of the Atlantic Ocean. Due to the need to protect mariners and spectators from the hazards associated with the fireworks displays, such as the accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris, vessel traffic will be temporarily restricted around the fireworks launch site.

C. Discussion of the Rule

The Coast Guard is establishing a safety zone on specified waters of the Atlantic Ocean in Virginia Beach, VA. All waters of the Atlantic Ocean within a 1000 yard radius of the launch site, located near the shoreline at approximate position latitude 36°51′12″ N, longitude 075°58′06″ W, will be affected. This safety zone will be established and enforced from 9:20 p.m. until 10:10 p.m. on September 12, 2013. Access to the safety zone will be restricted during the specified date and times. Except for individuals responsible for launching the fireworks and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those orders. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; (iii) mariners may transit the waters in and around this safety zone at the discretion of the Captain of the Port or designated representative; and (iv), the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 rule will not have a significant economic impact on a substantial number of small entities.

The rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in that portion of the Atlantic Ocean from 9:20 p.m. until 10:10 p.m. on September 12, 2013.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) The safety zone will only be in place for a limited duration; (ii) Before the enforcement period of September 12, 2013, maritime advisories will be issued allowing mariners to adjust their plans accordingly.

3. Assistance for Small Entities

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 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**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER IN FORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this 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 (NEPA) (42 U.S.C. 4321–4370f), and have determined this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a safety zone for a fireworks display launch site and fallout area and is expected to have no impact on the water or environment. This zone is designed to protect mariners and spectators from the hazards associated with aerial fireworks displays. This rule is categorically excluded from further review under paragraph (34)(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701; 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Add § 165.T05–0755 to read as follows:

§ 165.T05–0755 Safety Zone, North Atlantic Ocean; Virginia Beach, VA.

(a) *Definitions.* For the purposes of this section, Captain of the Port means the Commander, Sector Hampton Roads. *Representative* means any Coast Guard commissioned, warrant or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: All waters of the Atlantic Ocean within a 1000 yard radius of the launch site located near the shoreline at approximate position latitude 36°51′12″ N, longitude 075°58′06″ W, located off the beach between 17th and 31st Streets.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone Number (757) 668–5555.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement period.* This section will be enforced on Thursday, September 12, 2013 from 9:20 p.m. to 10:10 p.m. unless cancelled earlier by the Captain of the Port.

Dated: August 29, 2013.

John K. Little,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2013–22135 Filed 9–11–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 220

RIN 0596–AD01

National Environmental Policy Act: Categorical Exclusions for Soil and Water Restoration Activities

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: The U. S. Department of Agriculture, Forest Service, gives notice of revised procedures for implementing the National Environmental Policy Act and Council on Environmental Quality regulations. These final implementing procedures are being issued in regulations concerning National Environmental Policy Act Compliance, which describes categorical exclusions. Categorical exclusions (CE) are categories of actions that normally will not result in individual or cumulative significant impacts on the quality of the human environment and, therefore, do not require analysis or documentation in either an environmental assessment or an environmental impact statement.

The revision adds three new categorical exclusions for activities that restore lands negatively impacted by water control structures, disturbance events, and roads and trails. Activities that restore lands occupied by National Forest System Roads and National Forest System Trails are excluded from this final rule. These will allow the Forest Service to more efficiently analyze and document the potential environmental effects of soil and water restoration projects that are intended to restore the flow of waters into natural channels and floodplains by removing water control structures, such as dikes, ditches, culverts, and pipes; restore lands and habitat to pre-disturbance conditions, to the extent practicable, by removing debris and sediment following disturbance events; and restore lands occupied by roads and trails to natural conditions.

These categorical exclusions will not apply where resource conditions related to the potential effect of a proposed action constitute an extraordinary circumstance. Activities conducted under these categorical exclusions must be consistent with Agency procedures and applicable land management plans and must comply with all applicable Federal and State laws for protecting the environment.

The road and trail restoration category will be used for restoring lands impacted by roads and trails that are not

needed, not maintained, and/or where public access is prohibited. This category will not be used to make access decisions about which roads and trails are to be designated for public use.

DATES: This rule is effective September 12, 2013.

ADDRESSES: The Forest Service National Environmental Policy Act procedures, including its list of categorical exclusions, are set out in Title 36, Code of Federal Regulations, Part 220, which is available electronically via the World Wide Web/Internet at *http://www.gpoaccess.gov/cfr/index.html.* Single paper copies are available by contacting Peter Gaulke, Forest Service, USDA, Ecosystem Management Coordination Staff (Mail Stop 1104), 1400 Independence Avenue SW., Washington, DC 20250–1104. Additional information and analysis can be found at *http://www/fs/fed/us/emc/nepa.*

FOR FURTHER INFORMATION CONTACT: Peter Gaulke, Ecosystem Management Coordination staff, (202) 205–1521. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at (800) 877–8339 between 8:00 a.m. and 8:00 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

In 2009, Secretary of Agriculture Thomas J. Vilsack called for restoring forestlands to protect water resources, the climate, and terrestrial and aquatic ecosystems. The Forest Service spends significant resources on National Environmental Policy Act (NEPA) analyses and documentation for a variety of land management projects. The Agency believes that it is possible to improve the efficiency of the NEPA process to speed the pace of forest and watershed restoration, while not sacrificing sound environmental analysis.

The Forest Service is responsible for managing 192 million acres in National Forests, National Grasslands, and other areas known collectively as the National Forest System (NFS). The Chief of the Forest Service, through an organization of Regional Foresters, Forest Supervisors, and District Rangers, administers and manages the NFS's natural resources within the principle of multiple use and sustained yield. For decades, the Forest Service has implemented terrestrial and aquatic restoration projects. Some of these projects encompassed actions that promoted restoration activities related to floodplains, wetlands and watersheds, or damage resulting from past disturbance events. The Forest Service has found that under normal circumstances the environmental effects of certain restoration activities have not been individually or cumulatively environmentally significant. The Forest Service's experience predicting and evaluating the environmental effects of the category of activities outlined in this rule has led the Agency to supplement its NEPA regulations by adding three new categorical exclusions for activities that achieve soil and water restoration objectives.

Category 18 allows the restoration of wetlands, streams, and riparian areas by removing, replacing, or modifying water control structures such as, but not limited to, dams, levees, dikes, drainage tiles, ditches, culverts, pipes, valves, gates, and fencing to allow waters to flow into natural channels and floodplains that restore natural flow regimes to the extent practicable.

Category 19 allows for the removal of debris and sediment following disturbance events (such as floods, hurricanes, tornados, mechanical/engineering failures, etc.) to restore uplands, wetlands, or riparian systems to pre-disturbance conditions, to the extent practicable, such that site conditions will not impede or negatively alter natural processes.

Category 20 allows for implementing restoration activities that restore, rehabilitate, and/or stabilize lands occupied by roads and trails, excluding National Forest System Roads and National Forest System Trails, to a more natural condition by removing, replacing, or modifying drainage structures and ditches, reestablishing vegetation, reshaping natural contours and slopes, reestablishing drainage-ways, or other activities that will restore site productivity and reduce environmental impacts.

These three Forest Service categorically excluded actions promote hydrologic, aquatic, and landscape restoration activities and thereby sustain natural resource values through more efficient management. All three CEs involve activities that are intended to maintain or restore ecological functions and better align the Agency's regulations, specifically its CEs, with the Agency's current activities and experiences related to restoration.

Many national forests have unmaintained roads and trails that are not on the National Forest Transportation System or are unauthorized. These routes are often found adjacent or in close proximity to NFS roads and NFS trails. These roads and trails are a major challenge in many national forests and examples of significant environmental damage and safety issues.

Restoring lands occupied by roads and trails is important to promote hydrologic, aquatic, and watershed restoration. Activities that restore lands occupied by a road or trail may include reestablishing former drainage patterns, stabilizing slopes, restoring vegetation, blocking the entrance to the road, installing waterbars, removing culverts, removing unstable fills, pulling back road shoulders, and completely eliminating the road bed by restoring natural contours and slopes.

The Forest Service believes it is appropriate to establish soil and water restoration CEs based on NEPA implementing regulations at 40 CFR 1500.4(p) and 1500.5(k) that identify a CE as a means to reduce paperwork and delays in project implementation, and based on the Agency's abundant information showing that the majority of these identified restoration actions have no significant impacts.

The Forest Service prepares approximately 2,500 to 3,000 CE decision memos and 400 environmental assessments (EAs) each year. Because document preparation and review for CEs takes approximately 6 to 9 months less time than a typical EA that can be hundreds of pages long, cost savings are significant. By using CEs, the Forest Service gains efficiencies that allow the Agency to move more efficiently through the environmental review process while not short-cutting public involvement or sacrificing environmental protection.

The Council on Environmental Quality (CEQ) regulations at 40 CFR 1507.3 provide that agency's National Environmental Policy Act (NEPA) procedures, after notice and comment, may identify categories of actions that do not have significant impacts on the human environment and, consequently, do not require preparation of an environmental assessment (EA) or an environmental impact statement (EIS). Current Forest Service procedures for complying with and implementing NEPA are set out in 36 CFR Part 220. Title 36 CFR 220.6 of the Forest Service NEPA Regulations lists the categories of actions that do not require preparation of an EA or an EIS by the Forest Service absent extraordinary circumstances.

Pursuant to CEQ's implementing regulations at 40 CFR 1507.3 and the November 23, 2010, CEQ guidance memorandum on ''Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act,'' (*www.nepa.gov*) the Forest Service

gathered information supporting establishment of these three categorical exclusions.

Based on its review of all the information provided, the Forest Service finds that the CEs will not individually or cumulatively have significant effects on the human environment. The Agency's finding is predicated on data from implementing comparable past actions; the expert judgment of the responsible officials who made the findings for projects reviewed for this supporting statement; information from other professional staff, experts, and scientific analyses; a review and comparison of similar CEs implemented by other Federal agencies; and the Forest Service's experience implementing soil and water restoration activities and subsequent monitoring of potential associated impacts. This combination of reviews gives the Forest Service confidence that the CEs will facilitate scientifically sound, efficient, and timely planning and decision making for select soil and water restoration activities. Additional information regarding this review is available at *http://www.fs.fed.us/emc/nepa/restorationCE.*

Actions relying on any of these CEs remain subject to Agency requirements to conduct scoping and require a determination that there are not extraordinary circumstances that would otherwise require documentation in an EA or EIS. These CEs will require a project or case file and decision memo, including, in part, a rationale for using the CEs and a finding that extraordinary circumstances do not exist.

The main clarifications to the proposed CEs in this final rule include:

- Clarifying that activities to remove, replace, or modify water control structures will not alter or cancel valid existing rights or special use authorizations;
- Adding text to an example in CE 18 that illustrates the size and scope of dam removal;
- Replacing the term ''non-system roads and trails'' with ''excluding National Forest System Roads and National Forest System Trails'' in CE 20. This clarification ensures that terminology in CE 20 conforms to corresponding terminology in Forest Service regulations and directives (36 CFR 212.1 and Forest Service Manual (FSM) 7705);
- Deleting an example in CE 20 that duplicates actions in another example;
- Removing example text that either directly or indirectly overlaps with existing CE activities—such as the removal of downed or damaged trees to restore wildlife or aquatic habitat; and
- Removing the distinction between ''natural or human'' caused disturbance events.

Other clarifications are highlighted in the response to comments.

Pursuant to regulations at 40 CFR 1505.1 and 1507.3, the Forest Service consulted with CEQ during the development of the CEs. Prior to the publication of these final CEs, CEQ provided written confirmation that amending Forest Service NEPA procedures by adding the new CEs was in conformity with NEPA and the CEQ regulations. This letter is available at *http://www.fs.fed.us/emc/nepa/restorationCE.*

To improve clarity, the final rule received minor text adjustments and corrections to punctuation and grammar. These edits did not change the substance, meaning, or implementation of the CEs.

Comments on the Proposal

The proposed rule was published in the **Federal Register** on June 13, 2012 (77 FR 35323), for a 60-day comment period. The Forest Service received 9,660 responses, consisting of letters, emails, Web-based submissions, and facsimiles. Of those, 420 were original responses, and the remaining 9,240 responses were organized response campaign (form) letters. Comments were received from the public, local governments, and other State and Federal agencies. The respondents represented all 50 States, the District of Columbia, Puerto Rico, Federated States of Micronesia, and several foreign countries. The States with the largest number of responses include California (1,708), New York (839), and Florida (589). The Forest Service received responses from two Federal agencies and 12 county government officials.

Public comment on the proposed rule addressed a wide range of topics, many of which were directed at access and travel management issues on NFS lands. Many people supported the proposed CEs or favored further expansion of their categorically excluded activities, while many others opposed the proposal or recommended no further consideration of one or more of the categories. The Department considered all the comments and made a number of changes to the text of the CEs in response. A summary of comments received and the Department's responses follow.

Categorical Exclusion #18 Comments

Some respondents suggested that removal of water control structures could have significant indirect effects by reducing flows to livestock watering holes and wildlife habitat. Others were concerned that the lack of thresholds would cause direct and indirect effects that would warrant documentation in an EA or EIS.

Response: Typically, the Agency has found that these particular activities do not have significant effects. If the removal of a water control structure has potential for a ''significant'' effect, an EA or EIS will be prepared.

CEs are an essential part of NEPA that provide an agency's determination that certain actions do not result in significant impacts to the environment, eliminating the need for lengthy documentation. The reduced documentation requirement for projects applying categorical exclusions does not mean that the projects avoid or escape environmental analysis. Rather, a thorough environmental analysis is conducted but paperwork is limited commensurate with an agency's experience conducting similar actions and with full regard to the potential for extraordinary circumstances that warrant preparation of an EA or EIS.

These CEs will not apply where there are extraordinary circumstances such as adverse effects on threatened and endangered species or their designated critical habitat, wilderness areas, inventoried roadless areas, wetlands, and archeological or historic sites.

One comment highlighted that dams vary in size, amount of water impounded and the amount of excavation, dredging, placement of fill, and reengineering needed. Other respondents commented that CE 18, as worded, lacked specific quantifiable limitations on the amount of acceptable ground disturbance while others suggest that the use of the term ''minimal'' required additional clarity.

Response: CE 18 is limited to activities with a specific goal and outcome, which is restoration of lands impacted by water control structures. In response to the public comment for more specific limitations on the amount of ground disturbance, the Agency has further defined the category to not allow altering or canceling existing rights or special use authorizations; provided a specific example of a type of culvert to be replaced; and specific type and hazard potential of dams proposed for removal, replacement, or modification.

Based on Forest Service direction in Forest Service Manual (FSM) 7500, the text of CE 18 now includes an example that articulates the type and hazard potential of dams proposed for removal, replacement, or modification. This example provides a hazard classification that includes dams where failure, malfunction, or misoperation would

result in no probable loss of human life and minor damages limited to undeveloped or agricultural lands and for which significant improvements are not planned.

One respondent commented that any proposal that requires a Clean Water Act National Pollution Discharge Elimination System (NPDS) or Section 401 permit should require documentation in a full EA or EIS and not be categorically excluded.

Response: It is appropriate to coordinate NEPA review processes with other planning or environmental reviews (40 CFR 1500.2(c)). The mere existence of a State or Federal permit requirement is not a strong indicator of the degree of environmental significance of an action for purposes of NEPA. Also, State programs implementing NPDES requirements can be quite variable and would impede consistent application of NEPA across the National Forest System.

Some respondents highlighted the concern that removal of water control structures without consideration or respect for State water laws, valid adjudicated water rights, and the constitutionally held water rights of States and individual citizens could result in a complete or partial taking. Similarly, several respondents stated that the Forest Service cannot, in contradiction to Federal policy, close any rights-of-way and remove access to water rights for present and future mineral or ranching operations.

The Department recognizes the concern over protecting existing access and use of water and water-related facilities. Nothing in the final rule authorizes the alteration or revocation of any existing rights, contracts, permits, special use authorizations, or other legal instruments held by miners, grazing permittees, States, or other entities. To give further assurance that the function of this category deals exclusively with restoration of wetlands, streams and riparian areas, rather than affecting rights and privileges of use, CE 18 has been modified to include an express assurance and qualification that the category is only available where actions are consistent with valid existing rights and legal instruments.

One respondent commented that any decision with respect to the efficacy, safety, or functioning of any small dam regulated by individual States is beyond the competence of any District Office or personnel of the Forest Service.

Response: The Federal Guidelines for Dam Safety require periodic inspection and evaluation of dams to reduce the risk to human life and property from dam failure. In accordance with Forest Service direction (FSM 7504.6), Forest Supervisors are responsible for designating a qualified engineer to provide technical oversight of construction, inspection, and management of dams operated by the Forest Service.

An operation and maintenance (O&M) plan is required for any dam with a significant or high hazard potential classification operated by the Forest Service or the holder of a special use authorization on NFS lands (FSM 7513). O&M plans may be prepared for dams with a low hazard potential classification if warranted based on their significance or complexity. The owner of a dam is responsible for preparing and maintaining an O&M plan for that dam. Coordination with the Forest Service and appropriate State agencies in the preparation of O&M plans for dams operated by the holder of a special use authorization is required. O&M plans for dams operated by the holder of a special use authorization are reviewed by a qualified engineer and approved by the authorized officer. Further direction regarding inspection programs is found in FSM 7514.

Categorical Exclusion #19 Comments

One respondent suggested that the use of riprap, rocks, and bioengineering techniques are directly at odds with the concept of restoring natural processes.

Response: CE 19 aims to restore uplands, wetlands, or riparian systems, to the extent practical, through the removal of debris and sediment following disturbance events. In some instances, this may include the stabilization of sediment sources through the use of riprap, rocks, and other techniques. By reducing sources of sedimentation downslope or downstream, wetlands or riparian systems have an increased likelihood of successful recovery from disturbance events.

Some respondents commented on the use of the term ''human caused events'' and expressed concern that the term is ambiguous and could be broadly interpreted to include ''any multiple use activity undertaken by the Forest Service.''

Response: The Department agrees that the use of the term ''human-caused disturbance events'' provided a level of confusion. Similarly, limiting the category of actions to only ''natural disturbance events'' did not provide for restorative actions that result from events that result from man-caused events. In both cases, the intent of the category is for restoration activities that remove debris and sediment following disturbance ''events'', not correcting chronic sources of debris and sediment. With this in mind, the text of CE 19 was modified to remove reference to ''natural and human'' caused disturbance events by simply using the term ''disturbance event'' together with parenthetically including an example list of possible events. To clarify the intent of the category, the word ''directly'' now precedes the term disturbance event that focuses the restoration activities on disturbances, not past management activities.

Other respondents requested clarification on the terms ''pre-disturbance conditions'' and ''natural processes'' and how such conditions will be determined.

Response: The Department determined that in some cases restoring sites to a natural condition, such as those conditions within the natural range of variation, is not attainable without major site reconstruction or may not be desirable due to current management and use of the site. Therefore, the use of the term ''pre-disturbance conditions'' was included. The intent of CE 19 is to stabilize debris and sediment sources and restore the sites to the conditions that existed prior to the disturbance event. The intent is not to modify the existing management emphasis or current use of the site.

One comment highlighted the importance of downed and dead tree removal for restoration, clean-up, and repair activities along utility lines and corridors after a disturbance. Other respondents suggested that the proposed removal of downed and damaged trees is not needed to improve wildlife habitat and is unrelated to the restoration of soil and water resources. Another respondent suggested that the Forest Service should ensure that any potential benefits related to downed trees are evaluated prior to removing such debris from rivers and streams following natural events.

Response: The Department believes that in certain cases the removal of down and damaged trees is beneficial to the habitat of terrestrial or aquatic species. The intent of this example is to restore sites impacted by disturbance events where the amount and juxtaposition of downed and damaged trees is negatively impacting species habitat recovery or presents a health and safety risk to the public.

Upon further review, the Department believes that the Forest Service already has categories of actions that allow for wildlife habitat improvement; the maintenance of roads, trails, or utility lines; and the protection of public health and safety. For example, safety

hazard trees associated with roads, trails, recreation facilities, and administrative sites may be removed as part of routine maintenance of those facilities. Therefore, this example has been removed from CE 19 in the final rule.

Categorical Exclusion #20 Comments

Several respondents expressed a concern that the intent of CE 20 has not been clearly articulated or justified.

Response: The impact of roads and trails to watershed health has been widely documented. Roads affect watershed condition because more sediment is contributed to streams from roads and road construction than any other land management activity. Roads directly alter natural sediment and hydrologic regimes by changing streamflow patterns and amounts, sediment loading, transport, deposition, channel morphology and stability, and water quality and riparian conditions within a watershed. Roads can also increase sediment routing to streams by creating areas prone to surface runoff, altering slope stability in cut-and-fill areas, removing vegetation, and altering drainage patterns. Road density is known to add to sediment caused by erosion and mass wasting in upland forested landscapes in the Pacific Northwest, and it is reasonable to assume that similar relationships exist elsewhere. Road-related mass soil movements can continue for decades after roads have been constructed, and long-term slope failures frequently occur after road construction and timber harvest.

CE 20 focuses on the restoration of lands occupied by roads and trails to restore site productivity and reduce environmental impacts. Project decisions made using this CE will be aimed at restoration goals and will not be used to make access decisions. The Forest Service maintains this intent of CE 20 by excluding its application from National Forest System Roads and National Forest System Trails. This category's focus is on roads and trails that have been illegally created, or have already been removed from the Agency's designated road and trail system. The intent of this category is to restore lands occupied by roads and trails where legal access is already prohibited.

Many respondents expressed concern that establishment of CE 20 would make it easier for the Forest Service to reduce the number and mileage of trails and roads and therefore exclude many legitimate uses of the Forests. Another respondent commented that further restriction of use by hikers, bicycles, motorcycles, horses, campers, and so on only increases the damage to the trails/roads that remain.

Response: The road and trail restoration CE 20 will not be used to make access decisions about which roads and trails are to be designated open for public use, or which will be closed from public use. Nothing in the final rule revokes any contracts, special use authorizations, legal instruments, or right-of-way held by any entity. CE 20 will not restrict or remove the legal use or access of roads or trails by the recreational community, law enforcement personnel, search and rescue organizations, or other uses where that access and use is not already prohibited.

The restoration of lands occupied by roads and trails is important to promote hydrologic, aquatic, and watershed restoration. This CE will allow the Forest Service to restore roads and trails more efficiently where public access is not currently permitted—roads and trails that are already closed.

A number of respondents commented that the Forest Service should be opening up more lands for use by the public instead of removing roads and trails from the system, and characterized CE 20 as an effort to slowly remove any and all motorized vehicle access to NFS lands.

Response: The Department disagrees with this characterization of this rule. CE 20 will not be used to remove motorized vehicle access. It will be used to restore lands where access is already prohibited.

Additionally, unless specifically restricted, all NFS lands are open for use by the public. Yet, not all NFS lands are intended to be open or accessed by roads. The Forest Service's multiple-use mission does not contemplate that every acre of National Forest be managed for every multiple use as Congress recognizes that some land will be used for less than all of the resources (16 U.S.C. 531). The Forest Service provides for a wide range of user experiences, including remote recreational experiences that are accessed by non-road or trail access.

One respondent stated that it is not motorized activities, but rather the lack of enforcement of existing laws governing motorized use, that cause resource damage. Others believe that rather than creating new rules, we need to enforce the ones we have.

Response: Forest Service law enforcement personnel play a critical role in ensuring compliance with laws and regulations, protecting public safety, and protecting National Forest resources. However, the scope of this final rule does not address enforcement of motorized use on NFS lands. This final rule addresses environmental analysis and documentation efficiencies for the restoration of lands occupied by roads and trails, with the exception of National Forest System Roads and National Forest System Trails.

Several respondents expressed the concern that road and trail closures, as well as removal of water barriers and bridges, will have a negative impact on Americans with disabilities that rely on this access to recreate on NFS lands.

Response: Under section 504 of the Rehabilitation Act of 1973, no person with a disability can be denied participation in a Federal program that is available to all other people solely because of his or her disability. A person with a disability must be able to achieve the purpose of a Federal program without modification to the program that fundamentally alters its nature. A fundamental alteration of the nature of a program occurs when a basic aspect of that program is changed. USDA's program and activity requirements and compliance procedures implementing section 504 are set forth in 7 CFR Part 15e.

In conformance with section 504, Americans with disabilities are welcome on all NFS lands that are open for public access. However, allowing people with disabilities to use routes that are not open to the public would fundamentally alter the nature of the Forest Service's travel management program.

Many respondents commented that the Forest Service has not adequately assessed the present and future needs of its road and trail system to provide for its multiple-use mandate, including wildfire suppression, search and rescue activities, forest management, and multiple recreational activities.

Response: The Forest Service is continuing to implement the 2005 Travel Management Rule. Completion of Subpart A (36 CFR 212.5(b)) will identify a properly sized road system for each NFS unit. The ultimate goal is management and sustainability of a road system that minimizes adverse environmental impacts by assuring roads are in locations only where they are necessary to meet access needs, and can be maintained within budget constraints.

Apart from the goals and implementation of the 2005 Travel Management Rule, this final rule will be used for restoring lands impacted by roads and trails that are no longer needed, no longer maintained, and/or where access is already prohibited. This category will not be used to make access

decisions about which roads and trails are to be designated for public use.

A couple of respondents expressed concerns that the environmental effects of road obliteration are far greater and less desirable than allowing a roadway to recover naturally and ultimately could result in unforeseen and unacceptable indirect effects though flooding to downstream public and private property owners.

Response: CE 20 allows for, barring the presence of extraordinary circumstances, a range of activities designed to restore lands impacted by roads and trails, excluding National Forest System Roads and National Forest System Trails. This includes the mechanized decommissioning activities, blocking of unauthorized access and allowing routes to recover naturally. Project-specific decisions on the appropriate method to restore impacted lands are based on site-specific conditions and will require a project or case file and decision memo, including, in part, a rationale for using the CE and a finding that extraordinary circumstances do not exist.

Some respondents commented on the importance of roads and trails to tribal communities to access sacred sites and state that further reduction of these access routes would impact tribal elders who rely on this access to reach these areas. They recommended working with Tribes before making such decisions. Other respondents expressed concern over the impacts of decommissioning on cultural and archeological resources and on the historical importance that some of these routes hold for interpreting history.

Response: Effects on tribal sacred sites and other areas of historical, archeological, and cultural importance to Tribes, including effects of tribal access to those sites, may be possible on specific sites where the CEs will be used. As with the implementation of all CEs, Tribes will be contacted during the scoping process for projects with tribal implications, even if the project may be categorically excluded from further analysis and documentation in an EA or EIS.

Pursuant to Executive Order 13175, the Forest Service determined that this promulgation of this final rule would not have tribal implications requiring advance consultation. Yet the Forest Service maintains a strong commitment to government-to-government consultation on agency policies that may substantially affect Federally-recognized Indian Tribes, and to consulting with Alaska Native Corporations. Thus, on May 6, 2011, a package outlining the proposed rule was transmitted to each Forest Service Regional Forester for distribution and use in consultations with all Federally recognized Indian Tribes and Alaska Native Corporations

Several respondents commented that CE 20, as worded, lacked specific quantifiable limitations on the amount of acceptable soil displacement, ground disturbance, or miles of road allowable. Another respondent suggested the Forest Service should be overly cautious on implementing CE 20 and should exclude categorically excluded activities in floodplains, riparian areas, and areas near streams.

Other respondents state that while projects proposed under any CEs may have beneficial direct, indirect, and cumulative impacts that could be good; they also suggest numerical limits be placed on the size and scope of projects to ensure the benefits. Still other respondents contend that the proposed categories of actions do have significant effects and do not qualify for a CE.

Response: The three soil and water restoration CEs set forth in this final rule are intended to implement restorative activities that benefit wetlands, floodplains, riparian areas, stream courses, and those sites that are negatively impacting watershed and riparian health. Excluding their use from floodplains, riparian areas, or areas adjacent to streams would substantially diminish their ability to benefit watershed, riparian and upland health, and the Agency's ability to expedite restoration activities that fall under these three categories of actions.

CE 20 is for activities that restore, rehabilitate, or stabilize lands and to restore site productivity and reduce environmental impacts from existing site conditions. If there are extraordinary circumstances related to the proposed action, an EA or EIS will need to be prepared.

Any activity performed using one of the three new CEs must meet all applicable Federal, State, and local laws, as well as land and resource management plan standards and guidelines. Under the three new categories, the responsible official must conduct appropriate consultations with Federal and State regulatory agencies such as those required by the Endangered Species Act and the National Historic Preservation Act. For decades, the Forest Service has implemented terrestrial and aquatic restoration projects. The Agency's careful analysis during this rulemaking and long experience in dealing with soil and water restoration treatments leads the Agency to conclude that implementation of the three new categories will not result in significant impacts on the environment.

Several respondents argued that if a prior access decision was necessary to use CE 20, then little to no efficiency would be gained in the NEPA process.

Response: CE 20 applies to roads and trails. The deliberate removal of a forest road or trail from the unit's travel management atlas would generally be accomplished through a unit's identification of the minimum road system needed for safe and efficient access, and the administration, use and protection of NFS lands. Such reviews are science based and include to the degree practical a broad spectrum of interested and affected citizens and other groups. Proposals based on the reviews are evaluated in compliance with NEPA. In cases where access decisions and road and trail decommissioning decisions are made at the same time, CE 20 will not be necessary. However, not all access decisions include specific proposals for decommissioning and CE 20 will be available in these situations.

Several respondents expressed support and highlighted the importance of protecting and accelerating restoration on National Forests, including the water produced within its watersheds.

Response: These comments were in support of the proposal and need no specific response.

Several respondents suggested that it would be less expensive to maintain roads and trails than to decommission them. Others suggest that much of the resource damage on roads and tails is not from use by the public, but by the inability of the Forest Service to maintain them. In addition, several respondents addressed funding issues, such as how the Agency pays for restoration if it cannot pay for road maintenance.

Response: CE 20 applies to restoring lands occupied by roads and trails excluding National Forest System Roads and National Forest System Trails. The Agency expends appropriated funds to maintain National Forest System Roads and National Forest System Trails for motor vehicle use.

The Forest Service maintains forest roads and trails in accordance with their management objectives and availability of funding. Unfortunately, resources are limited, and the Forest Service has a substantial backlog of maintenance needs. The Agency's road maintenance funding has steadily decreased over the past decade, while trail maintenance funding has remained flat. These funding trends are anticipated to continue. Over time, all roads and trails

require some level of maintenance. In some cases, an extended lack of maintenance can lead to so much deterioration of a road or trail that it must be closed to administrative and public use or ecologically restored to address user safety or prevent severe environmental damage.

Restoring lands occupied by roads and trails requires a one-time expense vs. long-term reoccurring road and trail maintenance funding.

A number of respondents encouraged broadening the scope of CE 20 to include restoration of forest roads that are currently closed to motorized use while others encouraged the Forest Service to allow for NFS and unauthorized roads to be converted to NFS trails. Similarly, one respondent suggested that although some Forest roads are not designated for motor vehicle use, they could remain open to non-motorized uses, such as mountain bicycling and horseback riding and should not be decommissioned.

Response: Designation of routes for motor vehicle use is beyond the scope of this rulemaking. Designation of routes is occurring consistent with the Forest Service's travel management rule at the local level. Decisions regarding whether to authorize non-motorized uses on roads and trails not designated for motor vehicle use are also beyond the scope of this rulemaking. Decisions to authorize non-motorized uses on such routes are made at the local level, consistent with the applicable land management plan and road and trail management objectives and the long-term economic, social, and environmental sustainability of the unit's road and trail system.

At this time the Department has chosen to move forward with establishing a road and trail restoration CE that excludes National Forest System Roads and National Forest System Trails. The Department agrees that proposals to convert certain NFS roads to NFS trails may be appropriate, and the Agency will continue to propose these conversions and document the appropriate environmental analysis and decision-making through existing CEs, an EA or, if necessary, in an EIS. The Department believes that the establishment of a CE for decisions that remove public and administrative use of forest transportation system roads and trails at this time is unnecessary and would divert public and agency focus from the Agency's continued implementation of the 2005 Travel Management Rule.

The Department also believes that the evaluation of roads for conversion to other uses, including motorized and non-motorized trail designation, is best handled at the local level by officials with first-hand knowledge of the particular circumstances, uses and environmental impacts involved, working closely with local governments, users and other members of the public. The long-term economic, social, and environmental sustainability of the unit's road and trail system will also factor into this evaluation.

One respondent suggested the Forest Service prioritize the use of CE 20 to those roads and trails that are negatively impacting aquatic, hydrologic, or watershed resources.

Response: Roads and trails proposed for restoration are prioritized through a variety of criteria, including resource degradation, available funding, and public and private partnerships. Restoration activities, such as road and trail decommissioning, are also prioritized through the Watershed Condition Framework (WCF) (*http://www.fs.fed.us/publications/watershed/*), a comprehensive approach for proactively implementing integrated restoration on priority watersheds on National Forests and Grasslands. The WCF improves the way Forest Service approaches watershed restoration by targeting the implementation of integrated suites of activities in those watersheds that have been identified as priorities for restoration. The WCF prioritizes watersheds for restoration and develops watershed action plans that may include road and trail restoration proposals. Implementing CE 20 will allow the Agency to more efficiently improve watershed conditions by restoring lands occupied by unauthorized roads and trails that have been identified as sources of ecological degradation.

Several comments highlighted the concern that decommissioning roads that have valid existing rights-of-ways may have significant impacts to local economies if roads that access water, grazing allotments, mineral entries, or other inholdings were eliminated under these proposed CE. Others expressed concerns over the social, cultural, and economic impacts, and unintended consequences that communities would encounter from road closures.

Response: Most national forest visitors use authorized routes to access the national forests, whether for recreational sightseeing; camping and hiking; hunting and fishing; commercial purposes such as logging, mining, and grazing; administration of utilities and other land uses; outfitting and guiding; or many other multiple uses of NFS lands. Any access associated with the exercise of valid existing rights or other permitted authorized uses of the NFS will be on authorized private, NFS, or State, county, or local routes. Restoring roads and trails using CE 20 will not affect access via authorized routes.

One respondent suggested that the proposed rule did not take a hard look at the environmental justice impacts under Executive Order 12898.

Response: The Department takes its environmental justice responsibilities very seriously and principles of environmental justice are considered throughout decisionmaking. This final rule establishing these CEs does not itself compel or authorize any particular action and the Department sees no indication the establishment will cause disproportionately high and adverse effects on the environment and human health of minority and/or low-income populations. Further, the Forest Service applies strategies and techniques during its NEPA compliance efforts to ensure compliance with E.O. 12898 so that meaningful environmental justice considerations can be appropriately assessed at the project level.

One respondent expressed concern that the proposed rule seeks to obliterate unauthorized routes, and the Forest Service cannot then fulfill its promise under 36 CFR 212.50 that such routes may be added to the forest transportation system.

Response: The Department recognizes that the Forest Service's road and trail systems will continue to meet changing administrative and social needs and are based on the consideration of ecological, social, and economic sustainability. Designations of NFS roads, NFS trails, and areas on NFS lands pursuant to 36 CFR 212.51 may be revised as needed to meet changing conditions. Revisions of designations are made in accordance with the requirements for public involvement and the requirements for coordination with governments and Tribes. Public involvement is also required when restoration activities are proposed to be categorically excluded from documentation in an EA or EIS using CE 20.

One respondent commented that all roads not identified on a national forest's motor vehicle use map under the travel management rule and process are considered ''unauthorized'' and could be decommissioned without further public comment.

Response: Unauthorized roads defined in the travel management rule are not roads excluded from the Forest Service unit's motor vehicle use map. Any proposals to decommission roads (unauthorized or not), will go through the NEPA process, including ''scoping'' under Forest Service NEPA procedures.

Scoping is required for Forest Service categorical exclusions.

Several respondents commented that the public involvement process on initial access decisions does not dampen the issues associated with road closures, and broad public involvement is warranted for projects subject to proposed CE 20. Others expressed concern that proposed CE 20 would shortcut the public involvement process required by an EA or EIS conducted as part of the travel management process.

Response: Public involvement associated with decommissioning forest roads as part of transportation planning is required by 36 CFR 212.5(b). Public involvement associated with designation or revision of the motor vehicle use map maintained as part of the travel management rule is governed by 36 CFR 212.52. The Forest Service's experience is that the majority of issues associated with road and trail restoration activities are related to access and travel management policies, rather than from implementing restoration projects. CE 20 applies to restoration work on lands occupied by unneeded and unauthorized roads and trails and does not include National Forest System Roads and National Forest System Trails. When applying CE 20, Forest Service officials will conduct appropriate scoping and public involvement assuring that citizen views are taken into account in an appropriate manner given the context of the decisions being made.

Comments Applicable to All Three Categories

One respondent expressed concern that the proposed CEs would allow the Forest Service to conduct work outside of NFS boundaries and as such could not be supported.

Response: Establishing these CEs in the Agency's NEPA regulations does not expand the scope of the Forest Service's authority to fund, authorize or carry out restoration activities. Additionally, this rule does not authorize any on-the-ground actions, whether inside or outside the administrative boundary of the NFS. All Forest Service actions, whether on or off NFS lands, must be independently supported by valid statutory authority.

One respondent questioned that Forest Service Chief Thomas L. Tidwell did not have delegated authority to promulgate rules and regulations, such as these proposed CEs.

Response: The Chief of the Forest Service has been delegated authority to issue proposed rules relating to Forest Service programs (7 CFR 2.60(a)(37)). The authority to issue final rules and regulations relating to administration of Forest Service programs is reserved to the Secretary or Under Secretary for Natural Resources and Environment, except as otherwise provided (7 CFR 2.60(b)(1)).

Several respondents expressed concern that the proposed rule is an attempt to circumvent the NEPA and the CEs given the Forest Service latitude to implement a wide and abusive range of activities when the language ''examples include but are not limited to'' is included.

Response: When using these three CEs, the responsible officials will consider, on a project-by-project basis, whether or not any of the Forest Service identified extraordinary circumstances apply. The responsible official will prepare a project file and decision memo that will be available for public review (36 CFR 220.6(f)). The decision memo contains the responsible official's rationale for categorically excluding an action and selecting that particular category, and includes a determination that no extraordinary circumstances exist.

CEs are an integral part of NEPA compliance and use of CEs in no way evades compliance with NEPA. Additionally, CEs are a legitimate tool for reducing excessive paperwork and avoiding allocating resources where they are not needed, thereby allowing the Agency to devote more resources to environmental analysis and subsequent decision-making. The CEQ regulations for implementing the procedural provisions of NEPA direct Federal agencies to identify those typical classes of actions that normally do not require either an EIS or EA (40 CFR 1507.3). CEQ defines such classes of actions as CEs. ''Categorical exclusion'' means a category of actions that do not individually or cumulatively have a significant effect on the human environment and that have been found to have no such effect in procedures adopted by a Federal agency in implementation of these regulations (§ 1507.3) and for which, therefore, neither an EA nor an EIS is required (40 CFR 1508.4).

In subsequent guidance regarding NEPA regulations, CEQ explained that the use of CEs avoids unnecessary documentation of minor environmental effects in EAs and allows agencies to focus their environmental review efforts on the major actions that will have a significant effect on the environment (48 FR 34263), also see 40 CFR 1500.4(p)). CEQ also encourages agencies to identify CEs using broadly defined criteria that characterize types of actions that normally do not have significant environmental effects, including cumulative effects (48 FR 34263).

Concerns over the misuse of these CEs to allow soil and water restoration activities can be addressed through agency oversight on the application of the categories.

Several comments supported the proposed CEs and NEPA efficiencies for projects that are intended to benefit the environment, and are likely to have little if any negative environmental effects. Others believe the Forest Service can continue to implement restoration projects effectively without these proposed CEs.

Response: CEs are to be used for routine actions that have been found by the Forest Service through experience and environmental review to have no significant environmental effects either individually or cumulatively (40 CFR 1508.4). Forest Service NEPA procedures require that all proposed actions to be categorically excluded from documentation in an EA or EIS must be reviewed for extraordinary circumstances and may include appropriate surveys and analyses, taking into account best available science, and appropriate consultation with Tribes and regulatory agencies, as required by the Endangered Species Act, the National Historic Preservation Act, Clean Water Act, and Clear Air Act. Accordingly, these CEs do not apply where there are extraordinary circumstances (36 CFR 220.6(b)).

Some respondents commented that the proposed CEs are redundant and suggested there are categories of actions already in place that cover water restoration, road maintenance and repair, riparian and habitat protection, or that a simple EA could suffice in other situations.

Response: The Department has carefully reviewed the proposed rule against existing agency CEs and determined that the restoration activities promulgated in this final rule are not redundant with existing agency categories. The review of the proposed rule led to the elimination of CE 19, example #3, which was determined to be redundant with activities included under an existing category.

Some respondents suggested the Forest Service should not rely solely on the judgment of the responsible official to decide whether an impact displays the necessary relationships and potential for effects and the subsequent need for an EA or EIS. They recommend numeric thresholds to determine when proposals no longer fit under CEs to prevent line officers from abusing their authority.

Response: The Forest Service's NEPA procedures (36 CFR 220.6) list the categories of actions that the Agency has found typically will not have individually or cumulatively significant effects on the human environment. These procedures also provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect. These extraordinary circumstances includes a list of ''[r]esource conditions that should be considered in determining whether extraordinary circumstances related to the proposed action warrant further analysis and documentation in an EA [environmental assessment] or an EIS [environmental impact statement] . . .'' The regulations at 36 CFR 220.6(b)(2) also state,''[t]he mere presence of one or more of these resource conditions does not preclude use of a categorical exclusion. It is (1) the existence of a cause-effect relationship between a proposed action and the potential effect on these resource conditions and (2) if such a relationship exists, the degree of the potential effect of a proposed action on these resource conditions that determines whether extraordinary circumstances exist.

The Forest Service has consistently considered current information when making initial determinations on the use of a CE. Pursuant to existing direction, the Forest Service must conduct a sufficient review to determine that no extraordinary circumstances preclude the use of CEs. This determination may include appropriate surveys, consideration of the best available science, consultation with Tribes, and coordination with agencies that have regulatory responsibilities under other statues, such as the Endangered Species Act, National Historic Preservation Act, Clean Water Act, and Clean Air Act. Responsible Officials consider, on a project-by-project basis, whether or not extraordinary circumstances exist.

Many respondents expressed concern that the use of a CE does not provide for adequate public participation and disclosure, placing a proposal only in the Schedule of Proposed Actions is inadequate scoping, and that an EA or EIS is necessary for the activities proposed under these categories of actions.

Response: As directed by CEQ regulations (40 CFR 1507.3), the Forest Service has developed agency policy for implementing the NEPA and CEQ's regulations. As noted in Forest Service NEPA regulations (26 CFR 220.4(e)): ''Scoping is required for all Forest Service proposed actions, including those that would appear to be categorically excluded from further analysis and documentation in an EA [environmental assessment] or an EIS [environmental impact assessment].'' The FSH 1909.15, chapter 10, section 11 further clarifies this stating: ''Although the Council on Environmental Quality (CEQ) Regulations require scoping only for environmental impact statement (EIS) preparation, the Forest Service has broadened the concept to apply to all proposed actions.''

As part of the scoping process for proposals potentially covered by these CEs, the responsible official must determine the extent of interest and invite the participation of affected Tribes, Federal agencies, State agencies, local agencies, and other interested parties, as appropriate. The Forest Service is committed to fulfilling its public involvement responsibilities with all parties interested in projects potentially qualifying for these CEs.

Although not intended to be the sole scoping mechanism, the Forest Service also provides notice of upcoming proposals through the use of a Schedule of Proposed Actions (36 CFR 220.4(e)(3) and FSH 1909.15, Zero Code, sec. 06). The schedule gives early and informal notice of proposals to make the public aware of Forest Service activities and provides an opportunity for the public to indicate their interest in specific proposals. Schedules may be distributed in hard copy by the respective forest and can be found at *http://www.fs.fed.us/sopa.*

Finally, it is important to note that the level of environmental documentation, whether in a CE, EA, or EIS is based on the potential for or lack of significant environmental effects.

Many comments expressed concern that the use of a CE will reduce the need for public input and eliminate the notice, comment, and appeals procedure for these categories of actions.

Response: On March 19, 2012, the U.S. District Court for the Eastern District of California found that Forest Service regulations exempting certain categorically excluded projects from notice, comment, and appeal violated the Appeals Reform Act (ARA) and enjoined the Forest Service, from applying 36 CFR 215.4(a) and 215.12(f) for certain categorical exclusions.

The Forest Service has appealed that decision but instructed its Line Officers to abide and comply with the District Court's orders. At least for now, the three CEs are subject to the public notice, comment, and appeal procedures being applied for other CEs that require a decision memorandum (36 CFR 220.6(e)).

One respondent stated the Forest Service has no mission to restore lands to pre-disturbance or pre-settlement conditions and suggested the type of restoration proposed in this rule does not meet NFS needs.

Response: The authority for restoring NFS lands derives from many laws enacted by Congress that define the purpose of National Forests and Grasslands. Consistent with the Multiple-Use Sustained-Yield Act of 1960 (16 U.S.C. 528–531) (MUSYA), the Forest Service manages the NFS to sustain the multiple use of its renewable resources in perpetuity while maintaining the long-term health and productivity of the land. Resources are managed through a combination of approaches and concepts for the benefit of human communities and natural resources. Land management plans guide sustainable, integrated resource management of the resources within the plan area in the context of the broader landscape, giving due consideration to the relative values of the various resources in particular areas.

Thus the Forest Service has stated its mission is to ''Sustain the health, diversity, and productivity of the Nation's forests and grasslands to meet the needs of present and future generations'' (FSM 1000, Zero Code, section 1020.21).

FSM 2020 provides for using ecological restoration to manage NFS lands in a sustainable manner. This directive reaches across all program areas and activities applicable to managing NFS lands and resources so as to ensure integration and coordination at all levels and within all organizational units.

One respondent commented that the information supporting the establishment of these CEs did not adequately address the socio-economic effects, as well as environmental effects.

Response: The primary economic effects of the CEs for soil and water restoration activities are changes in costs of conducting environmental analysis and documentation. Under current NEPA procedures, the level of analysis and documentation required for these activities often required agency personnel to extend processing timeframes and expend undue resources and funding to document restoration projects in an EA. The Forest Service has determined that this categorical exclusion will not have an annual effect of $100 million or more on the economy or adversely affect productivity, competition, jobs, the environment, public health or safety, or tribal, State, or local governments. The economic effect from these CEs is expected to

result in a reduction in the administrative burden of preparing unnecessary EAs and findings of no significant impact.

Commenters suggested that the proposed policy runs counter to the collaborative process established by Federal land managers and the use of the proposed CEs are not acceptable without first coordinating proposed actions with local governments and interested and affected public.

Response: The Forest Service strongly believes in engaging Tribes and Native Corporations, other Federal agencies, State and local governments, individuals, and public and private organizations or entities, using collaborative processes where feasible and appropriate. CEs require scoping for public participation and the responsible official must determine the extent of interest and invite the participation of affected Federal agencies, affected Tribes, State and local agencies, and other interested parties, as appropriate. The scoping process may incorporate collaborative components in the public involvement process, as determined locally for a site-specific project based on the interested and affected public.

One commenter questioned the validity of reviewing other agency CEs in supporting this proposed rule stating other agencies have missions, environmental and geophysical conditions, and a scope of projects that are different than those encountered by the Forest Service.

Response: Pursuant to CEQ's November 23, 2010, CEQ guidance memorandum on ''Establishing, Applying, and Revising Categorical Exclusions under the National Environmental Policy Act,'' (*www.nepa.gov*) the Forest Service gathered information supporting establishment of these three CEs. The information gathered includes data from implementing comparable past actions; the expert judgment of the responsible officials who made the findings for the projects reviewed for this supporting statement; information from other professional staff and experts, and scientific analyses; a review and comparison of similar CEs implemented by other Federal agencies; and the Forest Service's experience implementing soil and water restoration activities and subsequent monitoring of potential associated impacts.

The November 23, 2010, CEQ guidance memo also allows for the ''benchmarking of other agency experiences,'' that is using comparable actions (categorically excluded actions) from other Federal agencies. The Forest Service has identified a set of CEs from other Federal agencies that have similar characteristics, similar methods of implementation; applicable procedures (including extraordinary procedures), and context and timing (including the environmental settings).

Conclusion

The USDA Forest Service finds that the category of actions defined in the CEs presented at the end of this notice do not individually or cumulatively have a significant effect on the human environment. The Agency's finding is first predicated on the reasoned expert judgment of the responsible officials who made the original findings and determinations in the restoration projects reviewed; the professional staff and experts consulted on the activities in these CEs; the benchmarked CEs of other Federal agencies; and, finally, the Agency's judgment that the profile of soil and water restoration activities represents the Agency's past practices and is indicative of the Agency's future activities.

These CEs will permit timely environmental documentation, decision-making and implementation of select soil and water restoration activities. Additionally, it will conserve limited agency funds.

The text of the final categorical exclusions is set out at the end of this notice.

Regulatory Certification

Environmental Impact

The intent of the final rule is to increase administrative efficiency in connection with conducting important restoration activities while assuring that no significant environmental effects occur. The amendment of Forest Service NEPA Regulations (36 CFR 220.6) concerns NEPA documentation for certain types of soil and water restoration activities. The CEQ does not direct agencies to prepare a NEPA analysis or document before establishing agency procedures that supplement the CEQ regulations for implementing NEPA. Agencies are required to adopt NEPA procedures that establish specific criteria for, and identification of, three classes of actions: Those that require preparation of an EIS; those that require preparation of an EA; and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). CEs are one part of those agency procedures, and therefore establishing CEs does not require preparation of a NEPA analysis or document. Agency NEPA procedures are internal procedural guidance to assist agencies in fulfilling Agency responsibilities under NEPA, but are not the Agency's final determination of what level of NEPA analysis is required for a particular proposed action. The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. The determination that establishing CEs does not require NEPA analysis and documentation has been upheld in *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. Ill. 1999), aff'd, 230 F. 3d 947, 954–55 (7th Cir. 2000).

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order 12866 on regulatory planning and review. The Office of Management and Budget has determined that this is not a significant rule. The final rule would not have an annual effect of $100 million or more on the economy, nor would it adversely affect productivity, competition, jobs, the environment, public health or safety, or State or local government. This final rule would not interfere with an action taken or planned by another agency, nor would it raise new legal or policy issues. Finally, this final rule would not alter the budgetary impacts of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients of such programs.

Regulatory Flexibility Act

This final rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). The Agency has determined that this final rule would not have a significant economic impact on a substantial number of small entities as defined by the Act because the final rule would not impose record-keeping requirements; it does not affect their competitive position in relation to large entities; and it would not affect their cash flow, liquidity, or ability to remain in the market.

Federalism

The Agency has considered this final rule under the requirements of Executive Order 13132, ''Federalism.'' The Agency has concluded that the final rule conforms with the federalism principles set out in this Executive Order; would not impose any compliance costs on the States; and would not have substantial direct effects on the states or the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has determined that no further assessment of federalism implications is necessary.

Consultation and Coordination With Indian Tribal Governments

Pursuant to Executive Order 13175 of November 6, 2000, ''Consultation and Coordination with Indian tribal Governments,'' the Agency has assessed the impact of this final rule on Indian Tribes and has determined that it would not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, and therefore the final rule would not have tribal implications. The final rule deals with requirements for NEPA analysis and has no direct effect on occupancy and use of NFS lands. The Agency has also determined that this final rule would not impose substantial direct compliance costs on Indian tribal governments or preempt tribal law. Therefore, it has been determined that this final rule does not require advance consultation with Indian Tribes under Executive Order 13175.

No Takings Implications

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights.'' The Agency has determined that the final rule would not pose the risk of a taking of protected private property.

Civil Justice Reform

The Agency has reviewed this final rule under Executive Order 12988 of February 7, 1996, ''Civil Justice Reform.'' After adoption of this final rule, (1) all State and local laws and regulations that conflict with this final rule or that would impede full implementation of this final rule would be preempted; (2) no retroactive effect would be given to this final rule; and (3) the final rule would not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the Agency has assessed the effects of this rule on State, local, and tribal governments and the private sector. This final rule would not compel the expenditure of $100 million or more by any State, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Energy Effects

The Agency has reviewed this final rule under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' The Agency has determined that this final rule does not constitute a significant energy action as defined in the Executive Order.

Controlling Paperwork Burdens on the Public

This final rule does not contain any additional record keeping or reporting requirements or other information collection requirements as defined in 5 CFR Part 1320 that are not already required by law or not already approved for use, and therefore, imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR Part 1320 do not apply.

List of Subjects in 36 CFR Part 220

Administrative practices and procedures, Environmental impact statements, Environmental protection, National forests, Science and technology.

For the reasons set out in the preamble, the Forest Service amends part 220 of Title 36 of the Code of Federal Regulations as follows:

PART 220—NATIONAL ENVIRONMENTAL POLICY ACT (NEPA) COMPLIANCE

■ 1. The authority citation for part 220 continues to read as follows:

Authority: 42 U.S.C. 4321 et seq.: E.O. 11514; 40 CFR parts 1500–1508; 7 CFR part 1b.

■ 2. In § 220.6, add paragraphs (e)(18), (19), and (20) to read as follows:

§ 220.6 Categorical exclusions.

* * * * *

(e) * * *

(18) Restoring wetlands, streams, riparian areas or other water bodies by removing, replacing, or modifying water control structures such as, but not limited to, dams, levees, dikes, ditches, culverts, pipes, drainage tiles, valves, gates, and fencing, to allow waters to flow into natural channels and floodplains and restore natural flow regimes to the extent practicable where valid existing rights or special use authorizations are not unilaterally altered or canceled. Examples include but are not limited to:

(i) Repairing an existing water control structure that is no longer functioning properly with minimal dredging, excavation, or placement of fill, and does not involve releasing hazardous substances;

(ii) Installing a newly-designed structure that replaces an existing culvert to improve aquatic organism passage and prevent resource and property damage where the road or trail maintenance level does not change;

(iii) Removing a culvert and installing a bridge to improve aquatic and/or terrestrial organism passage or prevent resource or property damage where the road or trail maintenance level does not change; and

(iv) Removing a small earthen and rock fill dam with a low hazard potential classification that is no longer needed.

(19) Removing and/or relocating debris and sediment following disturbance events (such as floods, hurricanes, tornados, mechanical/engineering failures, etc.) to restore uplands, wetlands, or riparian systems to pre-disturbance conditions, to the extent practicable, such that site conditions will not impede or negatively alter natural processes. Examples include but are not limited to:

(i) Removing an unstable debris jam on a river following a flood event and relocating it back in the floodplain and stream channel to restore water flow and local bank stability;

(ii) Clean-up and removal of infrastructure flood debris, such as, benches, tables, outhouses, concrete, culverts, and asphalt following a hurricane from a stream reach and adjacent wetland area; and

(iii) Stabilizing stream banks and associated stabilization structures to reduce erosion through bioengineering techniques following a flood event, including the use of living and nonliving plant materials in combination with natural and synthetic support materials, such as rocks, riprap, geo-textiles, for slope stabilization, erosion reduction, and vegetative establishment and establishment of appropriate plant communities (bank shaping and planting, brush mattresses, log, root wad, and boulder stabilization methods).

(20) Activities that restore, rehabilitate, or stabilize lands occupied by roads and trails, excluding National Forest System Roads and National Forest System Trails, to a more natural condition that may include removing, replacing, or modifying drainage structures and ditches, reestablishing vegetation, reshaping natural contours and slopes, reestablishing drainage-ways, or other activities that would restore site productivity and reduce

environmental impacts. Examples include but are not limited to:

(i) Decommissioning a road that is no longer a National Forest System Road to a more natural state by restoring natural contours and removing construction fills, loosening compacted soils, revegetating the roadbed and removing ditches and culverts to reestablish natural drainage patterns; (ii) Restoring an unauthorized trail to a natural state by reestablishing natural drainage patterns, stabilizing slopes, reestablishing vegetation, and installing water bars; and

(ii) Installing boulders, logs, and berms on an unauthorized road segment to promote naturally regenerated grass, shrub, and tree growth.

* * * * *

Dated: August 30, 2013.

Robert Bonnie,

Under Secretary, Natural Resources and Environment.

[FR Doc. 2013–22151 Filed 9–11–13; 8:45 am]

BILLING CODE 3410–11–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2011–0708; FRL–9900–86–Region8]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Second 10-Year Carbon Monoxide Maintenance Plan for Fort Collins

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving a State Implementation Plan (SIP) revision submitted by the State of Colorado. On May 25, 2011, the Governor of Colorado's designee submitted to EPA a Clean Air Act (CAA) section 175A(b) second 10-year maintenance plan for the Fort Collins area for the carbon monoxide (CO) National Ambient Air Quality Standard (NAAQS). This limited maintenance plan (LMP) addresses maintenance of the CO NAAQS for a second 10-year period beyond the original redesignation. This action is being taken under sections 110 and 175A of the CAA.

DATES: This rule is effective on November 12, 2013 without further notice, unless EPA receives adverse comment by October 15, 2013. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2011–0708, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: clark.adam@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Carl Daly, Director, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Carl Daly, Director, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2011–0708. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (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 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 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, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: 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. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, EPA Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION:

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V. Final Action
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Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *Colorado* and *State* mean the State of Colorado.

I. General Information

A. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://regulations.gov* or email. 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 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

Under the CAA Amendments of 1990, the Fort Collins area was designated as nonattainment and classified as a ''moderate'' CO area, with a design value of less than or equal to 12.7 parts per million (ppm) (56 FR 56694, November 6, 1991). On August 9, 2002, the Governor of Colorado submitted to EPA a request to redesignate the Fort Collins CO nonattainment area to attainment for the CO NAAQS. Along with this request, the Governor submitted a CAA section 175A(a) maintenance plan which established an attainment year of 1992, and demonstrated that the area would maintain the CO NAAQS through 2015. The State also submitted revisions to Colorado Air Quality Control Commission (AQCC) Regulation No. 11, ''Motor Vehicle Emissions Inspection Program,'' and AQCC Regulation No. 13, ''Oxygenated Fuels Program,'' which removed as federally-enforceable SIP control measures both the inspection/maintenance and oxygenated fuels programs in Fort Collins.[1] EPA approved the State's redesignation request, CAA section 175A(a) maintenance plan, base year emissions inventory, and revisions to AQCC Regulations No. 11 and 13 on July 22, 2003 (68 FR 43316).

Eight years after an area is redesignated to attainment, CAA Section 175A(b) requires the state to submit a subsequent maintenance plan to EPA, covering a second 10-year period.[2] This second 10-year maintenance plan must demonstrate continued maintenance of the applicable NAAQS during this second 10-year period. To fulfill this requirement of the Act, the Governor of Colorado's designee submitted the second 10-year Fort Collins CO maintenance plan (hereafter, ''revised Fort Collins Maintenance Plan'') to us on May 25, 2011. With this action, we are approving the revised Fort Collins Maintenance Plan.

The 8-hour CO NAAQS—9.0 ppm—is attained when such value is not exceeded more than once a year. 40 CFR 50.8(a)(1). The Fort Collins area has attained the 8-hour CO NAAQS from 1992 to the present.[3] In October 1995, EPA issued guidance that provided nonclassifiable CO nonattainment areas the option of using a less rigorous ''limited maintenance plan'' (LMP) option to demonstrate continued attainment and maintenance of the CO NAAQS.[4] According to this guidance, areas that can demonstrate design values at or below 7.65 ppm (85% of exceedance levels of the CO 8-hour NAAQS) for eight consecutive quarters qualify to use a LMP. For the revised Fort Collins Maintenance Plan, on which we are finalizing action, the State used the LMP option to demonstrate continued maintenance of the CO NAAQS in the Fort Collins area through 2023. We have determined that the Fort Collins area qualifies for the LMP option for this plan revision, since the area's maximum design value for the most recent eight consecutive quarters with certified data at the time the State adopted the plan (years 2008 and 2009) was 3.0 ppm.[5]

III. What was the state's process?

Section 110(a)(2) of the CAA requires that a state provide reasonable notice and public hearing before adopting a SIP revision and submitting it to us.

The Colorado AQCC held a public hearing for the revised Fort Collins Maintenance Plan on December 16, 2010. The AQCC adopted the revised Fort Collins Maintenance Plan directly after the hearing. The Governor's designee submitted the revised plan to EPA on May 25, 2011.

We have evaluated the SIP revision and have determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. On November 25, 2011, by operation of law under CAA section 110(k)(1)(B), the SIP revision was deemed to have met the minimum ''completeness'' criteria found in 40 CFR part 51, appendix V.

IV. EPA's Evaluation of the Revised Fort Collins Maintenance Plan

The following are the key elements of an LMP for CO: Emission Inventory, Maintenance Demonstration, Monitoring Network/Verification of Continued Attainment, Contingency Plan, and Conformity Determinations. Below, we describe our evaluation of each of these elements as it pertains to the revised Fort Collins Maintenance Plan.

A. Emission Inventory

The revised Fort Collins Maintenance Plan contains an emissions inventory for the base year 2008. The emission inventory is a list, by source category, of the air contaminants directly emitted into the Fort Collins CO maintenance area on a typical winter day in 2008.[6] The data in the emission inventory were developed using EPA-approved emissions modeling methods. A more detailed description of the 2008 inventory is documented in the Fort

[1] The oxygenated fuels and motor vehicle inspection programs were discontinued effective January 1, 2004.

[2] In this case, the initial maintenance period described in CAA section 175A(a) was required to extend for at least 10 years after the redesignation to attainment, which was effective on September 22, 2003. See 68 FR 43316. So the first maintenance plan was required to show maintenance at least through 2013. CAA section 175A(b) requires that the second 10-year maintenance plan maintain the NAAQS for ''10 years after the expiration of the 10-year period referred to in [section 175A(a)].'' Thus, for the Fort Collins area, the second 10-year period ends in 2023.

[3] The Fort Collins area has never exceeded the 1-hour CO standard of 35 ppm.

[4] Memorandum ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph W. Paisie, Group Leader, EPA Integrated Policy and Strategies Group, to Air Branch Chiefs, October 6, 1995 (hereafter referred to as ''LMP Guidance'').

[5] See Table 1 below. Additionally, according to the LMP guidance, an area using the LMP option must continue to have a design value ''at or below 7.65 ppm until the time of final EPA action on the redesignation.'' Table 1, below, demonstrates that the area meets this requirement.

[6] Violations of the CO NAAQS are most likely to occur on winter weekdays.

Collins CO maintenance plan Technical Support Document (TSD).[7] Included in this inventory are commercial cooking, fuel combustion, highway vehicle exhaust, non-road mobile sources, railroads, structure fires, woodburning, point sources, and emissions from a heliport. The revised maintenance plan and TSD contain detailed emission inventory information that was prepared in accordance with EPA guidance, and is acceptable to us.[8]

B. Maintenance Demonstration

EPA considers the maintenance demonstration requirement to be satisfied for areas that qualify for and are using the LMP option. As mentioned above, a maintenance area is qualified to use the LMP option if that area's maximum 8-hour CO design value for eight consecutive quarters does not exceed 7.65 ppm (85% of the CO NAAQS). EPA maintains that if an area begins the maintenance period with a design value no greater than 7.65 ppm, the applicability of prevention of significant deterioration requirements, the control measures already in the SIP, and federal measures should provide adequate assurance of maintenance over the 10-year maintenance period. Therefore, EPA does not require areas using the LMP option to project emissions over the maintenance period. Because CO design values in the Fort Collins area are consistently well below the LMP threshold (See Table 1 below), the State has adequately demonstrated that the Fort Collins area will maintain the CO NAAQS into the future.

TABLE 1—8-HOUR CO DESIGN VALUES FOR FORT COLLINS, COLORADO

Design value (ppm) *	Year
3.1	2004
2.4	2005
2.7	2006
2.4	2007
3.0	2008
1.8	2009
1.7	2010
1.3	2011
1.7	2012

* Design Values were derived from the EPA AirData Web site (*http://www.epa.gov/airdata/*).

C. Monitoring Network/Verification of Continued Attainment

In the revised Fort Collins Maintenance Plan, the State commits to continuing operation of an air quality monitoring network in accordance with 40 CFR Part 58 to verify continued attainment of the CO NAAQS. The State also commits to conducting an annual review of the air quality surveillance system in accordance with 40 CFR 58.10. Additionally, the plan indicates that if measured mobile source parameters change significantly over time, the State will perform appropriate studies to determine whether additional and/or re-sited monitors are necessary. We are approving these commitments as satisfying the relevant requirements.

D. Contingency Plan

Section 175A(d) of the CAA requires that a maintenance plan include contingency provisions to promptly correct any violation of the NAAQS that occurs after redesignation of an area. To meet this requirement, the State has indentified appropriate contingency measures along with a schedule for the development and implementation of such measures.

As stated in the revised Fort Collins Maintenance Plan, the contingency measures will be triggered by a violation of the CO NAAQS. No more than 60 days after notification from the Colorado Air Pollution Control Division (APCD) that a violation of the CO NAAQS has occurred, the North Front Range Metropolitan Planning Organization (NFRMPO), in conjunction with the APCD, AQCC, and local governments, will initiate a subcommittee process to begin evaluating potential contingency measures. The subcommittee will present recommendations within 120 days of notification, and the recommended contingency measures will be presented to the AQCC within 180 days of notification. The AQCC will then hold a public hearing to consider the contingency measures recommended by the subcommittee along with any other contingency measures the AQCC believes may be appropriate to effectively address the violation. The necessary contingency measures will be adopted and implemented within one year after a violation occurs.

The potential contingency measures that are identified in the revised Fort Collins maintenance plan include, but are not limited to: (1) A federally enforceable enhanced vehicle inspection and maintenance program;[9] (2) a 2.7% oxygenated gasoline program, as set forth in AQCC Regulation Number 13 as of September 2009; (3) re-establishing nonattainment new source review permitting for stationary sources; and (4) wood burning restrictions.

We find that the contingency measures provided in the revised Fort Collins Maintenance Plan are sufficient and meet the requirements of section 175A(d) of the CAA.

E. Transportation Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS (CAA 176(c)(1)(B)). EPA's conformity rule at 40 CFR part 93 requires that transportation plans, programs and projects conform to SIPs and establish the criteria and procedures for determining whether or not they conform. To effectuate its purpose, the conformity rule requires a demonstration that emissions from the Regional Transportation Plan (RTP) and the Transportation Improvement Program (TIP) are consistent with the motor vehicle emission budget (MVEB) contained in the control strategy SIP revision or maintenance plan (40 CFR 93.101, 93.118, and 93.124). A MVEB is defined as the level of mobile source emissions of a pollutant relied upon in the attainment or maintenance demonstration to attain or maintain compliance with the NAAQS in the nonattainment or maintenance area.[10]

Under the LMP guidance, emissions budgets generally are treated as not constraining for the length of the maintenance period. While EPA's LMP guidance does not exempt an area from the need to affirm conformity, it explains that the area may demonstrate conformity without submitting a MVEB. According to the LMP guidance, it is unreasonable to expect that a LMP area will experience so much growth in that period that a violation of the CO NAAQS would result.[11] However, the CO maintenance plan for Fort Collins that we approved in 2003 (68 FR 43316) contains MVEBs for 2010 through 2014 (98 tons per day of CO), and for 2015 (94

[7] The TSD for the revised Fort Collins Maintenance Plan can be found in the docket for this action.

[8] See ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' from John Calcagni, Director, Air Quality Management Division, EPA, September 4, 1992.

[9] A State-only enhanced inspection and maintenance program is already required for the Fort Collins area as part of the State's ''Ozone Action Plan.'' However, this existing program is not federally enforceable, and could be discontinued by the State without regard to the Fort Collins CO maintenance plan.

[10] Further information concerning EPA's interpretations regarding MVEBs can be found in the preamble to EPA's November 24, 1993, transportation conformity rule (see 58 FR 62193–62196).

[11] LMP Guidance at 4. October 6, 1995.

tons per day of CO), and the State did not revise or remove these MVEBs from the SIP. Under our conformity regulations, consistency with those MVEBs must continue to be demonstrated as long as such years are within the timeframe of the transportation plan. See 40 CFR 93.118(b)(2)(i) and (d)(2).[12]

When those years are no longer within the timeframe of the transportation plan, there will no longer be a need to demonstrate conformity with any MVEB for the Fort Collins CO maintenance area, for the reasons described in our LMP guidance. From that point forward, all actions that require conformity determinations for the Fort Collins CO maintenance area under our conformity rule provisions will be considered to have already satisfied the regional emissions analysis and ''budget test'' requirements in 40 CFR 93.118 because of our approval of the Fort Collins CO LMP.

However, since LMP areas are still maintenance areas, certain aspects of transportation conformity determinations still will be required for transportation plans, programs and projects. Specifically, for such determinations, RTPs, TIPs and projects still will have to demonstrate that they are fiscally constrained (40 CFR 93.108) and meet the criteria for consultation and Transportation Control Measure (TCM) implementation in the conformity rule provisions (40 CFR 93.112 and 40 CFR 93.113, respectively). In addition, projects in LMP areas still will be required to meet the applicable criteria for CO hot spot analyses to satisfy ''project level'' conformity determinations (40 CFR 93.116 and 40 CFR 93.123), which must also incorporate the latest planning assumptions and models available (40 CFR 93.110 and 40 CFR 93.111, respectively).

Our approval of the revised Fort Collins Maintenance Plan affects future CO RTP and TIP conformity determinations prepared by NFRMPO, the Colorado Department of Transportation, the Federal Highway Administration, and the Federal Transit Administration.

V. Final Action

We are approving the revised Fort Collins Maintenance Plan submitted on May 25, 2011. This maintenance plan meets the applicable CAA requirements, and we have determined it is sufficient to provide for maintenance of the CO NAAQS over the course of the second 10-year maintenance period out to 2023.

We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the Proposed Rules section of today's **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective November 12, 2013 without further notice unless we receive adverse comments by October 15, 2013. If we receive adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it 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).

This rule also does not have tribal implications because it will 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission; to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

The Congressional Review Act, 5 U.S.C. section 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

[12] As required by our transportation conformity adequacy process, we made a finding in an August 9, 2011 letter to the Colorado Department of Public Health and Environment (CDPHE) that the revised Fort Collins Maintenance Plan was adequate for transportation conformity purposes. This finding was based substantially on the fact that the Fort Collins CO maintenance area meets the LMP criteria, and is therefore not required to project future emissions. In a **Federal Register** notice dated May 25, 2012, we notified the public of our finding that the revised Fort Collins Maintenance Plan was adequate for transportation conformity purposes (see 77 FR 31351). This adequacy determination became effective on June 11, 2012.

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. 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 November 12, 2013. 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 today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that 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 CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

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

Dated: August 26, 2013.

Shaun L. McGrath,

Regional Administrator, Region 8.

40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

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

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

Subpart G—Colorado

■ 2. Section 52.349 is amended by adding paragraph (q) to read as follows:

§ 52.349 Control strategy: Carbon monoxide.

* * * * *

(q) Revisions to the Colorado State Implementation Plan, revised Carbon Monoxide Maintenance Plan for Fort Collins, as adopted by the Colorado Air Quality Control Commission on December 16, 2010 and submitted by the Governor's designee on May 25, 2011.

[FR Doc. 2013–21987 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R03–OAR–2012–0386; FRL–9900–71-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; West Virginia's Redesignation for the Parkersburg-Marietta, WV-OH 1997 Annual Fine Particulate Matter Nonattainment Area to Attainment and Approval of the Associated Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a redesignation request and State Implementation Plan (SIP) revision submitted by the State of West Virginia. The West Virginia Department of Environmental Protection (WVDEP) requested that the West Virginia portion of the Parkersburg-Marietta, WV-OH fine particulate matter ($PM_{2.5}$) nonattainment area (''Parkersburg-Marietta Area'' or ''Area'') be redesignated as attainment for the 1997 annual $PM_{2.5}$ national ambient air quality standard (NAAQS). In this rulemaking action, EPA is approving the 1997 annual $PM_{2.5}$ redesignation request for the West Virginia portion of the Area. EPA is also approving the maintenance plan SIP revision that the State submitted in conjunction with its redesignation request. The maintenance plan provides for continued attainment of the 1997 annual $PM_{2.5}$ NAAQS for 10 years after redesignation of the West Virginia portion of the Area. The maintenance plan includes an insignificance determination for the onroad motor vehicle contribution of $PM_{2.5}$, nitrogen oxides (NO_X), and sulfur dioxide (SO_2) for the West Virginia portion of the Area for purposes of transportation conformity. EPA is also approving West Virginia's insignificance determination for transportation conformity. In addition, EPA is also finding that the Area continues to attain the standard. This rulemaking action approving the 1997 annual $PM_{2.5}$ NAAQS redesignation request, maintenance plan, and insignificance determination for transportation conformity for the West Virginia portion of the Area is based on EPA's determination that the Area has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA).

DATES: This final rule is effective on September 12, 2013.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2012–0386. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (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 either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by email at *quinto.rose@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Parkersburg-Marietta Area is composed of Wood County and a portion of Pleasants County in West Virginia (West Virginia portion of the Area) and Washington County in Ohio. On December 11, 2012 (77 FR 73560), EPA published a notice of proposed rulemaking (NPR) for the State of West Virginia. Pursuant to sections 107(d)(3)(E) and 175A of the CAA, EPA proposed approval of West Virginia's redesignation request, a SIP revision that establishes a maintenance plan for the West Virginia portion of the Area that provides for continued attainment of the 1997 annual $PM_{2.5}$ NAAQS for at least 10 years after redesignation, and the insignificance determination for transportation conformity for the West Virginia portion of the Area. The formal SIP revision was submitted by WVDEP on March 5, 2012. In a separate action, EPA approved the base year emissions inventory on December 12, 2012 (77 FR

73924) meeting the requirements of section 172(c)(3) of the CAA.

On July 8, 2013 (78 FR 40655), EPA published a supplemental NPR that revised and expanded the basis for proposing approval of West Virginia's request in light of developments since EPA issued its initial proposal on December 11, 2012. Principally, the supplemental NPR addressed the effects of the United States Court of Appeals for the District of Columbia's January 4, 2013 decision to remand to EPA two final rules implementing the $PM_{2.5}$ NAAQS.

Other specific details of West Virginia's redesignation request, the associated maintenance plan SIP revision and insignificance determination, and the rationales for EPA's proposed actions are explained in both the NPR and the supplemental NPR and will not be restated here. No public comments were received on either of the NPRs.

II. Final Action

EPA is approving the redesignation request, maintenance plan, and insignificance determination for transportation conformity for the West Virginia portion of the Area that was submitted by WVDEP on March 5, 2012 because the requirements for approval have been satisfied. EPA has evaluated West Virginia's redesignation request, and determined that it meets the redesignation criteria set forth in section 107(d)(3)(E) of the CAA. Approval of this redesignation request will change the designation of the West Virginia portion of the Area from nonattainment to attainment for the 1997 annual $PM_{2.5}$ NAAQS. EPA is also approving the associated maintenance plan for the West Virginia portion of the Area, submitted on March 5, 2012, as a revision to the West Virginia SIP, because it meets the requirements of section 175A of the CAA. In addition, EPA is also approving the transportation conformity insignificance determination submitted by West Virginia for this Area in conjunction with its redesignation request.

In accordance with 5 U.S.C. 553(d), EPA finds there is good cause for this action to become effective immediately upon publication. A delayed effective date is unnecessary due to the nature of a redesignation to attainment, which eliminates CAA obligations that would otherwise apply. The immediate effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rulemaking actions may become effective less than 30 days after publication if the rule ''grants or recognizes an exemption or relieves a restriction,'' and section 553(d)(3), which allows an effective date less than 30 days after publication ''as otherwise provided by the agency for good cause found and published with the rule.'' The purpose of the 30-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Today's rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today's rule relieves West Virginia of the obligation to comply with nonattainment-related planning requirements for this $PM_{2.5}$ Area pursuant to Part D of the CAA. For these reasons, EPA finds good cause under 5 U.S.C. 553(d) for this action to become effective on the date of publication of this notice.

III. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 CAA. 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 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 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, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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 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).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 12, 2013. 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.

This action approving the redesignation request, maintenance plan, and transportation conformity insignificance determination for the

West Virginia portion of the Area 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, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

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

Dated: August 22, 2013.

W.C. Early,

Acting, Regional Administrator, Region III.

40 CFR parts 52 and 81 are 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 XX—West Virginia

■ 2. In § 52.2520, the table in paragraph (e) is amended by adding an entry for the 1997 Annual $PM_{2.5}$ Maintenance Plan for Parkersburg-Marietta, WV-OH Area at the end of the table to read as follows:

§ 52.2520 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
1997 Annual $PM_{2.5}$ Maintenance Plan for Parkersburg-Marietta WV-OH Area.	Wood County and a portion of Pleasants County.	3/5/12	9/12/13 *[Insert page number where the document begins].*	See § 52.2526(h).

■ 3. Section 52.2526 is amended by adding paragraph (h) to read as follows:

§ 52.2526 Control strategy: Particular matter.

* * * * *

(h) EPA approves the maintenance plan for the West Virginia portion of the Parkersburg-Marietta, WV-OH 1997 $PM_{2.5}$ Nonattainment Area (Wood County and a portion of Pleasants County). The maintenance plan establishes a determination of insignificance for $PM_{2.5}$, NO_X and SO_2 for transportation conformity purposes.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 4. The authority citation for Part 81 continues to read as follows:

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

■ 5. In § 81.349 the table for West Virginia—$PM_{2.5}$ (Annual NAAQS) is amended by revising the entry for the Parkersburg-Marietta, WV-OH Area to read as follows:

§ 81.349 West Virginia.

* * * * *

WEST VIRGINIA—$PM_{2.5}$

[Annual NAAQS]

Designated area	Designation [a]	
	Date [1]	Type
*	*	*
Parkersburg-Marietta, WV-OH:		
Pleasants County (part)Tax District of Grant	9/12/13	Attainment.
Wood County	9/12/13	Attainment.
*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

* * * * *

[FR Doc. 2013–21792 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 02–199; RM–10514; FCC 13–114]

Radio Broadcasting Services; Magnolia, Arkansas; and Oil City, Louisiana

AGENCY: Federal Communications Commission.

ACTION: Final rule; denial of application for review.

SUMMARY: In this document, the Federal Communications Commission (''Commission'') denies an Application for Review filed by Access.1 Louisiana Holding Company, LLC (''Access.1'') of a *Memorandum Opinion and Order* of the Media Bureau (''Bureau'') in this proceeding, which denied Access.1's Petition for Reconsideration of an earlier Bureau action, granting the reallotment,

class downgrade, and change of community of license of Station KQHN(FM) from Magnolia, Arkansas, to Oil City, Louisiana. The document finds that the Bureau did not err in approving the relocation of this FM station.

FOR FURTHER INFORMATION CONTACT: Andrew J. Rhodes, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Memorandum Opinion and Order,* FCC 13–114, MB Docket No. 02–199, RM–10514, adopted August 14, 2013, and released August 16, 2013. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *www.BCPIWEB.com.*

In the *Report and Order* in this proceeding, the Bureau granted a Petition for Rule Making filed by Cumulus Licensing, LLC's predecessor in interest (''Cumulus'') as licensee of Station KQHN(FM) for a downgrade in class of channel, and change of community of license for the station from Channel 300C1 at Magnolia, Arkansas, to Channel 300C2 at Oil City, Louisiana, *See* 70 FR 19337, April 13, 2005. In the *Memorandum Opinion and Order,* the Bureau affirmed the grant and concluded that the relocation of the station to Oil City did not constitute a ''move-in'' to the Shreveport, Louisiana, Urbanized Area because Cumulus had demonstrated that Oil City is sufficiently independent of the Shreveport Urbanized Area to warrant a first local service preference under the then-existing *Tuck* test. *See* 69 FR 8333, February 24, 2004.

On review, the Commission finds that the Bureau did not err in (1) determining that Oil City was independent of Shreveport; (2) declining to adopt Acceess.1's proposed processing policy of requiring a certification by a community of license modification proponent that it will not select a site that would provide substantial service to an urbanized area; and (3) finding that the proposed reallotment would serve the public interest. The Commission upholds those decisions for the reasons stated in the *Memorandum Opinion and Order.*

However, the Commission states that some additional discussion is warranted regarding the remaining issues raised by Access.1. Most importantly, the Commission finds that Cumulus had not engaged in misrepresentation and/or had not shown a lack of candor as to whether its proposal would be a ''move-in'' to the Shreveport Urbanized Area. The Commission explains that under the then-existing procedures, Cumulus was permitted to specify at the rule making stage reference coordinates of a theoretical fully spaced site and later in the implementing application to specify a different site. Absent any extrinsic evidence to the contrary, which Access.1 did not produce, the Commission concludes that a misrepresentation or lack of candor allegation based on the specification of a different application site is speculative.

This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of the *Memorandum Opinion and Order* to GAO, pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the Application for Review was denied.)

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–22211 Filed 9–11–13; 8:45 am]

BILLING CODE 6712–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 1037, 1039, 1042, and 1068

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 535

[EPA–HQ–OAR–2012–0102; NHTSA–2012–0152; FRL 9900–11–OAR]

RIN 2060–AR48; 2127–AL31

Heavy-Duty Engine and Vehicle and Nonroad Technical Amendments

Correction

In rule document 2013–19880 appearing on pages 49963 through 49967 in the issue of Friday, August 16, 2013, make the following correction.

1. On page 49965, in the second column, the equation beneath the first paragraph is corrected to read as set forth below.

§ 1037.104 Exhaust emission standards for CO_2, CH_4, and N_2O for heavy-duty vehicles at or below 14,000 pounds GVWR [Corrected]

$$Force - (\text{mass} \times \text{acceleration}) = F0 + F1 \cdot (velocity) + F2 \cdot (velocity)^2$$

[FR Doc. C1–2013–19880 Filed 9–11–13; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130402313–3748–02]

RIN 0648–BD15

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Queen Conch Fishery of Puerto Rico and the U.S. Virgin Islands; Regulatory Amendment 2

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Regulatory Amendment 2 to the Fishery Management Plan (FMP) for the Queen Conch Resources of Puerto Rico and the U.S. Virgin Islands (USVI) (Regulatory Amendment 2), as prepared by the Caribbean Fishery Management Council (Council). This final rule revises the commercial trip limit for queen conch in the Caribbean exclusive economic zone (EEZ) to be compatible with the trip limit in USVI territorial waters. The purpose of this provision is to improve the compatibility of Federal and USVI territorial regulations for queen conch in order to facilitate enforcement efforts while ensuring the long-term health of the queen conch resource. This final rule also changes the regulations specifying the queen conch fishing season to correct an inadvertent change to the text that occurred in a prior rulemaking. The revision better reflects the original and current intent of the Council.

DATES: This rule is effective October 15, 2013.

ADDRESSES: Electronic copies of Regulatory Amendment 2, which includes an environmental assessment, a Regulatory Flexibility Act analysis, and a regulatory impact review (RIR), may be obtained from the Southeast Regional Office Web site at: *http://sero.nmfs.noaa.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Maria del Mar Lopez, Southeast

Regional Office, NMFS, telephone: 727–824–5305, email: *Maria.Lopez@noaa.gov.*

SUPPLEMENTARY INFORMATION: The queen conch fishery in the U.S. Caribbean is managed under the FMP for the Queen Conch Resources of Puerto Rico and the USVI (Queen Conch FMP). The Queen Conch FMP was prepared by the Council, and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On June 7, 2013, NMFS published a proposed rule for Regulatory Amendment 2 and requested public comment (78 FR 34311). The proposed rule and Regulatory Amendment 2 outline the rationale for the actions contained in the final rule. A summary of the actions implemented by this final rule is provided below.

Management Measures Contained in This Final Rule

This final rule revises the commercial trip limit to 200 queen conch per vessel per day from the current 150 queen conch per licensed commercial fisher per day. The purpose of this provision is to improve the compatibility of Federal and USVI territorial regulations for queen conch in order to facilitate enforcement efforts while ensuring the long-term health of the queen conch resource.

Other Changes Contained in This Final Rule

This final rule also changes the language in 50 CFR 622.491 to correct an inadvertent change to the text specifying the queen conch fishing season. Fishing for queen conch is only allowed from November 1 through May 31, and only in the area east of 64°34′ W. longitude which includes Lang Bank east of St. Croix, USVI. In the rest of the Caribbean EEZ, there is a prohibition on the harvest and possession of queen conch. This revision corrects a mistake that occurred in prior rule-making (Regulatory Amendment 1; 76 FR 23907, April 29, 2011), in which the sentence was restructured, resulting in an inadvertent change in the meaning. This rule revises the codified text to its previous form. Changing the codified text to its previous form reflects the original and current intent of the Council.

Comments and Responses

NMFS received two comments on the proposed rule and Regulatory Amendment 2. A Federal agency stated it had no comments on the actions in Regulatory Amendment 2. The other comment was unrelated to the actions contained in Regulatory Amendment 2 and the proposed rule and, therefore, is not addressed here.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined that this final rule is necessary for the conservation and management of queen conch and is consistent with Regulatory Amendment 2, the Queen Conch FMP, the Magnuson-Stevens Act and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule, if adopted, would not have a significant adverse economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

On June 20, 2013, the Small Business Administration (SBA) issued a final rule revising the small business size standards for several industries effective July 22, 2013 (78 FR 37398). The rule increased the size standard for Finfish Fishing from $4.0 to $19.0 million, Shellfish Fishing from $4.0 to $5.0 million, and Other Marine Fishing from $4.0 to $7.0 million. Pursuant to the Regulatory Flexibility Act, and prior to SBA's June 20, 2013, final rule, an initial regulatory flexibility analysis was developed for this action using SBA's former size standards. Subsequent to the June 20, 2013 rule, NMFS has reviewed the analysis prepared for this action in light of the new size standards. Under the former, lower size standards, all entities subject to this action were considered small entities, thus they all would continue to be considered small entities under the new standards. NMFS has determined that the new size standards do not affect the analyses prepared for this action.

This rule is expected to directly affect commercial fishermen in St. Croix, USVI, who harvest queen conch. Queen conch harvest in the EEZ of the U.S. Caribbean is restricted to the Lang Bank area off St. Croix and all queen conch harvest from this area is believed to be landed in St. Croix because of the prohibitive travel distances that would be required to land in other locations. As a result, the assessment of the number of commercial entities expected to be affected by this rule is based on St. Croix commercial trip ticket data.

The USVI fishing year for all species is July 1 through June 30. Over the 2009/2010 through 2011/2012 fishing years, an average of 40 fishermen (range of 30–48) per fishing year recorded landings of queen conch in St. Croix. The average total revenue per fishing year from the harvest of all marine species (queen conch and all other species) by these fishermen was approximately $2.6 million (nominal or un-inflated dollars), or approximately $64,000 per fisherman ($2.6 million/40). These estimates include all fishermen with recorded queen conch landings in St. Croix, regardless of where the queen conch were harvested (EEZ or territorial waters). Precise comparable estimates for fishermen who harvested queen conch in the EEZ are not available because the area of harvest was not provided on all trip tickets (area fished was not reported on trip tickets that accounted for approximately 11 percent of the average queen conch harvest per fishing year). However, an average of 17 fishermen (range of 9–23) per fishing year reported queen conch harvests from the EEZ. The average total revenue from the harvest of all marine species by these fishermen during this period was approximately $1.0 million (nominal or un-inflated dollars), or approximately $60,000 per fishermen ($1.0 million/17).

The Small Business Administration (SBA) has established size criteria for all major industry sectors in the U.S. including fish harvesters. A business involved in marine fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $5 million (NAICS code 114112, shellfish fishing), $7 million (NAICS code 114119, other marine fishing), and $19 million (NAICS code 114111, finfish fishing) for all its affiliated operations worldwide. Both average revenue estimates, approximately $64,000 for all fishermen with commercial queen conch landings and approximately $60,000 for fishermen who reported harvesting queen conch from the EEZ, are significantly lower than all of these SBA thresholds. As a result, all commercial fishermen expected to be affected by this rule are determined, for the purpose of this assessment, to be small business entities.

This rule increases the number of queen conch that can be harvested per vessel per day if one licensed commercial fisherman is on board the vessel, and decreases the allowable harvest if multiple licensed commercial fishermen are on board. However, only 2 percent or fewer of the trips that harvest queen conch are believed to carry multiple licensed commercial

fishermen and no licensed commercial fishermen are known to exclusively fish with other licensed commercial fishermen on board. As a result, the effects of increasing the allowable queen conch harvest per vessel per day on trips with a single licensed commercial fisherman on board is expected to account for the majority of the economic impacts of this rule.

The net direct economic effects of this rule cannot be quantified with available data. Increasing the number of queen conch that can be harvested per vessel per trip is expected to increase the average daily harvest and associated revenue per trip for trips on which queen conch are harvested. Total operating costs may be reduced if fishermen take fewer trips to harvest the queen conch annual catch limit (ACL). An increase in the revenue per trip and a decrease in operating costs results in an increase in profit to affected small entities.

The queen conch commercial ACL in St. Croix is 50,000 lb (22,680 kg) and queen conch harvest and possession in the EEZ is prohibited when the St. Croix ACL is reached. As a result, the total average annual revenue to all commercial fishermen from queen conch harvest is not expected to be affected by this rule other than as a result of a possible reduction in average price if increased harvest rates result in a derby fishery and depress prices. However, of the estimated average 40 fishermen who harvest queen conch per year, only an estimated average of 17 fishermen per year harvest queen conch in the EEZ. Closure of the fishery due to the ACL being reached has only occurred once since the 2008/2009 fishing year and approximately two-thirds of the total queen conch harvest in St. Croix comes from territorial waters. As a result, any increased harvest rate that might occur in response to the increase in the trip limit in the EEZ may not significantly reduce the length of the open season and, thus, may have minimal to no effect on queen conch prices. Therefore, increasing the daily average harvest rate, which may occur as a result of the increase in the trip limit, may have only a small effect on increasing the likelihood of the fishery closing due to the ACL being reached and/or reducing the average price for queen conch.

In addition to the effects described in the previous paragraph, fishing for, and revenue from, other species may increase as a result of this rule if fishermen are able to take fewer trips to harvest the queen conch ACL and increase fishing effort for other species. However, any increase in revenue from other species will be an indirect effect of this rule.

This rule also changes the language in the codified text specifying the queen conch fishing season. This change corrects an inadvertent change to the text that occurred in a prior rulemaking, as discussed in the preamble. The revision better reflects the original and current intent of the Council. Queen conch fishing in the Caribbean EEZ has been consistent with the season specified by the change and, therefore, this change is not expected to result in any economic effects on any small entities.

In summary, the average fisherman expected to be directly affected by this rule is expected to experience an increase in revenue and profit. However, the amount of this increase cannot be determined with available data.

The information provided above supports a determination that this rule will have beneficial effects on affected small entities, and therefore would not have a significant adverse economic impact on a substantial number of small entities. An initial regulatory flexibility analysis (IRFA) was prepared for the proposed rule, and the resultant analysis concluded the same finding of positive economic impacts. No challenge of this determination or other substantive issue was received through public comment of the proposed rule, and thus, no changes were made in the rule. Accordingly, a final regulatory flexibility analysis was not required or prepared. Copies of the RIR and IRFA are available (see **ADDRESSES**).

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Queen conch, St. Croix, U.S. Virgin Islands.

Dated: September 9, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.491, paragraph (a) is revised to read as follows:

§ 622.491 Season and area closures.

(a) No person may fish for or possess on board a fishing vessel a Caribbean queen conch in or from the Caribbean EEZ, except from November 1 through May 31 in the area east of 64°34′ W. longitude which includes Lang Bank east of St. Croix, U.S. Virgin Islands.

* * * * *

■ 3. In § 622.495, paragraph (a) is revised and paragraph (b) is added to read as follows:

§ 622.495 Commercial trip limit.

* * * * *

(a) *Applicability.* The trip limit of paragraph (b) of this section applies to a vessel that has at least one person on board with a valid commercial fishing license issued by Puerto Rico or the U.S. Virgin Islands. If no person on board the vessel has a valid commercial fishing license issued by Puerto Rico or the U.S. Virgin Islands, the bag limit specified in § 622.494(b) applies.

(b) *Trip limit.* The trip limit for queen conch in or from the Caribbean EEZ is 200 queen conch per day.

[FR Doc. 2013–22212 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 177
Thursday, September 12, 2013

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[Docket No. PRM–50–105; NRC–2012–0056]

In-Core Thermocouples at Different Elevations and Radial Positions in Reactor Core

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM), PRM–50–105, submitted by Mark Leyse (the petitioner) on February 28, 2012. The petitioner requested that the NRC require all holders of operating licenses for nuclear power plants (NPPs) to operate NPPs with in-core thermocouples at different elevations and radial positions throughout the reactor core to enable the operators to accurately measure a large range of in-core temperatures in NPP steady-state and transient conditions. The NRC is denying the PRM because: there are no protection or plant control functions that utilize inputs from core exit thermocouples (CETs); there is no operational necessity for more accurate measurement of temperatures throughout the core; the petition provided inadequate justification of why precise knowledge of core temperature at various elevations and radial positions would enhance safety or change operator action; and the NRC believes that, despite the known limitations of CETs, CETs are sufficient to allow NPP operators to take timely and effective action in the event of an accident.

DATES: The docket for the petition for rulemaking, PRM–50–105, is closed on September 12, 2013.

ADDRESSES: Please refer to Docket ID NRC–2012–0056 when contacting the NRC about the availability of information for this petition. You may access information related to this petition by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search on Docket ID NRC–2012–0056. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *The NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library 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. In addition, for the convenience of the reader, the ADAMS Accession Numbers are provided in a table in Section V, ''Availability of Documents,'' of this document.
- *The NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Tara Inverso, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1024; email: *Tara.Inverso@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. NRC Technical Evaluation
III. Public Comments on the Petition
IV. Ongoing NRC Activities Related to Reactor and Containment Instrumentation
V. Availability of Documents
VI. Determination of the Petition

I. Background

The NRC received a petition for rulemaking (ADAMS Accession No. ML12065A215) on February 28, 2012, and assigned it Docket No. PRM–50–105. The NRC published a notice of receipt and request for public comment in the **Federal Register** (FR) on May 23, 2012 (77 FR 30435).

The petitioner requested that the NRC amend its regulations in Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' to require all holders of operating licenses for NPPs to operate NPPs with in-core thermocouples at different elevations and radial positions throughout the reactor core to enable NPP operators to accurately measure a large range of in-core temperatures in NPP steady-state and transient conditions. The petitioner asserted that, in the event of a severe accident, in-core thermocouples would provide NPP operators with crucial information to help operators manage the accident. In support of the petition, the petitioner cited several reports and findings, including the Report of the President's Commission on the Accident at Three Mile Island [TMI]: ''The Need for Change: The Legacy of TMI,'' dated October 1979. The petitioner asserted that ''[i]n the last three decades, NRC has not made a regulation requiring that NPPs operate with in-core thermocouples at different elevations and radial positions throughout the reactor core to enable NPP operators to accurately measure a large range of in-core temperatures in NPP steady-state and transient conditions, which would help fulfill the President's Commission recommendations.'' The petitioner further stated that, if another severe accident were to occur in the United States, NPP operators would not know what the in-core temperatures would be during the progression of the accident, and concluded that, in a severe accident, core-exit thermocouples would be the primary tool used to detect inadequate core cooling and core uncovery.

II. NRC Technical Evaluation

The petitioner requested that the NRC require in-core thermocouples be installed in all NPPs; this would include both pressurized water reactors (PWRs) and boiling water reactors (BWRs). However, BWRs do not use CETs, and thermocouple response in BWR applications is not currently known. Furthermore, the experiments referenced throughout the PRM studied only PWRs. Because the issues and arguments raised in the PRM do not apply to BWRs, and because the PRM does not list any limitations on BWR

instrumentation, there is no basis provided to evaluate this PRM for BWRs. Therefore, the NRC is evaluating this PRM as it pertains to PWRs only.

During normal operation in a PWR, reactor coolant system (RCS) hot leg and cold leg temperatures are the primary indications of core condition. Measurements of RCS hot and cold leg temperatures from safety-related instrumentation provide the necessary input to a plant's reactor protection system. There are no reactor protection or plant control functions that use inputs from the CETs. Additionally, the CETs are not the only source of information relied on to initiate reactor operator responses to accident conditions. The uses of CETs will be described in more detail, as part of the NRC's evaluation of the issues raised in the PRM with respect to the use of CETs.

PRM Issue 1: Core Exit Thermocouple Limitations

The petitioner stated that, ''in a severe accident, in many cases, a predetermined core exit temperature measurement (e.g., 1200 °F) would be used to signal the time for NPP operators to transition from EOPs [Emergency Operating Procedures] to implementing SAMGs [Severe Accident Management Guidelines].'' However, experimental data indicates that CET measurements have significant limitations. A report [1] prepared by the Organization for Economic Cooperation and Development (OECD) Nuclear Energy Agency (NEA), Committee on the Safety of Nuclear Installations, entitled, ''Core Exit Temperature (CET) [2] Effectiveness in Accident Management of Nuclear Power Reactor,'' dated November 26, 2010, concluded:

- The use of CET measurements has limitations in detecting inadequate core cooling and core uncovery,
- The CET indication displays in all cases a significant delay (up to several hundred [seconds]), and
- The CET reading is always significantly lower (up to several 100 [Kelvin]) than the actual maximum cladding temperature.

The petition asserted that the NRC and the nuclear industry have ignored experimental data indicating that CET measurements have significant limitations. The results of four tests performed in the loss-of-fluid test (LOFT) facility show that: 1) There was a delay between the core uncovery and the thermocouple response, and 2) the measured core exit thermocouple response was several hundred Kelvin lower than the maximum cladding temperatures in the core. The petitioner cited NUREG/CR–3386, ''Detection of Inadequate Core Cooling with Core Exit Thermocouples: LOFT PWR Experience,'' dated November 1983 (ADAMS Accession No. ML13032A566), which states: ''There may be accident scenarios in which these [thermocouples] would not detect inadequate core cooling that preceded core damage.''

The NRC reviewed PRM Issue 1 and acknowledges that the CET limitations cited by the petitioner are extensively documented in test reports from the identified experimental programs. However, while these test programs were conducted at large-scale test facilities appropriately scaled (using a power to volume relationship) to produce thermal-hydraulic phenomena similar to phenomena that could occur in a commercial PWR, the scaling distortions introduced by the facilities and the effects of plant-specific CET installation methods preclude the direct extrapolation of the test results to reactor scale. In fact, the same OECD report referenced by the petitioner also states:

> Qualitative application/extrapolation of the CET response to reactor scale is possible. However, direct extrapolation in quantitative terms to the reactor scale should be avoided in general or done with special care due to limitations of the experimental facilities in terms of geometrical details, unavoidable distortion in the scaling of the overall geometry, and of the heat capacity of structures.

The NRC views these results within the context of their applicability to full-scale plants in order to use the data to assess the capability of the computer models used to perform full-plant simulations. The separate test facilities, such as LOFT and Primarkreislauf Test Facility Project (PKL), are simulated using computer models, and the results from the simulations are compared with the corresponding data. Once sufficient agreement between the simulation and the data is achieved, or consistent biases are determined, a full-plant simulation can be performed and more definitive, quantitative statements about CET performance can be made. Therefore, these experimental results cannot be, and are not intended to be, quantitatively extrapolated to full-scale plants, as suggested in the petition.

During normal operation, RCS hot leg and cold leg temperatures are the primary indications of core condition. Measurements of RCS hot and cold leg temperatures from safety-related instrumentation provide the necessary input to a plant's reactor protection system. There are no reactor protection or plant control functions that use inputs from the CETs.

During accident conditions, the most significant functions provided by CETs are the determination of a trend in RCS sub-cooling and the known correlation of the indicated temperature to general core conditions for the purposes of identifying the onset of core damage (i.e., a severe accident). For these purposes, the CETs provide the indication necessary to make operational decisions with respect to core damage and perform these essential functions within the expected useful range. In the initial stages of an accident, CETs provide accurate indication of core temperatures for the purposes of determining sub-cooling margin when forced circulation has been lost and confirming that the core remains covered. As an event progresses, CETs provide an indication of initial stages of core damage and are generally used as an entry condition and diagnostic tool during implementation of SAMGs.

Upon entry into the SAMGs, core exit temperature is used as one indication in a diagnostic process to determine core damage; other indications include: RCS level, RCS pressure, containment pressure, containment hydrogen concentration, nuclear instrumentation, and containment high range radiation monitors. As CET readings rise above 1200 °F, it becomes likely that the temperature for some sections of cladding will have exceeded 1800 °F, and therefore it can be assumed that core damage has commenced. With this determination, actions to restore key safety functions will continue in order to restore core cooling and to ensure that fission product barriers remain intact. At no point, either during diagnosis or follow-on actions to restore core cooling, is there an operational necessity for an exact measurement of core temperatures at various locations throughout the core. The petitioner did not provide explicit examples where knowing more precise temperatures would result in more effective operator action. Further, the NRC's evaluation of this petition and relevant information did not reveal added insights on how knowing precise in-core temperatures would result in more effective operator action in a core damage sequence. The correlation between CET readings and fuel cladding temperature, in conjunction with other indications, is sufficient for determining the onset of

[1] *Available at http://www.oecd-nea.org/nsd/docs/2010/csni-r2010-9.pdf.*

[2] Note that the OECD report uses the acronym CET to refer to core exit temperature, but the NRC uses the acronym CET to refer to core exit thermocouples in this document.

fuel damage and the need for operator action. Actions taken to restore core cooling would not depend upon a precise measurement of in-core temperature. As the accident progresses, core vessel breach determination is primarily made by utilizing containment pressure and containment radiation indications, and nuclear instrumentation. Core exit thermocouple indications are not used for this determination.

After considering the functions and indications provided by CETs in normal and accident conditions, the NRC determined that the CETs provide adequate indications for their intended purpose.

PRM Issue 2: Nuclear Power Plant Operators' Use of In-Core Thermocouples

The petition asserted that, in the event of a severe accident, in-core thermocouples would enable NPP operators to accurately measure in-core temperatures better than CETs, and would provide crucial information to help operators manage the accident; one example is an indication that it is time to transition from EOPs to implementing SAMGs. Therefore, the petition requested that all holders of operating licenses for NPPs operate NPPs with in-core thermocouples at different elevations and radial positions throughout the reactor core to enable NPP operators to accurately measure a large range of in-core temperatures in NPP steady-state and transient conditions.

As previously stated BWRs do not use CETs, and thermocouple response in BWR applications is not currently known. Furthermore, the experiments referenced throughout the PRM studied only PWRs. Therefore, the NRC is evaluating this PRM as it pertains to PWRs only. The NRC further notes that, in BWRs, saturation conditions exist within the reactor vessel and fuel temperatures are closely related to the saturation pressure. Under accident conditions, reactor vessel water level is the best indication of conditions relating to imminent core damage and drywell radiation monitors are typically the primary method for determining core damage and SAMG entry conditions. For BWRs, SAMG entry conditions are also tied to parameters such as water level, containment hydrogen concentration, and component failures. With regard to PWRs, CETs are located at various radial positions. Therefore, the intent of the petitioner's request to account for various radial temperatures is addressed by the current design.

The petition does not specify any benefit the data from in-core thermocouples could provide or how that benefit would be greater than that provided by core exit thermocouples. As discussed earlier, the limitations of CETs are already well understood and accounted for in existing SAMGs. The benefit provided by CETs, even in recognition of their limitations, is discussed in greater detail in the NRC response to PRM Issue 1. Furthermore, the petitioner cited no actions that would be driven by the additional information obtained from in-core thermocouples.

It is also important to note that the same OECD document referenced by the petitioner contains additional information that provides a perspective that is different from that of the petitioner. For example, from page 48 of the report:

> The conduct of the experiment was rather complicated with repeated openings of two blowdown lines. The timeline for the experiment was thus not very representative of a real accident. . . . Measured cladding temperatures exceeded 2100 K . . . The temperatures were in excess of 2100K for several minutes and the peak temperatures were probably several hundred degrees higher than that. Material examinations showed material formations consistent with temperatures in the range of 2800 K and in local areas over 3000 K.

''An Account of the OECD LOFT Project'' of this experiment (LP–FP–2) [3] additionally states on page 53:

> Thermocouples used in the CFM [Center Fuel Module] were calibrated as high as 2100 K. However, many of the CFM temperature measurements were affected by thermocouple cable shunting effects [formation of a new thermocouple junction due to exposure to high temperature] before the temperature at the thermocouple location reached 2100 K.

These statements indicate that in-core thermocouples may not be any more accurate than, or as reliable as, the core exit thermocouples currently used in PWRs, and that they may be subject to additional limitations. It is impractical to mount thermocouples to the fuel cladding surface or fuel spacers. Reactor vessel head modifications would be necessary, as well as the addition of a significant amount of instrumentation wiring and support structures. Furthermore, the addition of in-core thermocouples and the associated supporting components would likely result in significant adverse effects on fluid flow in the core. For instance, fin effects would disturb temperature profiles within the core, and could create calibration difficulties. In addition, installing in-core thermocouples could increase loose parts potential, independence and separation issues, and seismic considerations.

While the previous discussion applies to fuel-cladding-surface-mounted thermocouples, the NRC also considered the petitioner's request as it may relate to a requirement to install thermocouples in bulk coolant areas within the fuel matrix, such as within instrument tubes. Extensive research has been performed to characterize the relationship between liquid and vapor temperatures and heat transfer rates in the dispersed flow regime expected within the core during severe accident conditions. Significant temperature differences can exist between the bulk coolant, which would contain droplets of liquid water at saturation conditions, and the fuel cladding surface. R.S. Dougall and W.M. Rohsenow, for instance, characterized surface temperatures that exceeded saturation temperatures by 400 to 700 degrees Fahrenheit in their experimental work.[4] Subsequent work has validated Dougall's and Rohsenow's findings. Because of the significant temperature differences that can exist within the post-accident core region, thermocouples located within the instrument tubes would provide information that offers no greater benefit than that provided by the CETs.

For these reasons, the NRC determined that, for operating PWRs, in-core thermocouples are not necessary, nor would they help operators manage an accident. In addition to these reasons, the NRC notes that the installation and maintenance associated with in-core thermocouples would result in higher doses to plant workers, with no added safety benefit.

The petition requested that the requirement for in-core thermocouples be applied to ''all holders of operating licenses for [nuclear power plants].'' The NRC interprets this request as applying to both current and future holders of operating licenses under 10 CFR Part 50, as well as current and future holders of combined licenses under 10 CFR Part 52. The NRC believes that this is a reasonable interpretation, inasmuch as combined licenses under 10 CFR Part 52 combine the authority provided under a construction permit and an operating license (albeit with

[3] *Available at http://www.oecd-nea.org/nsd/reports/OECD_LOFT_final_report_T3907_May1990.pdf.*

[4] R.S. Dougall and W.M. Rohsenow, ''Film Boiling on the Inside of Vertical Tubes with Upward Flow of the Fluid at Low Qualities,'' 1963, *available at http://hdl.handle.net/1721.1/62142.*

certain conditions and restrictions as set forth in 10 CFR Part 52, Subpart C [5]) into one license. In addition, because the two existing combined licenses reference the AP1000 design certification rule (10 CFR Part 52, Appendix D), which controls the design of the reactor instrumentation, including the placement of thermocouples, the NRC interprets the petition as a request to amend the AP1000 design certification rule.

Because the core of the AP1000 design is similar to the PWRs described throughout this document, the NRC's evaluation of, and determination on, this PRM with respect to PWRs also applies to the AP1000 design and no changes to the AP1000 design are necessary.

PRM Issue 3: Post-Three Mile Island Accident Actions

The petition included a citation from an October 1979 recommendation from the President's Commission on the Three Mile Island Accident, which stated:

> Equipment should be reviewed from the point of view of providing information to operators to help them prevent accidents and to cope with accidents when they occur. Included might be instruments that can provide proper warning and diagnostic information; for example, the measurement of the full range of temperatures within the reactor vessel under normal and abnormal conditions.

The petitioner asserted that the NRC has not made a regulation requiring NPPs to operate with in-core thermocouples at different elevations and radial positions throughout the reactor core to enable NPP operators to accurately measure a large range of in-core temperatures in NPP steady-state and transient conditions, which the petitioner avows would help fulfill the President's Commission's recommendations. The petitioner further asserted that if another severe accident were to occur in the United States, NPP operators would not know what the in-core temperatures were during the progression of the accident.

Following the accident at TMI, the NRC ordered a broad range of safety enhancements at U.S. NPPs. These enhancements include sub-cooled margin monitors, post-accident monitoring instrumentation systems (including CET indications available to operators), and the reactor vessel level monitoring system. These enhancements, combined with other post-TMI requirements for enhanced EOPs and operator training, form part of the Agency's response to the recommendation of the President's Commission on the Three Mile Island Accident.

Regarding the President's Commission's example of ''measurement of the full range of temperatures within the reactor vessel under normal and abnormal conditions,'' evidence of the NRC's consideration of in-core thermocouples may be found in NUREG–0737, ''Clarification of TMI Action Plan Requirements'' (ADAMS Accession No. ML051400209), Section II.F.2, ''Instrumentation for Detection of Inadequate Core Cooling (ICC).'' Item (6) on page 3–114 under Clarifications states:

> The indication must cover the full range from normal operation to complete core uncovery. For example, water-level instrumentation may be chosen to provide advanced warning of two-phase level drop to the top of the core and could be supplemented by other indicators such as incore and core-exit thermocouples provided that the indicated temperatures can be correlated to provide indication of the existence of ICC [inadequate core cooling] and to infer the extent of core uncovery. Alternatively, full-range level instrumentation to the bottom of the core may be employed in conjunction with other diverse indicators such as core-exit thermocouples to preclude misinterpretation due to any inherent deficiencies or inaccuracies in the measurement system selected.

The alternative noted in this excerpt, to use full-range level indication combined with core exit thermocouples, was ultimately the preferred option. Part of the consideration to use the alternative may be found in the NRC's stated position on ICC that requires unambiguous, easy-to-interpret indication of ICC. The NRC chose to use process variables that map directly to clear, easy-to-interpret emergency operating procedures to elicit safe and consistent operator responses to accident scenarios.

PRM Issue 4: Consideration of Experimental Data

The petitioner asserted that the NRC and Westinghouse do not consider that experimental data at four facilities (LOFT, PKL, Rig of Safety Assessment Large-Scale Test Facility (ROSA/LSTF), and OECD/NEA computer codes validation project (PSB–VVER)) indicate that CET measurements would not be an adequate indicator for when to transition from EOPs to implementing SAMGs in a severe accident. The petition listed 13 conclusions from the OECD report that are common to the evaluation of the tests in all four facilities summarized by that report:

- ''The use of CET measurements has limitations in detecting inadequate core cooling and core uncovery;''
- ''The CET indication displays in all cases a significant delay (up to several 100 [seconds]);''
- ''The CET reading is always significantly lower (up to several 100 [Kelvin]) than the actual maximum cladding temperature;''
- ''CET performance strongly depends on the accident scenarios and the flow conditions in the core;''
- ''The CET reading depends on water fall-back from the upper plenum (due to: e.g., reflux condensing [steam generator] mode or water injection) and radial core power profiles. During significant water fall-back the heat-up of the CET sensor could even be prevented;''
- ''The colder upper part of the core and the cold structures above the core are contributing to the temperature difference between the maximum temperature in the core and the CET reading;''
- ''The steam velocity through the bundle is a significant parameter affecting CET performance;''
- ''Low steam velocities during core boil-off are typical for [small-break loss-of-coolant accident] transients and can advance 3D flow effects;''
- ''In the core as well as above (i.e., at the CET measurement level) a radial temperature profile is always measured (e.g., due to radial core power distribution and additional effects of core barrel and heat losses);''
- ''Also at low pressure (i.e., shut down conditions) pronounced delays and temperature differences are measured, which become more important with faster core uncovery and colder upper structures;''
- ''Despite the delay and the temperature difference the CET reading in the center reflects the cooling conditions in the core;''
- ''Any kind of [accident management] procedures using the CET indication should consider the time delay and the temperature difference of the CET behavior;'' and
- ''In due time after adequate core cooling is re-established in the core the CET corresponds to no more than the saturation temperature.''

Finally, the petitioner continued to reference the OECD report, stating that, during the LOFT LP–FP–2 experiment when maximum core temperatures were measured to exceed 3300 °F, CETs were

[5] The conditions and limitations of a combined license issued under 10 CFR Part 52 are consistent with, and are intended to comply with, the statutory requirements for combined licenses in Section 185b of the Atomic Energy Act of 1954, as amended.

typically measured at 800 °F (more than 2500 °F lower than the maximum core temperatures). He provided that ''during the rapid oxidation phase the CET appeared essentially to be disconnected from core temperatures.''

The NRC and the industry have long acknowledged the limitations of CETs, but conclude that the use of CETs remains appropriate and would help operators to manage an accident. This awareness is documented in several reports, such as ''Limitations of Detecting Inadequate Core Cooling'' (U.S. Department of Energy's Office of Scientific and Technical Information ID 6797561) published in 1984 and WCAP–14696–A, Revision 1, ''Westinghouse Owners Group Core Damage Assessment Guidance,'' dated July 1996 (ADAMS Accession No. ML993490267). The delayed indication would not necessarily be a concern during a severe accident. First, the NPP staff relies on other indications to diagnose conditions, such as the reactor vessel level instrumentation system, hot-leg resistance temperature detectors, and containment hydrogen and radiation monitors. Second, whereas the CET indication delay may be up to a few minutes, post-accident operator actions are determined and implemented on a scale that exceeds several minutes. On this time scale, the noted time delay is acceptable.

The petition cited a number of conclusions about CET deficiencies that were noted in the OECD report, and cited on page 8 of the PRM, but the PRM did not specifically acknowledge the following statement from page 129 of the OECD report: ''Despite the delay and the temperature difference the CET reading in the center reflects the cooling conditions in the core.'' It is the NRC's position that scaling challenges, described earlier in this document, exist when extrapolating the results to a full-scale NPP, and these challenges tend to exacerbate the extent of the CET deficiencies cited in the experimental results. Therefore, while the noted deficiencies should be considered qualitatively, overall, in terms of plant applicability, the CETs performed the intended function, as described in the NRC's response to PRM Issue 2.

III. Public Comments on the Petition

The NRC received three public comment submissions on the PRM, one each from the following: the Nuclear Energy Institute (NEI), Exelon Generation Company, and the petitioner. In addition to those submissions, the NRC received a late-filed comment submission from the petitioner in response to the NEI comment submission. The late-filed comment submission, submitted by the PRM–50–105 petitioner, contains some reiteration of information and assertions in PRM–50–105. The NRC is not addressing those portions of the late-filed comment response. However, the late-filed comment submission also discussed matters related to the use of in-core thermocouples in gamma thermometers, the use of in-core thermocouples in the Economic Simplified Boiling Water Reactor (ESBWR) design, and the radiation dose to workers due to in-core thermocouples; these issues were not raised in the original PRM. Therefore, the NRC is addressing these three new matters in this comment response section.

The comments are grouped into four comment categories: General Discussion of PRM–50–105, Comments on In-Core Thermocouples, Comments Related to Westinghouse AP1000, and Comments on Experimental Data. A comment identifier (e.g., NEI–1) follows each comment summary. The comments and the associated NRC responses follow.

General Discussion of PRM–50–105

Comment: The NRC should not amend its regulations to require all holders of operating licenses to operate nuclear power plants with in-core thermocouples at different elevations and radial positions throughout the reactor core. (NEI–1)

NRC Response: The NRC agrees with this comment. The NRC is denying PRM–50–105 for the reasons set forth in this document.

Comments on In-Core Thermocouples

Comment: Use of in-core thermocouples would result in higher doses to workers both to implement plant modifications and to maintain the proposed system with minimum if any benefit to plant safety. (NEI–2)

NRC Response: The NRC agrees with the comment, but notes that the comment did not provide any basis for this assertion.

Comment: In response to another commenter's statement that in-core thermocouples would result in a higher radiation dose to workers both to implement plant modifications and to maintain the proposed system with minimum, if any, benefit to plant safety, one commenter provided the following quote from General Electric Hitachi (GEH) Nuclear Energy: ''A [gamma thermometer] system has no moving parts, no under vessel tubing, virtually no radiation dose to maintenance since it is a fixed in-core probe, and is expected to be very reliable.'' [6] The commenter asserts that in-core thermocouples could be placed inside instrument tubes, distributed through the reactor core, like gamma thermometers are, and thus cause virtually no radiation dose to workers during maintenance. (Leyse2–5)

NRC Response: The NRC disagrees with the comment that in-core thermocouples would cause virtually no radiation dose to workers during maintenance. The NRC notes that the GEH report, referenced by the PRM as support for the comment, applies only to a comparison of the current BWR moveable and retractable probe (the TIP system) with the ESBWR fixed incore gamma thermometers. It does not apply to the installation of in-core thermocouples in currently operating reactors. The NRC agrees that the use of fixed versus bottom entry retractable sensors may reduce exposure for routine maintenance. The NRC continues to believe that in-core thermocouples would result in a higher radiation dose to workers while implementing the necessary plant modifications for installation and to maintain the proposed system, particularly when replacement of sensor strings due to long-term radiation exposure is required. Also, except for existing tubing for bottom-entry removable sensors, any existing instrument tubes are already occupied. It is likely that new instrument tubes would need to be installed. Tubes installed through the vessel head would also require provisions for mechanical and electrical connections. These installation efforts, whether the new tubing enters the core through the vessel head or bottom, are likely to require significant worker exposure, and may also raise concerns related to pressure boundary integrity.

Comment: In some designs, in-core thermocouples could be more susceptible to failures and misdiagnosis than CETs because of proximity to thermal and radiation sources. It is not feasible to attach thermocouples directly to the fuel cladding. Thermocouples would need to be located in existing instrument tubes (e.g., BWR Local Power Range Monitor tubes) and would not be in direct contact with the reactor coolant. Therefore, thermocouples would provide only indirect readings of fuel temperature and would be subject to heat transfer delays/response times. The time response and accuracy of the reading as it relates to the reactor

[6] GE Hitachi Nuclear Energy, ''Licensing Topical Report: Gamma Thermometer System for [Local Power Range Monitor] LPRM Calibration and Power Shape Monitoring,'' NEDO–33197–A, p. 1 (available at ADAMS Accession No. ML102810320).

coolant would be highly questionable. The presence of the fuel channel on a BWR fuel assembly would further inhibit and interfere with the readings of a thermocouple in an instrument tube. (NEI–3) (Exelon-2)

NRC Response: The NRC acknowledges that in-core thermocouples could be more susceptible to failure and misdiagnosis in some designs. However, as stated throughout this document, because CETs perform their desired functions and because precise knowledge of in-core temperatures would not change operator actions, further consideration of the potential limitations of in-core thermocouples is not necessary.

Comment: In response to another commenter's assertion that in-core thermocouples may be more susceptible to failures and misdiagnosis than CETs, one commenter stated that in-core thermocouples have been tested and used in nuclear reactors for decades as the primary component of in-core gamma thermometers (devices that measure gamma flux in nuclear reactors). Radcal gamma thermometers were installed in PWRs in the 1980s. Radcal thermometers are also installed in BWRs. General Electric Hitachi Nuclear Energy has plans to use in-core thermocouples in gamma thermometers in the ESBWR design. (Leyse2–1) (Leyse2–2) (Leyse2–4)

NRC Response: The NRC continues to believe that CETs are acceptable for use in current applications. Where current nuclear power plants have fixed in-core gamma thermometers, they are for power shape monitoring and calibration, not for actual temperature measurements. Further, the gamma thermometer GEH plans to install in the ESBWR is a device for measuring the gamma flux for the purpose of calibration of the local power range monitors and power shape monitoring; the gamma thermometers are *not* for the purpose of measuring axial and radial core temperature. The GEH gamma thermometers utilize a local differential temperature directly within the sensor at the specific sensor location to infer the gamma flux inside the reactor core rather than the actual temperature measurements at that location. Actual temperature measurements are not available outside the reactor core. For these reasons, the information about the use of gamma thermometers at nuclear power reactors and in the ESBWR design certification do not affect the NRC's position that CETs are acceptable for use in current applications to perform their specified function.

Comment: An Idaho National Laboratory (INL) report stated that INL ''developed and evaluated the performance of a high temperature resistant thermocouple that contains doped molybdenum and a niobium alloy. Data from high temperature (up to 1500 °C), long duration (up to 4000 hours) tests and on-going irradiations at INL's Advanced Test Reactor demonstrate the superiority of these sensors to commercially-available thermocouples. However, several options have been identified that could further enhance their reliability, reduce their production costs, and allow their use in a wider range of operating conditions.'' [7] (Leyse2–3)

NRC Response: The information in the comment is not relevant to the PRM, and therefore does not change the NRC's position that CETs are acceptable for use in performing their specified function, thereby obviating the need to install in-core thermocouples. The NRC also notes that the pre-publication INL report dated 2009 referenced by the commenter described a research product that is not yet ready for commercial use by the nuclear industry. The NRC does not believe that the statements in the report that are referenced in the comment are relevant to the acceptability of CETs in current applications.

Comment: The transition from EOPs to SAMGs based on existing plant parameters is adequate. Pressurized Water Reactors already use CETs to make the transition to SAMGs. The potential delay in the response of indirectly reading in-core thermocouples could actually be longer than the response of other plant parameters, including CETs, in identifying potential severe accident conditions. (Exelon-3)

NRC Response: The NRC agrees that the current transition from EOPs to SAMGs is adequate. The NRC notes that SAMGs are developed based on the recognition that CETs could differ from actual core temperatures. This concept is described in Section II, ''NRC Technical Evaluation,'' of this document.

Comment: During steady-state operations for both PWRs and BWRs, the fuel cladding (surface) temperature is a function of coolant Temperature—Enthalpy (T–H) properties. The coolant steady-state properties (i.e., temperature) do not vary significantly axially or radially during steady-state operation and therefore, in-core thermocouples would not provide useful information. There are more accurate means of measuring core conditions than in-core thermocouples already in place. Adding in-core thermocouples would not improve the ability or accuracy of measuring core conditions. (Exelon-1)

NRC Response: The NRC agrees with the comment. The PWR in-core conditions, for example, are measured using hot and cold leg temperatures, reactor coolant pressure, and neutron flux. These parameters are then used as inputs to the reactor protection system to ensure that the reactor shuts down if core operating conditions deviate significantly from the expected normal operating conditions. The BWRs are equipped with similar equipment intended for monitoring normal, steady-state operation. The addition of in-core thermocouples, either to measure fuel surface or reactor coolant temperatures, would add little value to the information already available for monitoring normal operation.

Comment: The petitioner asserted that, in the event of a severe accident, in-core thermocouples would provide nuclear power plant operators with ''crucial information to help operators manage the accident.'' However, the petitioner provided no basis that actions taken by operators would be more effective than actions based on existing CETs. Operators are trained to recognize off-normal operating conditions that have potential for resulting in core damage and to maneuver the plant to a more conservative operating envelope (i.e., provide coolant to the reactor core). In a severe accident, operator strategies control parameters across large regions of the core or across the entire core. The additional information regarding local fuel temperature provided by in-core thermocouples would not be crucial relative to restoring coolant, nor would it change the steps and actions available to operators to maintain or restore adequate core cooling conditions. There is no evidence to show that temperatures sensed at a single location could be used more effectively than actions based on CET temperatures. (Exelon-4) (NEI–4) (NEI–6)

NRC Response: The NRC agrees with the comment. Precise measurement of local fuel temperatures at distinct locations throughout the core would not provide essential data for informing severe accident management decisions, and the petitioner cited no actions that would be driven by the additional information obtained from in-core

[7] Joshua Daw, et al., Idaho National Laboratory, ''High Temperature Irradiation-Resistant Thermocouple Performance Improvements,'' INL/CON–09–15267, Sixth American Nuclear Society International Topical Meeting on Nuclear Plant Instrumentation, Control, and Human-Machine Interface Technologies, April 2009, p. 1 (available at *http://www.inl.gov/technicalpublications/documents/4235634.pdf*).

thermocouples. In the event of an extended loss of core cooling that leads to core damage, the actions taken by the operators will be focused on restoring core cooling, with or without the knowledge of precise fuel temperatures in the core.

Comments Related to Westinghouse AP1000

Comment: One commenter provided several comments on the emergency response guidelines for Westinghouse's AP1000 design:

- Westinghouse maintains that core exit gas temperature would reach 1200 °F in Time Frame 1, but the LOFT LP–FP–2 experiments show that core exit temperatures were measured at around 800 °F when in-core thermocouples measured fuel cladding temperatures exceeded 3300 °F. Thus, after the onset of the rapid zirconium-steam reaction, core exit temperatures were measured at around 800 °F. (Leyse–4)
- There are problems with Westinghouse's emergency response guidelines for the AP1000. Plant operators are instructed to actuate the AP1000 containment hydrogen igniters after the CET measurements exceeded 1200 °F, which would most likely be some time after a meltdown had commenced. (Leyse–6)
- There are problems with Westinghouse's plan to have plant operators rely on CET measurements in the event of a severe accident, because plant operators might reflood an overheated core without realizing that the core was in fact overheated. Consider a scenario where there were similar temperature differences between in-core and core exit temperatures as were observed in LOFT LP–FP–2. If plant operators were to reflood the core when core exit temperatures were well below 1200 °F, the core could already be overheated (i.e., fuel-cladding temperatures could be over 3300 °F), nearing the temperature where zirconium melts. In such a case there would also be some liquefaction of core components because of eutectic reactions (i.e., the eutectic reaction between zirconium and stainless steel) taking place at temperatures as low as 2200 °F. Unintentionally reflooding an overheated core could be very dangerous. In a severe accident, during the reflooding of an overheated reactor core up to 300 kilograms of hydrogen could be generated in one minute. (Leyse–7)
- It is evident that with Westinghouse's plan to have plant operators rely on CET measurements in the event of a severe accident, operators could unintentionally reflood an overheated core, which would rapidly generate additional hydrogen, at a rate as high as 5.0 kilograms per second, which could, in turn, compromise the containment if the hydrogen were to detonate. (Leyse–8)
- For severe accidents, Westinghouse's plan for AP1000 plant operators to rely on core exit temperature measurements to monitor the condition of the core and to wait for a core exit temperature measurement of 1200 °F to signal when to actuate the hydrogen igniters and implement other procedures would be neither productive nor safe. (Leyse–10)

NRC Response: The NRC disagrees with the comments that the Westinghouse emergency response guidelines for the AP1000 design are inadequate, based upon CET limitations. As discussed throughout this document, the CET limitations noted in both this comment and the PRM are acknowledged by the NRC and have been documented in industry reports. The CETs, even with their known limitations, are sufficient to provide the necessary information to nuclear power plant operators. More precise knowledge of in-core temperatures would not change the operational decisions necessary in the event of a severe accident. Therefore, the NRC does not believe that the comment provided information supporting the PRM's request that nuclear power plant licensees be required by rule to install in-core thermocouples.

To the extent that the comments raise issues with respect to the adequacy of the AP1000 design and hydrogen control, the NRC regards this portion of the comment to be outside the scope of the issues raised in this PRM. The NRC notes, however, that these AP1000 issues were raised in a 10 CFR 2.206 petition on Vogtle, Units 3 and 4 (ADAMS Accession No. ML12061A218), and resolved as part of the NRC's action on the petition. The NRC's resolution of the 10 CFR 2.206 petition is available at ADAMS under Accession No. ML13105A308.

Comments on Experimental Data

Comment: The commenter cited the OECD Nuclear Energy Agency report, which states: ''During the rapid oxidation phase [core exit temperatures] appeared essentially to be disconnected from core temperatures.'' (Leyse–5)

NRC Response: The following sentence appears in the same section of the OECD report referenced by the commenter: ''For core runaway conditions with rapid fuel oxidation, LOFT results indicated that the CETs essentially were disconnected from the core temperatures. This is perhaps a lesser problem since such conditions cannot be well addressed by accident management measures.'' Currently, CET indications are used to help determine core uncovery and initiate appropriate actions during that phase of an accident. In following phases, core temperatures do not provide information that is used to initiate actions to mitigate an accident.

Comment: Two of the main conclusions from data from experiments simulating design basis accidents conducted at four different facilities are that core exit temperature measurements display in all cases a significant delay (up to several hundred seconds) and that core exit temperature measurements are always significantly lower (up to several hundred degrees Celsius) than the actual maximum cladding temperature. (Leyse–9)

NRC Response: The NRC agrees with this comment. The NRC was directly involved in most of the experimentation referenced by the petitioner, and the NRC and other nuclear industry stakeholders have been aware for several years of the CET limitations concluded from the experiments and verified by independent analyses. Evidence of this can be seen in WCAP–14696–A, Revision 1 (November 1999; ADAMS Accession No. ML993490267), which states that ''Analyses performed for the WOG [Westinghouse Owners Group] ERGs [Emergency Response Guidelines] for indication of inadequate core cooling concluded that the temperature indicated by the core exit thermocouples, especially during transient heat up conditions, is always several hundred degrees lower than the fuel rod cladding temperatures.'' The NRC notes that SAMGs are developed based on the recognition that CETs could differ from actual core temperatures. This concept is described in Section II, ''NRC Technical Evaluation,'' of this document.

Miscellaneous Comments

Comment: An April 2012 Advisory Committee on Reactor Safeguards (ACRS) report states that the NRC ''has recognized the need for enhanced reactors . . . instrumentation and is in the process of adding this to the implementation of the NTTF [Near-Term Task Force] recommendations.'' And the NTTF report ''recommends strengthening and integrating onsite emergency response capabilities such as EOPs and SAMGs.'' The April 2012 ACRS report states that ''such integration could focus on the need to clarify the transition points'' that would occur in a NPP accident. In-core

thermocouples would fulfill the need for enhanced reactor instrumentation. In-core thermocouples would provide NPP operators with crucial information to help them track the progression of core damage and manage an accident; for example, indicating the correct time to transition from EOPs to implementing SAMGs. (Leyse–1)

NRC Response: The NRC disagrees with this conclusion. As stated previously in this document, at no point, neither during diagnosis nor follow-on actions to restore cooling, is there an operational necessity for an exact measurement of core temperatures at various locations throughout the core. However, as noted in Enclosure 3 to SECY–12–0095, ''Tier 3 Program Plans and 6-month Status Update in Response to Lessons Learned from Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami,'' dated July 13, 2012 (ADAMS Accession No. ML12208A210), the NRC indicated that it added the ACRS recommendation that ''Selected reactor and containment instrumentation should be enhanced to withstand beyond-design-basis accident conditions'' to the Tier 3 activities implementing a set of the NRC's Near-Term Task Force (NTTF) recommendations (*Recommendations for Enhancing Reactor Safety in the 21st Century,* dated July 12, 2011, ADAMS Accession No. ML112510271). The scope of the Tier 3 long-term evaluation is much broader than, and does not focus on, the use of thermocouples. Rather, the Tier 3 evaluation will focus on the entire suite of instrumentation available to operators during a beyond-design-basis accident.

Comment: BWRs need to operate with in-core thermocouples and noted the following:

- CETs are not installed in BWRs. In the event of a severe accident, BWRs are supposed to detect inadequate core cooling and core uncovery by measuring the water level in the reactor core. However, ''BWR high drywell temperature and low pressure accidents ([for example,] LOCAs) can cause the water level to read erroneously high . . . and BWR water level readings are unreliable after core damage.'' (Leyse–2a)
- By the time BWR operators confirm an accelerated core melt (by measuring increased reactor and containment pressure rates and/or wetwell water temperature rises), the reactor core would already be overheated and reflooding an overheated core could generate hydrogen, at rates as high as 5.0 kg per second. (Leyse–2b)
- In the event of a BWR severe accident, in-core thermocouple measurements would be more accurate and immediate for detecting inadequate core cooling and core uncovery than readings of the reactor water level, reactor pressure, containment pressure, or wetwell water temperature. (Leyse–3)

NRC Response: The NRC considers this comment to be outside the scope of the matters raised in the PRM. As discussed at the beginning of the NRC's technical evaluation of this PRM, and in ''PRM Issue 2: Nuclear Power Plant Operators' Use of In-Core Thermocouples,'' the NRC is evaluating the PRM as it pertains to PWRs only for the reasons indicated in those sections. Furthermore, the section addressing PRM Issue 2 describes some challenges with the use of in-core thermocouples, both surface-mounted thermocouples and thermocouples in bulk coolant areas. Those challenges would exist in BWR applications, as well.

Comment: The proposed additional instrumentation is relevant only to postulated core conditions where CETs indicate some small amount of sub-cooling while in-core thermocouples indicate locally higher temperatures with less sub-cooling. Where CET sub-cooling is minimal, operators are trained to take actions to increase this margin. Existing procedures and a predetermined CET value concurrently provide adequate indication for plant operators to transition from EOPs to implementing SAMGs. (NEI–5)

NRC Response: The NRC agrees with the comment. As stated in response to comments Exelon–4/NEI–4/NEI–6 and Leyse–5, operator actions are not focused on localized core conditions. Rather, actions are based on bulk CET readings. These readings are established in consideration of expected differences between local conditions and the associated CET conditions.

IV. Ongoing NRC Activities Related to Reactor and Containment Instrumentation

As noted in the ''Miscellaneous Comments'' subsection of Section III of this document, the NRC has added the ACRS recommendation that ''Selected reactor and containment instrumentation should be enhanced to withstand beyond-design-basis accident conditions'' to the Tier 3 activities implementing a set of the NRC's NTTF recommendations. The scope of the Tier 3 long-term evaluation will focus on the entire suite of instrumentation available to operators during a beyond-design-basis accident. These activities will support decisions on whether there is a need for subsequent regulatory action, including rulemaking, in that area. If the NRC decides that rulemaking is necessary in the area of reactor instrumentation, the public will have an opportunity to provide comments as part of publication of a proposed rule in the **Federal Register.**

V. Availability of Documents

The following table provides information on how to access the documents referenced in this document. For more information on accessing ADAMS, see the **ADDRESSES** section of this document.

Date	Document	ADAMS accession number/**Federal Register** citation/URL
February 28, 2012	Incoming Petition (PRM–50–105) from Mr. Mark Leyse	ML12065A215.
May 23, 2012	Mr. Mark Leyse; Notice of Receipt of Petition for Rulemaking	77 FR 30435.
November 26, 2010	Organisation de Cooperation et de Developpement Economiques; ''Core Exit Temperature (CET) Effectiveness in Accident Management of Nuclear Power Reactor (NEA/CSNI/R(2010)9)''.	*http://www.oecd-nea.org/nsd/docs/2010/csni-r2010-9.pdf.*
1963	Dougall, R.S. and W.M. Rohsenow, ''Film Boiling on the Inside of Vertical Tubes with Upward Flow of the Fluid at Low Qualities''.	*http://hdl.handle.net/1721.1/62142.*
January 1, 1974	Adams, J.P. and G.E. McCreery, ''Limitations of Detecting Inadequate Core Cooling''.	*http://www.osti.gov/energycitations/product.biblio.jsp?osti_id=6797561.*
November 1999	WCAP–14696–A, Revision 1, ''Westinghouse Owners Group Core Damage Assessment Guidance''.	ML993490267.
November 1980	NUREG–0737, ''Clarification of TMI Action Plan Requirements''	ML051400209.
July 13, 2012	Enclosure 3 to SECY–12–0095, ''Tier 3 Program Plans and 6-month Status Update in Response to Lessons Learned from Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami''.	ML12208A210.

Date	Document	ADAMS accession number/**Federal Register** citation/URL
October 2010	Licensing Topical Report, ''Gamma Thermometer System for LPRM Calibration and Power Shape Monitoring''.	ML102810320.
April 2009	Idaho National Laboratory, ''High Temperature Irradiation-Resistant Thermocouple Performance Improvements''.	*http://www.inl.gov/technicalpublications/documents/4235634.pdf.*
February 28, 2012	2.206 Petition on Vogtle, Units 3 and 4	ML12061A218.
April 30, 2013	Closure Letter to Mr. Mark Leyse re. 2.206 Petition on Vogtle, Units 3 and 4.	ML13105A308.
July 12, 2011	Recommendations for Enhancing Reactor Safety in the 21st Century	ML112510271.
August 2, 2012	Comment Submission (1) from Nuclear Energy Institute	ML12216A082.
August 6, 2012	Comment Submission (2) from Mr. Mark Leyse	ML12219A362.
August 7, 2012	Comment Submission (3) from Exelon Generation	ML12230A296.
August 22, 2012	Comment Submission (4) from Mr. Mark Leyse	ML12237A263.

VI. Determination of the Petition

During normal operation in a PWR, RCS hot leg and cold leg temperatures are the primary indications of core condition. Measurements of RCS hot and cold leg temperatures from safety-related instrumentation provide the necessary input to a plant's reactor protection system. There are no reactor protection or plant control functions that use inputs from the CETs. Additionally, the CETs are not the only source of information relied on to initiate reactor operator responses to accident conditions.

The NRC has determined that there is no operational necessity for an exact measurement of core temperatures at various locations throughout the core. The petitioner provided no justification why the precise knowledge of core temperature would enhance safety or change operator actions during normal or accident conditions. Furthermore, there are no reactor protection or plant control functions that use inputs from the CETs.

Contrary to the petition's assertion that an OECD report supports a determination that CETs have limitations, the NRC notes that the same OECD report stated that ''despite the delay and the difference in the measured temperatures, the time evolution of the CET signal readings in the center section seem to reflect the change of the cooling conditions in the core and thus the tendency of the maximum cladding temperatures quite well.'' The NRC acknowledges the limitations of CETs but concludes that CETs are sufficiently accurate to support appropriate operator action in a timely fashion during an accident. The NRC's conclusion is consistent with the conclusions of various industry organizations that the use of CETs is appropriate and safe.

For these reasons, the NRC declines to undertake rulemaking to require installation and use of in-core thermocouples. Accordingly, the NRC is denying PRM–50–105 in accordance with 10 CFR 2.803. The NRC's decision to deny the PRM included consideration of public comments received on the PRM.

Dated at Rockville, Maryland, this 6th day of September, 2013.

For the Nuclear Regulatory Commission.

Richard J. Laufer,

Acting Secretary of the Commission.

[FR Doc. 2013–22234 Filed 9–11–13; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0859; Directorate Identifier 2012–NM–090–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA withdraws a notice of proposed rulemaking (NPRM) that proposed to rescind airworthiness directive (AD) 2008–06–03, which applies to certain The Boeing Company Model 737–600, –700, –700C, –800 and –900 series airplanes; and Model 757–200, –200PF, –200CB, and –300 series airplanes. The NPRM would have rescinded AD 2008–06–03, which requires an inspection to determine if certain motor-operated shutoff valve actuators for the fuel tanks are installed, and related investigative and corrective actions if necessary. AD 2008–06–03 also requires revising the Airworthiness Limitations (AWLs) section of the Instructions for Continued Airworthiness to incorporate certain AWLs. Since the NPRM was issued, we have determined that it does not adequately address the safety concerns. Accordingly, the NPRM is withdrawn.

DATES: As of September 12, 2013, the proposed rule, which was published on August 27, 2012 (77 FR 51722), is withdrawn.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD action, the proposed rule (77 FR 51722, August 27, 2012), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Rebel Nichols, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6509; fax: (425) 917–6590; email: *Rebel.Nichols@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We proposed to amend 14 CFR part 39 with a notice of proposed rulemaking (NPRM) to rescind AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008). AD 2008–06–03 applies to the specified products. The NPRM published in the **Federal Register** on August 27, 2012 (77 FR 51722). The NPRM proposed to rescind AD 2008–06–03, which requires an inspection to determine if certain motor-operated shutoff valve actuators for the fuel tanks are installed, and related investigative and corrective actions if necessary. AD 2008–06–03 also requires revising the AWLs section of the Instructions for Continued

Airworthiness to incorporate AWL No. 28–AWL–21, No. 28–AWL–22, and No. 28–AWL–24 (for Model 737–600, –700, –700C, –800, and –900 series airplanes); and No. 28–AWL–23, No. 28–AWL–24, and No. 28–AWL–25 (for Model 757–200, –200PF, –200CB, and -300 series airplanes). AD 2008–06–03 resulted from fuel system reviews conducted by the manufacturer. The proposed actions were intended to prevent an unsafe condition from being introduced on airplanes affected by AD 2008–06–03.

Comments

We gave the public the opportunity to participate in considering the proposal (77 FR 51722, August 27, 2012) to rescind AD 2008–03–03, Amendment 39–15415 (73 FR 13081, March 12, 2008). The following presents relevant comments received on the proposal and the FAA's response to those comments.

Requests To Clarify ''Different Unsafe Condition''

FedEx, American Airlines, and Boeing requested clarification of the different unsafe condition introduced by the actions required by AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008). Boeing also stated that the NPRM (77 FR 51722, August 27, 2012) does not indicate if the different unsafe condition is applicable to all actuator locations required by AD 2008–06–03.

We agree that clarification of the different unsafe condition is necessary. AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008), addresses the potential for an electrical current to flow through certain motor-operated shutoff valve actuators into the fuel tank. The new motor-operator valve (MOV) actuators are required by AD 2008–06–03 for three locations on Model 737 airplanes and six or seven locations on Model 757 airplanes (depending on configuration); and that AD addresses an unsafe condition related to Special Federal Aviation Regulation No. 88 (''SFAR 88'' (66 FR 23086, May 7, 2001), Amendment 21–78, and subsequent Amendments 21–82 and 21–83).

However, the new motor-operated shutoff valve actuators have been found to have a risk of latent failure. At two of the locations on Model 737 airplanes and at three locations on Model 757 airplanes, this actuator failure could result in a different unsafe condition—i.e., an inability to shut off fuel flow to an auxiliary power unit (APU) (on Model 757 airplanes only) or engine during an engine fire. This latent failure is not a safety risk in the other three to four locations.

We have determined that AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008), should not be rescinded, but should continue to require actions that address SFAR 88-related safety. Because AD 2008–06–03 does address a significant safety risk, it is not in the interest of safety to rescind that AD. For the new MOV actuators, we are considering further rulemaking to address the certain locations where a latent failure of the actuator could result in a failure to shut off fuel flow during an engine fire.

Request To Extend Compliance Time

Allegiant Air supported the proposed rescission (77 FR 62833, August 27, 2012) and requested that, if the FAA decided not to adopt the rescission, the FAA provide an extension of the compliance time required by AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008), by using a ''global'' alternative method of compliance (AMOC). Allegiant Air stated that the proposed rescission has brought uncertainty to operators of the affected Model 737 and 757 airplanes. We infer the subject of the uncertainty involves an operator still needing to schedule time to do the required actions prior to the compliance time required in AD 2008–06–03.

We disagree. We have not received any AMOC requests to extend the compliance time. We also have not received justification to extend an AMOC to all the airplanes affected by AD 2008–06–03, Amendment 39–15415 (73 FR 13081, March 12, 2008). However, under the provisions of paragraph (i) of AD 2008–06–03, we will consider individual operator requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. We have determined that no change to AD 2008–06–03 is necessary.

FAA's Conclusions

Upon further consideration, we have determined that the NPRM (77 FR 51722, August 27, 2012) does not adequately address the safety concern. Accordingly, the NPRM is withdrawn.

Withdrawal of the NPRM (77 FR 51722, August 27, 2012) does not preclude the FAA from issuing another related action nor commit the FAA to any course of action in the future.

Regulatory Impact

Since this action only withdraws an NPRM (77 FR 51722, August 27, 2012), it is neither a proposed nor a final rule and therefore is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Withdrawal

Accordingly, we withdraw the NPRM, Docket No. FAA–2012–0859, Directorate Identifier 2012–NM–090–AD, which was published in the **Federal Register** on August 27, 2012 (77 FR 51722).

Issued in Renton, Washington, on September 5, 2013.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–22187 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 312

RIN 3084–AB20

Children's Online Privacy Protection Rule Proposed Parental Consent Method; Imperium, LLC Application for Approval of Parental Consent Method

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Request for public comment.

SUMMARY: The Federal Trade Commission requests public comment concerning the proposed parental consent method submitted by Imperium, LLC (''Imperium'') under the Voluntary Commission Approval Processes provision of the Children's Online Privacy Protection Rule.

DATES: Written comments must be received on or before October 9, 2013.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/pmcoppaimperiumapp,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex E), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Kandi Parsons, Attorney, (202) 326–2369, or Peder Magee, Attorney, (202) 326–3538, Division of Privacy and Identity Protection, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Section A. Background

On October 20, 1999, the Commission issued its final Rule [1] pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501 *et seq,* which became effective on April 21, 2000.[2] On December 19, 2012, the Commission amended the Rule, and these amendments became effective on July 1, 2013.[3] The Rule requires certain Web site operators to post privacy policies and provide notice, and to obtain verifiable parental consent, prior to collecting, using, or disclosing personal information from children under the age of 13. The Rule enumerates methods for obtaining verifiable parental consent, while also allowing an interested party to file a written request for Commission approval of parental consent methods not currently enumerated.[4] To be considered, the party must submit a detailed description of the proposed parental consent method, together with an analysis of how the method meets the requirements for parental consent described in 16 CFR 312.5(b)(1).

Pursuant to Section 312.12(a) of the Rule, Imperium has submitted a proposed parental consent method to the Commission for approval. The full text of its application is available on the Commission's Web site at *www.ftc.gov.*

Section B. Questions on the Parental Consent Method

The Commission is seeking comment on the proposed parental consent method, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the Commission's consideration of the petition and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the number of the question being answered. For all comments submitted, please provide any relevant data, statistics, or any other evidence, upon which those comments are based.

1. Is this method already covered by existing methods enumerated in Section 312.5(b)(1) of the Rule?

2. If this is a new method, provide comments on whether the proposed parental consent method meets the requirements for parental consent laid out in 16 CFR 312.5(b)(1). Specifically, the Commission is looking for comments on whether the proposed parental consent method is reasonably calculated, in light of available technology, to ensure that the person providing consent is the child's parent.

3. Does this proposed method pose a risk to consumers' personal information? If so, is that risk outweighed by the benefit to consumers and businesses of using this method?

Section C. Invitation To Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 9, 2013. Write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, such as Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, including medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[5] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/pmcoppaimperiumapp,* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex E), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 9, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–22120 Filed 9–11–13; 8:45 am]

BILLING CODE 6750–01–P

[1] 64 FR 59888 (1999).

[2] 16 CFR Part 312.

[3] 78 FR 3972 (2013).

[4] 16 CFR 312.12(a); 78 FR at 3991–3992, 4013.

[5] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2011–0708; FRL–9900–87–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Second Ten-Year Carbon Monoxide Maintenance Plan for Fort Collins

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted to EPA by the State of Colorado. On May 25, 2011, the Governor of Colorado's designee submitted a Clean Air Act (CAA) section 175A(b) second 10-year maintenance plan for the Fort Collins area for the carbon monoxide (CO) National Ambient Air Quality Standard (NAAQS). This limited maintenance plan (LMP) addresses maintenance of the CO NAAQS for a second 10-year period beyond the original redesignation. This action is being taken under sections 110 and 175A of the CAA.

DATES: Written comments must be received on or before October 15, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2011–0708, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: clark.adam@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Carl Daly, Director, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Carl Daly, Director, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instruction on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Adam Clark, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules'' section of this **Federal Register**, EPA is approving Colorado's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. See the information provided in the Direct Final action of the same title which is located in the Rules section of this **Federal Register**.

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

Dated: August 26, 2013.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2013–21988 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0023; FRL–9399–7]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before October 15, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov;* or Lois Rossi, Registration Division (RD) (7505P), telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the division

listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. 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 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 346a), requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available online at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerance

1. *PP 2F8015.* (EPA–HQ–OPP–2012–0515). Chemtura Corporation, 199 Benson Road, Middlebury, CT 06749, requests to establish tolerances in 40 CFR part 180 for residues of the insecticide diflubenzuron, N-[[(4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide (DFB) and its metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA), in or on Fruit, citrus, Group 10–10 at 3.0 parts per million (ppm), and citrus, oil at 32.0 ppm. Residues of the individual analytes are detectable and quantifiable using three separate analytical methods. Residues of diflubenzuron (DFB) were quantitated by liquid chromatography/tandem mass spectrometry (LC–MS/MS), and residues of the metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) were derivatized with HFBA and quantitated by GC/MS. (RD)

2. *PP 2F8099.* (EPA–HQ–OPP–2012–0941). Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596, requests to establish tolerances in 40 CFR part 180 for inadvertent residues of the fungicide fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, as an indicator of combined residues of fluopicolide and its metabolite, 2,6-dichlorobenzamide (BAM), in or on corn, field, forage at 0.09 ppm; corn, field, grain, at 0.01 ppm; and corn, field, stover at 0.3 ppm, resulting from the proposed use as a fungicide. Additional data included in the petition, to assess potential dietary exposure from P1x and PCA, show no inadvertent residues of P1x or PCA in the corn grain. Practical analytical methods for detecting and measuring levels of fluopicolide and its metabolites have been developed and validated in/on all appropriate plant and animal matrices. An analytical method for detecting fluopicolide and BAM in field corn matrices has been submitted with this petition. (RD)

3. *PP 3E8175.* (EPA–HQ–OPP–2013–0428). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540, supported in this action by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide, avermectin (abamectin) determined by measuring only avermectin B_1, a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5- *O* -demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5- *O* -demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1), and its delta-8,9-isomer in or on Caneberry subgroup 13–07A at 0.20 ppm. The analytical methods involve homogenization, filtration, partition, and cleanup with analysis by high performance liquid chromatography (HPLC)-fluorescence detection. The methods are sufficiently sensitive to detect residues at or above the proposed tolerance. All methods have undergone independent laboratory validation. (RD)

4. *PP 3E8183.* (EPA–HQ–OPP–2013–0496). Interregional Research Project

Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for the combined residues of the fungicide, *cis*- and *trans*-1,3-dichloropropene, including its metabolites and degradates, in or on pineapple at 0.02 ppm. It is proposed that compliance with the tolerance levels specified in § 180.636 is to be determined by measuring *cis*- and *trans*-1,3-dichloropropene and its metabolites *cis*- and *trans*-3-chloroacrylic acid, and *cis*-and *trans*-3-chloroallylalcohol, in or on the commodity. The proposed tolerances are to support post plant use in pineapple, similar to the established drip irrigation use of 1,3-dichloropropene in grapes. Adequate enforcement methodology, using capillary gas chromatography with mass selective detection (GC/MS), is available to enforce the tolerance expression. Analytical methods determine residues of 1,3-dichlorpropene, 3-chloroallyl alcohol, and 3-chloroacrylic acid at trace concentrations in samples of pineapple using GC/MS. (RD)

5. *PP 3F8163.* (EPA–HQ–OPP–2013–0255). BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide metrafenone, ((3-bromo-6-methoxy-2-methylphenyl) (2,3,4-trimethoxy-6-methylphenyl)methanone), in or on Fruits, pome, group 11–10 at 1.5 ppm. The residues of parent metrafenone in/on apple and pear RAC samples were quantitated using an LC/MS/MS multi-residue QuEChERS method (BASF Study No. 398340). (RD)

6. *PP 3F8184.* (EPA–HQ–OPP–2013–0428). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419, requests to establish tolerances in 40 CFR part 180 for residues of the insecticide, avermectin B_1 (which is a mixture of a minimum of 80% avermectin B_{1a} and a maximum of 20% avermectin B_{1b}) and the delta 8,9-isomer of the B_{1a} and of the B_{1b} components of the parent insecticide, in or on corn, field, sweet and pop at 0.01 ppm; corn, field and pop, forage at 0.2 ppm; corn, field and pop, grain at 0.01 ppm; corn, field and pop, stover at 0.6 ppm; corn, sweet, forage at 0.2 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.5 ppm; soybean at 0.01 ppm; soybean forage at 0.3 ppm; soybean, hay at 1 ppm; and soybean, seed at 0.01 ppm. The HPLC-fluorescence detection method is used to measure and evaluate the chemical abamectin. (RD)

New Tolerance Exemption

1. *PP 2F8103.* (EPA–HQ–OPP–2013–0569). Northwest Agricultural Products, 821 South Chestnut Avenue, Pasco, WA 99301, requests to establish an exemption from the requirement of a tolerance for residues of the herbicide, *Pseudomonas fluorescens* strain D7, in or on growing crops and rangeland. The petitioner believes no analytical method is needed because an analytical method for residues is not applicable, as Northwest Agricultural Products is proposing an exemption from the requirement of a tolerance. (BPPD)

2. *PP 3F8177.* (EPA–HQ–OPP–2013–0574). Amy Plato Roberts of Technology Science Group, Inc., 712 Fifth St., Suite A, Davis, CA 95616 on behalf of IAB, S.L. (Investigaciones y Aplicaciones Biotecnologicas S.L.), Avda. Paret del Patriarca 11–B, Ap. 30, 46113 Moncada (Valencia), Spain, requests to establish an exemption from the requirement of a tolerance for residues of the fungicide, *Bacillus subtilis* strain IAB/BS03, in or on all food commodities. The petitioner believes no analytical method is needed because it is expected that, when used as proposed, *Bacillus subtilis* strain IAB/BS03, would not result in residues that are of toxicological concern. (BPPD)

3. *PP IN–10549.* (EPA–HQ–OPP–2013–0601). Ecolab, Inc., EPA Company Number 1677, 370 N. Wabasha Street, St. Paul, MN 55102, requests to establish an exemption from the requirement of a tolerance for residues of 9-octadecenoic acid (9Z)-, sulfonated, oxidized (CAS No. 1315321–93–7) (when formed using the pre-reaction material 9-octadecenoic acid (9Z)-sulfonated, (CAS No. 68988–76–1)); 9-octadecenoic acid (9Z)-, sulfonated, oxidized, potassium salts (CAS No. 1315321–94–8) (when formed using the pre-reaction material 9-octadecenoic acid (9Z-) sulfonated, potassium salt (CAS No. 68609–93–8)); and 9-octadecenoic acid (9Z)-, sulfonated, oxidized, sodium salts, (CAS No. 1315321–95–9) (when formed using the pre-reaction material 9-octadecenoic acid (9Z)-, sulfonated, sodium salt (CAS No. 68443–05–0)) (also referred to as peroxy sulfonated oleic acids (PSOA)) for use as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils in accordance with 40 CFR 180.940(a) at 250 ppm. The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. (RD)

4. *PP IN–10605.* (EPA–HQ–OPP–2013–0525). Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381, requests to establish an exemption from the requirement of a tolerance for residues of tall oil, polymer with polyethylene glycol and succinic anhydride monopolyisobutylene derivs., minimum number average molecular weight (in amu), 1,400; (CAS No. 1398573–80–2) under 40 CFR 180.960 when used as a pesticide inert ingredient surfactant in food use pesticide formulations. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. (RD)

5. *PP IN–10606.* (EPA–HQ–OPP–2013–0526). Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381, requests to establish an exemption from the requirement of a tolerance for residues of octadecanoic acid, 12-hydroxy-, homopolymer, ester with 2-methyloxirane polymer with oxirane monobutyl ether, minimum number average molecular weight (in amu), 1,900; (CAS No. 1373125–59–7) under 40 CFR 180.960 when used as a pesticide inert ingredient surfactant in food use pesticide formulations. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. (RD)

6. *PP IN–10607.* (EPA–HQ–OPP–2013–0540). Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381, requests to establish an exemption from the requirement of a tolerance for residues of 2,5-furandione, polymer with ethenylbenzene, reaction products with polyethylene-polypropylene glycol 2-aminopropyl Me ether, minimum number average molecular weight (in amu), 10,000 (CAS No.162568–32–3) under 40 CFR 180.960 when used as a pesticide inert ingredient surfactant in food use pesticide formulations without limit. The petitioner believes no analytical method is needed because this information is not required for the establishment of a tolerance exemption. (RD)

Amended Tolerance

PP IN–10544. (EPA–HQ–OPP–2013–0210). Spring Trading Company, 10805 W. Timberwagon Cir., Spring, TX 77380–4030, on behalf of Akzo Nobel Surface Chemistry, LLC; 525 West Van Buren, Chicago, IL 60607–3823, is requesting a change in the 40 CFR sections under which the requested tolerance exemptions would be established from 180.920, 180.930, or 180.960 to 180.910, 180.930, 180.940(a) or 180.960. Their initial Notice of Filing

(NOF) published in the **Federal Register** of July 19, 2013 (78 FR 43115) (FRL–9392–9), where EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN–10544). The petitioner is now requesting, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to revise the exemption from the requirement of tolerances for [alpha]-alkyl-[omega]-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons under 40 CFR 180.910, 180.930, 180.940(a), or 180.960 in or on the raw agricultural commodities after harvest or growing crops, animals and food contact surface sanitizing solutions and [alpha]-alkyl-[omega]-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons, minimum number average molecular weight (in amu) 1,100 under 40 CFR 180.960, when used as a pesticide inert ingredient in pesticide formulations, to include the following Chemical Abstract Service Registry Numbers (CAS Reg. Nos.): 67254–71–1; 161025–22–5; 68409–59–6; 160901–20–2; 159653–49–3; 160901–19–9; 103331–86–8; 126950–62–7; 74499–34–6; 161025–21–4; 176022–76–7; 68603–20–3; 68526–95–4; 64425–86–1; 139626–71–4; 152231–44–2; 120944–68–5; 157707–41–0; 288260–45–7; 287935–46–0; 126646–02–4; 954108–36–2; 71011–10–4; 121617–09–2; 69227–20–9; 116810–32–3; 79771–03–2; 67763–08–0; 68439–48–5; 72066–65–0; 68991–48–0; 303176–75–2; 116810–33–4; 157707–43–2; 68954–94–9; 160901–09–7; 102782–43–4; 68920–69–4; 154518–36–2; 157627–88–8; 68439–53–2; 103819–03–0; 70955–07–6; 74432–13–6; 68439–30–5; 9038–29–3; 68238–81–3; 68409–58–5; 68238–82–4; 37311–00–5; 37311–01–6; 52232–09–4; 73018–31–2; 9038–43–1; 63303–01–5; 37311–04–9; 65150–81–4; 63658–45–7; 139381–39–8; 72484–69–6; 59112–62–8; 50861–66–0; 103657–84–7; 103657–85–8; 67784–96–7; 25190–05–0; 26636–39–5; 64415–24–3; 65104–72–5; 9040–05–5; 27252–75–1; 64415–25–4; 9035–85–2; 72108–90–8; 25231–21–4; 62648–50–4; 63793–60–2; 63303–00–4; 57455–38–6; 57497–74–2; 70955–69–0; 26401–47–8; 39278–93–8; 9004–87–9; 68987–90–6; 26403–74–7; 9046–09–7; and 288095–59–0. The petitioner does not expect that the addition of these CAS numbers to result in additional exposure or risk. An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of tolerances without any numerical limitation. (RD)

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 5, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–22218 Filed 9–11–13; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 10–90; DA 13–1846]

Wireline Competition Bureau Announces Availability of Version 3.2 of the Connect America Fund Phase II Cost Model Illustrative Results

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Wireline Competition Bureau announces the availability of the next version of the Connect America Cost Model (CAM v3.2), which includes certain adjustments to the CAM to reflect the unique circumstances and operating conditions in the non-contiguous areas of the United States. The Bureau seeks comment on these changes, specifically the addition of the capability to model costs for undersea cable connecting non-contiguous areas to the contiguous United States, plant mix values submitted by Alaska Communications Systems Group, Inc. (ACS) for Alaska, and using the default value of ''1'' for the regional cost adjustment for the U.S. Virgin Islands, which has the effect of increasing labor costs. Lastly, the Bureau seeks comment on using the plant mix values that were filed separately in models previously filed by Puerto Rico Telephone Company, Inc. (PRTC) and Virgin Islands Telephone Corporation d/b/a Innovative Telephone (Vitelco) in the next version of the CAM.

DATES: Comments are due on or before September 12, 2013 and reply comments are due on or before September 19, 2013.

ADDRESSES: Interested parties may file comments on or before September 12, 2013 and reply comments on or before September 19, 2013. All pleadings are to reference WC Docket No. 10–90. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty).

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Katie King, Wireline Competition Bureau at (202) 418–7491 or TTY (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Wireline Competition Bureau's Public Notice (Notice) in WC Docket No. 10–90; DA 13–1846, released August 29, 2013. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160 or (202) 863–2893, facsimile (202) 863–2898, or via Internet at *http://www.bcpiweb.com.*

1. The Wireline Competition Bureau (Bureau) announces the availability of the next version of the Connect America Cost Model (CAM v3.2), which includes certain adjustments to the CAM to reflect the unique circumstances and operating conditions in the non-contiguous areas of the United States. The Bureau seeks comment on these changes, specifically the addition of the capability to model costs for undersea cable connecting non-contiguous areas to the contiguous United States, plant mix values submitted by ACS for Alaska, and using the default value of ''1'' for the regional cost adjustment for the U.S. Virgin Islands, which has the effect of increasing labor costs. The Bureau also seeks comment on using the

plant mix values that were filed separately in models previously filed PRTC and Vitelco in the next version of the CAM.

2. *Description of Changes in CAM v3.2.* CAM v3.2 updates the prior version (CAM v3.1.4) in a number of respects, and the Bureau seeks comment on several of the changes. First, this version adds code changes and a new Undersea tab in the Capital Expenditures (Capex) workbook that includes inputs for undersea cable and landing stations. These changes and inputs are used to calculate the investment and cost for undersea and landing station facilities that connect areas outside of the contiguous United States, including Alaska, Hawaii, Puerto Rico, the U.S. Virgin Islands and Northern Mariana Islands, to the contiguous United States. Second, this version includes plant mix values for Alaska that were recently filed by ACS.

3. In addition, this version makes a number of other changes. It adjusts the regional cost adjustment table to reflect that Zip 3 = 008, which had been previously coded for Puerto Rico, is in the U.S. Virgin Islands and sets the value of the cost adjustment for Zip 3 = 008 to 1.0 (i.e., no adjustment) in the absence of R.S. Means data regarding labor costs for the Virgin Islands. It includes minor modifications to some existing investment calculations to more accurately reflect network infrastructure. Finally, it includes several updates to the documentation and makes additional clean-up changes to the Capex workbook. These changes are reflected in two solution sets that can be accessed by accessing CAM v3.2, and visiting the Posted Data Sets page. These solution sets can be found under the Model Outputs section of the Posted Data Sets tab: SSYYYYMMDD CAM32ACF8UndSeaCpx and SSYYYY MMDDCAM32ACF9UndSeaCpx solution sets under Model Outputs.

4. *Issue for Comment: Submarine Cable.* CAM v3.2 includes the capability to model costs for undersea cable to non-contiguous areas. CAM v3.2 also adds a new ''Undersea'' tab in the Capex workbook, which includes the inputs used to calculate the investment and cost for undersea cable and landing station facilities needed to transport traffic to and from landing stations in non-contiguous areas to landing stations in the contiguous United States. To help parties understand and comment on the adjustments incorporated in v3.2, the Bureau explains the modeling assumptions below.

5. First, the Bureau seeks comment on CAM v3.2's approach to connecting the non-contiguous areas to the contiguous United States. In the maps appended to the Public Notice, CAM v3.2 models undersea cables: From Alaska to Oregon and Washington; from the Northern Marianas to Guam and from Guam to Oregon; from Hawaii to California; from the U.S. Virgin Islands to Puerto Rico and from Puerto Rico to Florida; and from Puerto Rico to Florida. The specific endpoints of the undersea cables are marked on the maps.

6. The length or ''footage'' of these undersea cable connections is a key cost driver. The Bureau seeks comment on the footage estimates in Table 1. Note that to ensure resiliency, the footage for each connection includes the additional footage needed for path redundancy. In addition, each spur connects independently to a tandem location within the contiguous United States.

7. Table 1: Undersea Cable Footage

Area	Undersea cable footage
Alaska	21,206,745
Hawaii	26,029,830
North Marianas Islands	61,602,894
Puerto Rico	11,258,578
U.S. Virgin Islands	12,072,945

8. The Bureau also seeks comment on CAM v3.2's assumption that the cost of materials and labor per foot of undersea cable is $11.05. This cost per foot is based on publicly available information regarding AKORN, an undersea cable between Alaska and Oregon. It is the same for each undersea cable because, unlike land-based connections where costs vary by the soil type in a given area, CAM v3.2 assumes that the costs for undersea cable do not vary based on the body of water in which the cable is located.

9. Next, the Bureau seeks comment on CAM v3.2's methodology for modeling whether a carrier would construct such an undersea cable or instead lease capacity on an existing international undersea cable. This version of the model input assumes that the presence and capacity of international undersea cables are driven primarily by international traffic demand, not by the traffic of the local exchange carrier (LEC) in areas with landing stations. This version of the model inputs assumes that, if the demand from the modeled network would outstrip capacity on these existing international undersea systems, without concurrent increases in demand for bandwidth that passes through the location, then construction of a new system would be economically justifiable. If, however, the capacity required would amount to only a fraction of available capacity, CAM v3.2 assumes that a carrier would lease capacity on an existing cable.

10. It is assumed that the cost of transport back to the contiguous United States would be the fraction of cost associated with the fraction of the cable being consumed by peak demand of the modeled network. This assumes that the price for a LEC to buy capacity on an existing cable would be comparable to the cost of providing that access plus a rate of return comparable to the one assumed in CAM. Given that each non-contiguous area with an international cable route is served by multiple cable systems, we believe that this is a reasonable assumption. To the extent commenters disagree with these assumptions and instead argue that rates are substantially higher, they should provide specific information on these rates to the Bureau, including the route and amount of capacity being purchased.

11. To make that determination, Bureau staff first looked at existing capacity. As seen in Table 2, below, most of the non-contiguous areas have international cable routes with landing stations on them, and most of the cable routes have additional capacity available.

12. Table 2: International Cable Route and Capacity Table

Area	Cable route name	Total capacity (Tbps)	LIT Capacity (Gbps)
Alaska	N/A	N/A	N/A
Hawaii	AAG	2.88	700
Hawaii	Southern Cross	6	2,000
Hawaii	TPC–5	0.01	10
Northern Marianas Islands (Guam)	AAG	2.88	700
Northern Marianas Islands (Guam)	TGN-Pacific	7.68	5,120
Puerto Rico	America Movil-1	0.10	40
Puerto Rico	Americas-II	0.21	80

Area	Cable route name	Total capacity (Tbps)	LIT Capacity (Gbps)
Puerto Rico	ARCOS–1	1.02	80
Puerto Rico	PCCS	80	100
Puerto Rico	Sam-1	1.92	310
U.S. Virgin Islands	Americas-I	0.32	120
U.S. Virgin Islands	Americas-II	0.21	80
U.S. Virgin Islands	MAC	0.07	70

13. Moreover, to evaluate whether capacity on these existing undersea cables will be sufficient to meet future demand during Connect America Phase II, the same busy hour offered load assumptions incorporated into CAM v3.2 were used to compare demand (i.e. required capacity) to supply (i.e. lit and total capacity of the international fiber routes with landing sites on each non-contiguous area). The comparison of future demand to current lit capacity (of the highest capacity fiber in the area) may over-state the extent to which new undersea systems are required, while the comparison to total capacity (of the highest capacity fiber in the area) may understate costs in the near-term. Therefore, the comparisons were averaged.

14. Table 3, below, shows the comparisons of capacity to both the lit and total capacity of the largest single cable, as well as the average of those comparisons. The Bureau seeks comment on this approach to evaluating capacity and on the calculations reflected in the table.

15. Table 3: Comparisons of Demand to Supply

Area	Demand (Gbps)	Highest total capacity (Tbps)	% Demand to total capacity	Highest LIT capacity (Gbps)	% Demand to LIT capacity	Average (percent)
Hawaii	213.6	6	3.956	2,000	11.867	7.91
North Marianas Islands (Guam to Oregon)	7.7	7.68	0.111	5,120	0.166	0.14
Puerto Rico	587.9	80	0.816	310	100	50.00
U.S. Virgin Islands (Puerto Rico to Florida)	20.0	80	0.028	310	7.168	3.60

16. Finally, CAM v3.2 estimates the cost that carriers will face in securing transport to and from the contiguous United States by applying the averages listed in Table 3 to the CAM-calculated cost of the total route. Because the Alaska route and the Northern Marianas to Guam portion of the Northern Marianas route are not shared with any international traffic, CAM v3.2 includes 50 percent of the costs of connecting Alaska to Oregon and Washington, the Northern Marianas to Guam, and the U.S. Virgin Islands to Puerto Rico, which is the default middle mile allocation in CAM v3.2. Table 4, below, shows the resulting cost per location per month. The Commission seeks comment on these averages and/or allocations and whether the resulting monthly cost per location is a reasonable estimate.

17. Table 4: Monthly Cost Per Location

Area	Investment for the route (millions)	Monthly cost per location
Alaska	$85.6	$5.40
Hawaii	24.4	0.65
North Marianas Islands	18.9	15.44
Puerto Rico	72.9	0.72
U.S. Virgin Islands	20.0	6.34

18. *Issue for Comment: Plant Mix.* As noted above, CAM v3.2 includes in the Plant Mix input collection table the Alaska-specific plant mix values recently proposed by ACS. These values are reproduced in Table 5, below. The ACS filed plant mix values for suburban distribution and suburban feeder as filed did not total 100%. (Total of aerial, buried and underground plant mix values for distribution and feeder equaled 101 percent.) The values shown in the table reflect a staff adjustment to force the filed values to equal 100%. Staff multiplied each of the values by 100/101 to reflect the same relationship and make the sum of aerial, buried and underground equal 100%.

19. Table 5: ACS Proposed Plant Mix Values

State	Density	Distribution			Feeder			IOF		
		Aerial (percent)	Buried (percent)	Under-ground (percent)	Aerial (percent)	Buried (percent)	Under-ground (percent)	Aerial (percent)	Buried (percent)	Under-ground (percent)
AK	Rural	25.0	61.0	14.0	25.0	61.0	14.0	28.0	58.0	14.0
AK	Suburban	23.8	48.5	27.7	23.8	48.5	27.7	24.0	55.0	21.0
AK	Urban	20.0	40.0	40.0	20.0	40.0	40.0	15.0	50.0	35.0

20. ACS also submitted its current plant mix values which are reproduced in Table 6, below.

21. Table 6: ACS Current Plant Mix Values

Density	Aerial (percent)	Buried (percent)	Underground (percent)
Plant Mix: All			
Rural	27	63	10
Suburban	32	64	4
Urban	33	43	24
Plant Mix: Copper			
Rural	28	68	4
Suburban	33	64	3
Urban	35	47	19
Plant Mix: Fiber			
Rural	19	19	61
Suburban	16	62	22
Urban	23	21	56

22. The current plant mix submitted by ACS differs from what ACS proposes should be used in the CAM. For the other carriers, CAM v3.2 uses carrier-supplied plant mix values that reflect their current plant mix. The Bureau seeks comment on whether to make any adjustments to the Alaska-specific plant mix values contained in CAM v3.2, in light of ACS's current plant mix.

23. The Bureau also seeks comment on whether it should incorporate into the next version of the CAM the plant mix values for Puerto Rico and the Virgin Islands that PRTC and Vitelco previously submitted in conjunction with their proposals for standalone models.

24. *Issue for Comment: Cost Adjustment for the U.S. Virgin Islands.* Because the source that CAM relies on for regional cost adjustments for the rest of the United States does not include values for the U.S. Virgin Islands, CAM v3.2 sets the value of the cost adjustment for Zip 3 = 008 to 1.0 (i.e., no adjustment). The Bureau seeks comment on using this value for the U.S. Virgin Islands.

25. *Other Proposals.* The Bureau notes that ACS has proposed additional modifications to the CAM that it contends would more appropriately reflect the costs of serving Alaska. The Bureau is continuing to evaluate those proposals.

26. If parties, including carriers serving other non-contiguous areas, have other proposals or data that they wish to file concerning the treatment of non-contiguous areas in the CAM, such information should be filed by the reply comment deadline specified on the first page of this Public Notice. All submissions should be in a form that can be readily incorporated into the CAM. Parties should contact Bureau staff indicated at the beginning of this summary if they wish to file any information confidentially in order to discuss how to submit that information in a way that can be incorporated into the next version of the CAM.

27. *Access to CAM v3.2.* To access CAM v3.2, parties should follow the same procedures announced for previous versions. In particular, parties may access CAM v3.2 at *http://www.fcc.gov/encyclopedia/caf-phase-ii-models or https://cacm.usac.org.* Additionally, authorized users who have signed the attachments to the protective order will have access to a system evaluator package that provides a test environment populated with a sample database, allowing users to view database structures, observe the processing steps of CAM for a subset of the country, and see changes in the database.

28. *Updated Documentation.* In conjunction with the release of CAM v3.2, the Bureau also announces the availability of updated methodology documentation for CAM v3.2, to assist the public in understanding the current model architecture, processing steps, and data sources. The methodology documentation is available at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-323071A1.pdf.*

29. *Illustrative Results.* The Bureau also is releasing illustrative model outputs from running CAM v3.2 using different combinations of possible model inputs and support assumptions. To demonstrate a range of potential outcomes, the Bureau is providing illustrative model outputs with funding thresholds of $49.15, $52, and $55.40. The reports show potential support amounts and number of supported locations, by carrier, by study area, and by state, using the default input values in CAM v3.2. The reports are available at *http://www.fcc.gov/encyclopedia/connect-america-cost-model-illustrative-results.* Because the Bureau has not yet finalized and adopted a cost model, the illustrative results that the Bureau is releasing are not final support amounts.

I. Procedural Matters

A. Initial Regulatory Flexibility Act Analysis

30. The *Non-Contiguous Areas PN,* 78 FR 12006, February 21, 2013, included an Initial Regulatory Flexibility Analysis (IRFA) pursuant to 5 U.S.C. 603, exploring the possible significant economic impact on small entities of the policies and rules proposed therein. The Commission invites parties to file comments on the IRFA in light of this additional *Public Notice.*

B. Paperwork Reduction Act

31. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

C. Filing Requirements

32. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or

before the dates indicated on the first page of this document. Comments are to reference WC Docket No. 10–90 and DA 13–1846, and may be filed by paper or by using the Commission's Electronic Comment Filing System (ECFS).

▪ *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*

▪ *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

▪ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

▪ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

▪ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

33. In addition, we request that one copy of each pleading be sent to each of the following:

(1) Dania Ayoubi, Telecommunications Access Policy Division, Wireline Competition Bureau, 445 12th Street SW., Room 6–A322, Washington, DC 20554; email: *Dania.Ayoubi@fcc.gov*;

(2) Charles Tyler, Telecommunications Access Policy Division, Wireline Competition Bureau, 445 12th Street SW., Room 5–A452, Washington, DC 20554; email: *mailto:Charles.Tyler@fcc.gov.*

34. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

The proceeding this Notice initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Federal Communications Commission.

Kimberly A. Scardino,

Chief, Telecommunications Access Policy Division, Wireline Competition Bureau.

[FR Doc. 2013–21888 Filed 9–11–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2013–0100; 4500030113]

RIN 1018–AY72

Endangered and Threatened Wildlife and Plants; Threatened Status for Arabis georgiana (Georgia rockcress)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to list *Arabis georgiana* (Georgia rockcress), a plant species in Georgia and Alabama, as threatened under the Endangered Species Act of 1973, as amended (Act). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Plants and extend the Act's protections to this species.

DATES: We will accept comments received or postmarked on or before November 12, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by October 28, 2013.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2013–0100, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2013–0100; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Information Requested section below for more details).

FOR FURTHER INFORMATION CONTACT: Sandy Tucker, Field Supervisor, U.S. Fish and Wildlife Service, 105 Westpark Dr., Suite D, Athens, GA 30606; telephone 706–613–9493; facsimile 706–613–6059. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION: We will refer to *Arabis georgiana* by its common name, Georgia rockcress, in this proposed rule.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) Georgia rockcress's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for growth and reproduction;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors affecting its continued existence.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, of this species, including the locations of any additional populations of this species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.* Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the species' biology, field identification, and habitat requirements; have firsthand experience working with this species; and are currently reviewing the species status report, which will inform our determination. We will invite comment from the peer reviewers during the public comment period for this proposed rule (see **DATES**).

Previous Federal Actions

The Act (16 U.S.C. 1531 *et seq.*) directed the Secretary of the Smithsonian Institution to prepare a report on endangered and threatened plant species, which was published as House Document No. 94–51. The Service published a notice on July 1, 1975 (40 FR 27824), in which it announced that more than 3,000 native plant taxa named in the Smithsonian's report, as well as other taxa, including Georgia rockcress, would be reviewed for possible inclusion in the List of Endangered and Threatened Plants. The 1975 notice was superseded on December 15, 1980 (45 FR 82480), by a new comprehensive notice of review for native plants that took into account the earlier Smithsonian report and other accumulated information. Complete updates of the notice of review for native plants were published on September 27, 1985 (50 FR 39526), on February 21, 1990 (55 FR 6184), and on September 30, 1993 (58 FR 51144). In these documents, Georgia rockcress was listed as a Category 2 candidate, a taxon for which information in the possession of the Service indicated that proposing to list as endangered or threatened was possibly appropriate, but for which sufficient data on biological vulnerability and threats were not available to support listing rules. Further biological research and field study usually were necessary to ascertain the status of taxa in this category. On February 26, 1996, the Service published a notice of review for wildlife and plants that eliminated candidate categories, and Georgia rockcress was not included as a candidate in that document. Georgia rockcress was again elevated to candidate status on October 25, 1999 (64 FR 57534). The plant appeared in subsequent candidate notices of review on October 30, 2001 (66 FR 54808), June 13, 2002 (67 FR 40657), May 4, 2004 (69 FR 24876), May 11, 2005 (70 FR 24870), September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), and

November 21, 2012 (77 FR 69993). We received an additional petition on May 11, 2004, for this species, which we responded to in the May 11, 2005, candidate notice of review (70 FR 24870); the species retained its designation as a candidate as a result.

Elsewhere in today's **Federal Register**, we propose to designate critical habitat for Georgia rockcress under the Act.

Background

Georgia rockcress was first collected in 1841, by Boykin from the vicinity of the Chattahoochee River in Georgia. Several other collections of this species were made in the late 1800s; however, Harper was the first to document its distinctiveness, after seeing it in fruit in 1901, on the bank of the Chattahoochee River in Stewart County, Georgia. Harper later described it as a distinct species in 1903 (Allison 1995, p. 4). Georgia rockcress was maintained as a distinct species (*Arabis georgiana*) in Hopkins's 1937 monograph of *Arabis* in the eastern United States (Allison 1995, p. 3).

Georgia rockcress is a perennial herb up to 90 centimeters (cm) (35 inches (in.)) tall. The basal leaves are oblanceolate (lance-shaped but broadest above the middle and tapering toward the base), rounded at the apex, toothed on the margins, 4 to 8 cm (2 to 3 in.) long, and with or without long, tapered petioles. The basal leaves form a basal rosette and usually persist through the fruiting season with green lower surfaces. The stem leaves are alternate, lanceolate (lance-shaped) to narrowly elliptic, 1 to 5 cm (0.4 to 2.0 in.) long, and somewhat clasping around the stems. The upper surfaces of the stem leaves have stiff, branched hairs when young and are smoothish when mature. All leaves tend to be finely hairy. The flowers are borne in a terminal inflorescence (cluster at the tip of the stem) that is somewhat loosely branched. There are four, white petals that measure 6 to 10 millimeters (mm) (0.2 to 0.4 in.) long. The fruit stands erect as a slender (1 mm or 0.04 in. wide), relatively long (5 to 7 cm or 2 to 3 in.) pod that splits in two, leaving behind a thin, papery, lengthwise partition. Seeds are brownish, oblong, about 2 mm (0.1 in.) long, and are borne in single rows on each side of the partition. Flowering occurs from March to April, with fruiting beginning in May and into early July (Allison 1995, p. 4; Patrick et al. 1995, pp. 17–18; Chafin 2007, pp. 47–48; Schotz 2010, p. 3).

Georgia rockcress is primarily associated with high bluffs along major river courses, with dry-mesic to mesic soils of open rocky woodland and forested slopes, generally within regions underlain or otherwise influenced by granite, sandstone, or limestone. Georgia rockcress grows in a variety of dry situations, including shallow soil accumulations on rocky bluffs, ecotones of sloping rock outcrops, and sandy loam along eroding riverbanks. It is occasionally found in adjacent mesic woods (or glades), but it will not persist in heavily shaded conditions. This species is adapted to high or moderately high light intensities, generally with a mature canopy providing partial shading; the habitat supports a relatively closed to open canopy typified by *Juniperus virginiana* (eastern red cedar), *Ostrya virginiana* (American hophornbeam), *Quercus muehlenbergii* (chinquapin oak), *Fraxinus americana* (white ash), *Acer barbatum* (southern sugar maple), and *Cercis canadensis* (eastern redbud) with a rich diversity of grasses and forbs characterizing the herb layer, which might include: *Carex cherokeensis* (Cherokee sedge), *Bromus purgans* (hairy woodland brome), *Chasmanthium sessiliflorum* (longleaf woodoats), *Piptochaetium avenaceum* (blackseed speargrass), *Pellaea atropurpurea* (purple cliffbreak), *Melica mutica* (two-flower melic grass), *Poa autumnalis* (autumn bluegrass), *Delphinium alabamicum* (Alabama larkspur), *Myosotis macrosperma* (largeseed forget-me-not), *Desmodium ochroleucum* (cream ticktrefoil), *Dodecatheon meadia* (shooting star), *Solidago auriculata* (eared goldenrod), *Symphyotrichum shortii* (Short's aster), and many more. The combination of a mature canopy on extreme slope with shallow soils lends this habitat to discrete disturbance events with wind-thrown trees or sloughing soils that create canopy gaps and preclude leaf litter accumulation. Georgia rockcress exploits the exposed soil and increased light created by the canopy gap dynamics.

This species occurs on soils that are circumneutral to slightly basic (or buffered) from the Lower Gulf Coastal Plain, Upper Gulf Coastal Plain, Red Hills, Black Belt, Piedmont, and the Ridge and Valley Physiographic Provinces (Schotz 2010, pp. 4–6). Extensive searches have been conducted for this species throughout these physiographic provinces in both Alabama and Georgia (Allison 1995, pp. 1–31; Allison 1999, pp. 1–7). Allison (1995, pp. 18–31) conducted the first comprehensive survey and compiled existing data on known occurrences. As part of this effort, he surveyed 205 sites over nine counties in Georgia and discovered only four previously unknown populations (a 2 percent success rate). Schotz (2010, p. 7) visited a total of 44 sites (16 historically occupied and 28 new sites), and of the 16 historically occupied sites, 14 were still extant and 2 sites appeared to be extirpated. In addition, one new site was discovered. Currently, 18 populations are documented to occur across Alabama and Georgia. Twelve of these occur solely in Alabama; five occur solely in Georgia; and one extends into both States. Of the 12 populations in Alabama, 6 occur in the Ridge and Valley region (all in Bibb County), and 6 occur in the Coastal Plain region (Dallas (2), Elmore, Wilcox, Monroe and Sumter Counties). Of the five populations found solely in Georgia, three occur in the Ridge and Valley region (Floyd and Gordon Counties); one occurs in the Piedmont region (Harris/Muscogee Counties); and one occurs in the Coastal Plain region (Clay County). The one population that extends into both States (Russell County, AL/Chattahoochee County, GA) also occurs in the Coastal Plain region (Allison 1995, pp. 13–14; Allison 1999, pp. 1–7; Moffett 2007, p. 1; Schotz 2010, pp. 48–50). A historical location from Stewart County, Georgia, has not been relocated despite repeated searches, including the most recent attempt in 2005 (Moffett 2007, p. 1).

Georgia rockcress is rare throughout its range. Moffett (2007, p. 8) found approximately 2,140 plants from all known sites in Georgia. During surveys in 1999, Allison (1999, pp. 1–7) found that populations of this species typically had a limited number of individuals restricted over a small area. Of the nine known localities (six populations) in Georgia, Allison (1995, pp. 18–28) reported that six sites consisted of only 3 to 25 plants, and the remaining three sites had 51 to 63 individuals. However, a 2007 survey, by Moffett (2007, p. 8), of the six Georgia populations resulted in counts of 5 or fewer plants at one population; 30 to 50 plants at two populations; 150 plants at one population; and two populations (greatly expanded from 1995) of almost 1,000 plants each. In 2009, plants could not be relocated at one Floyd County, Georgia, site, and only one plant was seen at another site where 25 to 50 had been documented in 2007 (Elmore 2010, p. 1). Moffett (2007, pp. 1–2) indicated that the overall status of the three populations in the Ridge and Valley ecoregion (Floyd and Gordon Counties, Georgia) was poor, as these populations tended to be small, and declining in size and vigor. The largest population in Georgia is the multi-site Goat Rock Dam

complex in the Piedmont province (Harris/Muscogee Counties) with approximately 1,000 flowering stems at last census (Moffett 2007, p. 2). Fort Benning also supports a vigorous population with an estimated 1,000 plants (Moffett 2007, p. 2). Georgia rockcress has been extirpated from its type locality near Omaha, Georgia, in Stewart County (Moffett 2007, p. 2). At another site, Blacks Bluff, Georgia, rockcress had declined to a few individuals by 2007 (Moffett 2007, p. 2), but 100 individuals were replanted in 2009. During a count done in 2013, 31 individuals were found to be surviving at the site, and more than 500 seeds were broadcast to supplement this population (Goldstrohm 2013, p. 1).

Schotz (2010, p. 8) documented fewer than 3,000 plants from all known sites in Alabama. Populations from Bibb County, Alabama, had between 16 and 229 plants, with 42 and 498 from Dallas County, 47 from Elmore County, 414 from Monroe County, 842 from Russell County, 4 from Sumter County, and 551 from Wilcox County. Allison (1999, pp. 2–4) originally documented this species at 18 localities (representing seven populations) in Bibb County. However, one of these Bibb County populations was not relocated during surveys in 2001 (Allison 2002, pers. comm.), and plants were not relocated at two other sites in Alabama (Schotz 2010, pp. 13 and 57). Therefore, it is believed that Georgia rockcress has been extirpated from these three sites in Alabama.

Summary of Factors Affecting the Species

The Act directs us to determine whether any species is an endangered species or a threatened species based on the factors, singly or in combination, that are set forth in section 4(a)(1) of the Act, which are:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affection its continued existence.

In this section, we summarize the biological condition of the species and its resources, and the influences on such to assess the species' overall viability and the risks to that viability.

Georgia rockcress generally occurs on steep river bluffs often with shallow soils overlaying rock or with exposed rock outcroppings. These edaphic conditions result in micro-disturbances, such as sloughing soils with limited accumulation of leaf litter or canopy gap dynamics, possibly with wind-thrown trees, which provide small patches of exposed mineral soil in a patchy distribution across the river bluff (Schotz 2010, p. 6). While Georgia rockcress needs small-scale disturbances with slightly increased light, limited competition for water, and exposed soils for seed germination, the species is a poor competitor and is easily outcompeted by aggressive competitors (Alison 1995, p. 8; Moffett 2007, p. 4; Schotz 2010, p. 9). Natural large-scale disturbances, such as fire and catastrophic flooding, are unlikely to occur on the steep river bluffs occupied by Georgia rockcress. However, human-induced disturbance has fragmented river bluff habitats and created conditions favorable to invasion of nonnative species (Factor E).

Populations of Georgia rockcress are healthiest in areas receiving full or partial sunlight. This species seems to be able to tolerate moderate shading, but it exists primarily as vegetative rosettes in heavily shaded areas (Moffett 2007, p. 4). Those populations occurring in forested areas will decline as the forest canopy closes. Allison (1999, p. 4) attributed the decline of a population in Bibb County, Alabama, to canopy closure. In addition, the small number of individuals at the majority of the sites makes these populations vulnerable to local extinctions from unfavorable habitat conditions such as extreme shading.

Habitat fragmentation is a major feature of many landscapes within the eastern deciduous forest and creates boundaries or edges where disturbed patches of vegetation are adjacent to intact habitat. Disturbance events fragment the forest, creating edge habitat and promoting the invasion of nonnative species (Honu and Gibson 2006, pp. 263–264). Edges function as sources of propagules for disturbed habitats and represent complex environmental gradients with changes in light availability, temperature, humidity, wind speed, and soil moisture, with plant species responding directly to environmental changes (Meiners et al. 1999, p. 261). Edge effect, including any canopy break due to timber harvest, fields, or maintained rights-of-way, may penetrate as far as 175 meters (574 feet), resulting in changes in community composition (Honu and Gibson 2006, p. 264; Gehlhausen et al. 2000, p. 21; Meiners et al. 1999, p. 266; Fraver 1994). Roads create a canopy break, destroy the soil profile, and disrupt hydrology of the bluff habitat. Roads are also known corridors for the spread of invasive plant species (Forman et al. 2003, pp. 75–112), as disturbed soil and the maintenance of open, sunny conditions create favorable conditions where invasive species can establish and spread into the forest interior (Fraver 1994, pp. 828–830). Aspect is an important factor in determining how forest microclimate and vegetation are influenced by the external environment (Gehlhausen et al. 2000, p. 30; Fraver 1994, pp. 828–830). Aspect likely increases the distance that the edge effect can influence microclimate and plays an important role on the steep bluff habitat occupied by Georgia rockcress. Edge effects are reduced by a protective border with buffers that eliminate most microhabitat edge effect (Honu and Gibson 2006, p. 255; Gehlhausen et al. 2000, p. 32).

Currently, habitat degradation, more than its outright destruction, is the most serious threat to this species' continued existence. Most of the Coastal Plain rivers surveyed by Allison (1995, p. 11) were considered unsuitable for Georgia rockcress because their banks had been disturbed to the point where there was no remaining vegetative buffer. Recent habitat degradation (i.e., vegetation denuded and replaced by hard-packed, exposed mineral soil) has occurred at several Georgia sites in association with residential development and campsites atop the bluffs (Moffett 2007, pp. 3–4). Disturbance associated with timber harvesting, road building, and grazing in areas where the plant exists has created favorable conditions for the invasion of nonnative weeds in this species' habitat (Factor E) (Schotz 2010, p. 10). Timber operations that remove the forest canopy promote early successional species and result in the decline of Georgia rockcress (Schotz 2010, p. 10). Encroachment of development in the form of bridges, roads, houses, commercial buildings, or utility lines allowing for the introduction of nonnative species (Factor E) also result in the decline of Georgia rockcress (Schotz 2010, pp. 9–10; Moffett 2007, pp. 2–7; Alison 1995, pp. 7–18).

The riparian bluff habitat surrounding 17 of the known populations has been adversely impacted in some way, and in many cases the habitat has suffered multiple impacts. Blacks Bluff, Fort Benning (Georgia), McGuire Ford, Limestone Park, Prairie Bluff, and Fort Benning (Alabama) all have roads that bisect the habitat while Murphys Bluff, Pratts Ferry, Fort Tombecbee, and Resaca Bluffs have roads associated with bridges that impact bluff habitat (Schotz 2010, pp. 20–57; Moffett 2007, pp. 5–8; Allison 1999, pp. 3–8; Allison

1995, pp. 18–28). Housing development requires a road network and further impacts bluff habitat by creating canopy gaps and soil disturbances, with landscaping that may introduce nonnative plants. McGuire Ford, Prairie Bluff, Fort Tombecbee, and Creek Side Glades have bluff habitat that has been impacted by housing development (Schotz 2010, pp. 20–57; Allison 1999, pp. 3–8). Commercial development has the same impact as housing; Resaca Bluff and Fort Tombecbee are impacted by commercial development (Schotz 2010, pp. 20–57; Moffett 2007, pp. 5–8; Allison 1999, pp. 3–8; Allison 1995, pp. 18–28). McGuire Ford and Fort Toulouse have maintained fields for pasture or recreational use (Schotz 2010, pp. 20–57; Allison 1999, pp. 3–8). The removal of the canopy to maintain a field provides an opportunity for nonnatives to invade. Utility lines have created canopy breaks at Creek Side Glades, Little Schulz Creek, and Goat Rock Dam (Schotz 2010, pp. 20–57; Moffett 2007, pp. 5–8; Allison 1999, pp. 3–8; Allison 1995, pp. 18–28). Timber harvesting activities create soil disturbance and canopy breaks that provide access for nonnative plants to invade. Durant Bend, Portland Landing, Fort Gains, Pratts Ferry, Fern Glade and Six Mile Creek, and Whitmore Bluff have all been impacted by timber harvesting activates (Schotz 2010, pp. 20–57; Moffett 2007, pp. 5–8; Allison 1999, pp. 3–8; Allison 1995, pp. 18–28). While these impacts are to the bluff habitat that surrounds these populations, these disturbances eliminate potential habitat for expansion of populations, fragment the populations, and introduce nonnative species (Factor E).

TABLE 1—IMPACTS TO POPULATIONS OF GEORGIA ROCKCRESS FROM HUMAN-INDUCED FACTORS AND NONNATIVE PLANTS

Site name	County/state	Human-induced impact (factor A)	Impacted by nonnative plants (factor E)
Fort Tombecbee	Sumter/AL	Road with bridge, Housing, Commercial.	None.
Marshalls Bluff	Monroe/AL	Quarry	None.
Prairie Bluff	Wilcox/AL	Road, Housing, Hydropower	Chinese privet and Japanese honeysuckle.
Portland Landing River Slopes	Dallas/AL	Timber harvest, Hydropower	China berrytree, Japanese honeysuckle, and kudzu.
Durant Bend	Dallas/AL	Timber harvest	Chinese privet and Japanese honeysuckle.
Murphys Bluff Bridge Cahaba River	Bibb/AL	Road with bridge	Chinese privet, Japanese honeysuckle, and others.
Creekside Glades and Little Schulz Creek.	Bibb/AL	Housing, Utility lines	None.
Cottingham Creek Bluff and Pratts Ferry	Bibb/AL	Road with bridge, Timber harvest.	Chinese privet and Japanese honeysuckle.
Fern Glade and Six Mile Creek	Bibb/AL	Timber harvest	Chinese privet and Japanese honeysuckle.
Browns Dam Glade North and South	Bibb/AL	None	Chinese privet.
McGuire Ford √ Limestone Park	Bibb/AL	Road, Housing, Maintained field	None.
Fort Toulouse State Park	Elmore/AL	Maintained field/recreation	Japanese honeysuckle.
Fort Gaines Bluff	Clay/GA	Timber harvest	Japanese honeysuckle.
Fort Benning (GA) and (AL)	Chattahoochee/GA and Russell/AL.	Road	Chinese privet and Japanese honeysuckle.
Goat Rock North and South	Harris, Muscogee/GA	Hydropower and Utility lines	Chinese privet and Japanese honeysuckle.
Blacks Bluff Preserve	Floyd/GA	Road, Quarry	Napalese browntop and Japanese honeysuckle.
Whitmore Bluff	Floyd/GA	Timber harvest	Japanese honeysuckle.
Resaca Bluffs	Gordon/GA	Road with bridge, Commercial	Chinese privet and Japanese honeysuckle.

Quarrying destroys the bluff habitat by removing the canopy and soil. The Blacks Bluff population of Georgia rockcress in Floyd County, Georgia, appears to be a surviving remnant of a once larger population. The primary habitat at this locality has been extensively quarried (Allison 1995, p. 10). The Marshalls Bluff population in Monroe County, Alabama, is adjacent to an area that was once quarried (Schotz 2010, pp. 45–47). Rock bluffs along rivers have also been favored sites for hydropower dam construction. The construction of Goat Rock Dam in Harris County, Georgia, destroyed a portion of suitable habitat for a population of Georgia rockcress, and the current population there may also represent a remnant of a once much larger population (Allison 1995, p. 10). The Prairie Bluff and Portland landing populations in Wilcox and Dallas Counties, Alabama, occur on the banks of William ''Bill'' Dannelly Reservoir, where potential habitat was likely inundated (Schotz 2010, pp. 41 and 56). Due to the obscure nature of Georgia rockcress, it is likely that other populations on rocky bluffs, in the Piedmont and Ridge and Valley provinces, were destroyed by quarrying or inundated by hydropower projects (Allison 1995, p. 10).

Conservation efforts by The Nature Conservancy (TNC) in Bibb County, Alabama, have included the land acquisition of the entire population of Georgia rockcress at Browns Dam Glade and a small portion of the Cottingham Creek Bluff population, and the proposed acquisition of the Six Mile Creek population.

The Blacks Bluff Preserve population, Floyd County, Georgia, is in private ownership with a conservation easement held by TNC on the property. There were 27 Georgia rockcress reported on this site in 1995; however, the presence of nonnative species has since extirpated Georgia rockcress from

this site. The Georgia Plant Conservation Alliance (GPCA) and TNC agreed to bolster the existing population with plants grown from seed collected at the two nearby (Ridge and Valley physiographic province) populations: Whitmore Bluff and Resaca Bluffs. The Chattahoochee Nature Center collected seed and grew 35 plants from Whitmore's Bluff and 65 plants from Resaca Bluffs. In 2008, 100 Georgia rockcress plants were planted in this unit, with 31 Georgia rockcress surveyed on this site in 2013 (Goldstrohm 2013, p. 3). In April 2013, an additional 15,000 seeds where sown directly onsite to attempt to recruit new plants to this population (Goldstrohm 2013, p.1).

Two populations are on land owned by the Federal Government, and two on land owned by the State of Alabama. In Federal ownership, the entire Fern Glade population, Bibb County, Alabama, is on land within the Cahaba National Wildlife Refuge. Also, along the banks of the Chattahoochee River in Russell County, Alabama, and Chattahoochee County, Georgia, the entire population at Fort Benning is on land that is in Federal ownership. The Department of Defense is aware of the two sites on the Fort Benning property and is working with TNC to monitor and provide for the conservation of these populations (Elmore 2010, pp. 1–2). However, the current integrated natural resources management plan (INRMP) for Fort Benning does not address Georgia rockcress or its habitat (INRMP 2001). The Prairie Bluff population in Wilcox County, Alabama, may be within an area under a U.S. Army Corps of Engineers easement. The State of Alabama owns Fort Tombecbee in Sumtner County and Fort Toulouse State Park in Elmore County, but there is no protection afforded to these State-owned properties.

The majority of the Goat Rock Dam population in Georgia (Harris/Muscogee Counties) is mostly located on buffer lands of the Georgia Power Company and receives a level of protection in the form of a shoreline management plan with vegetative management buffers to developed to prohibit disturbance and protect Georgia rockcress; this management plan was developed during Federal Energy Regulatory Commission (FERC) licensing (FERC 2004, pp. 7, 18–19, 29–30; Moffett 2007, p. 4). However, the southernmost portion of the Goat Rock Dam population is on privately owned land.

In total at least some portions of nine populations are on land owned by potential conservation partners; however, none of these populations have a formal management plan to benefit Georgia rockcress. These populations are afforded varying degrees of protection, and while none of these lands are likely to be developed, they could be subject to other impacts including recreation, military training, road construction, inappropriate timber harvest, and continued pressure from invasive species. None of the populations are on land that is subject to a management plan, and only the Goat Rock Dam and Blacks Bluff populations are on land on which efforts have been directed to managing for Georgia rockcress.

Historically, suitable habitat was destroyed or degraded due to quarrying, residential development, timber harvesting, road building, recreation, and hydropower dam construction. Severe impacts continue to occur across the range of this species, from quarrying, residential development, timber harvesting, road building, recreation, and hydropower dam construction, and one or more of these activities pose ongoing threats to all known populations. Given the extremely small size of Georgia rockress populations, projects that destroy even a small amount of habitat can have a serious impact on this species, including existing genetic diversity of the species (Factor E).

Overutilization is not known to pose a threat to this species (Alison 1995, p. 10; Moffett 2007, p. 2; Schotz 2010, p. 11).

Limited browsing of Georgia rockcress plants has been noted in Georgia (Allison 1995, p. 10; Moffett 2007, p. 3; Schotz 2010, p. 11). However, disease and predation are not considered to be a threat to this species.

Georgia rockcress is listed as threatened by the State of Georgia (Patrick et al. 1995, p. 17; Chaffin 2007, p. 47). This State listing provides legal standing under the Georgia Wildflower Preservation Act of 1973. This law prohibits the removal of this and other wildflower species from public land and regulates the taking and sale of plants from private land. This law also triggers the Georgia Environmental Protection Act process in the event of potential impacts to a population by State activities on State-owned land (Moffett 2007, p. 3). However, the greater problem of habitat destruction and degradation is not addressed by this law (Patrick et al. 1995, p. 6); therefore, there is no protection from projects like road construction, construction of reservoirs, installation of utility lines, quarrying, or timber harvest that degrade or fragment habitat, especially on private lands. Moreover, the decline of the species in Georgia is also attributed to invasive species (Factor E), and there are no State regulatory protections in place to ameliorate that threat on private lands. In Alabama, there is no protection or regulation, either direct or indirect, for Georgia rockcress (Schotz 2010, pp. 2, 11).

Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah and Lovejoy 2005, p. 4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field et al. 1999, pp. 1–3; Hayhoe et al. 2004, p. 12422; Cayan et al. 2005, p. 6; Intergovernmental Panel on Climate Change (IPCC) 2007, p. 1181). Climate change may lead to increased frequency and duration of severe storms and droughts (Golladay et al. 2004, p. 504; McLaughlin et al. 2002, p. 6074; Cook et al. 2004, p. 1015).).

While severe drought would be expected to have an effect on the plant community, including the mature canopy and canopy gap dynamic, and increased storm intensity could accelerate erosion-related disturbances, the information currently available on the effects of global climate change and increasing temperatures does not make sufficiently precise estimates of the location and magnitude of the effects. In addition, we are not currently aware of any climate change information specific to the habitat of the Georgia rockcress that would indicate which areas may become important to the species in the future.

The primary threat to extant populations of Georgia rockcress is the ongoing invasion of nonnative species due to the degradation of its habitat. Encroachment from timber management and development in the form of bridges, roads, houses, commercial buildings, or utility lines allowing for the introduction of nonnative species has resulted in the decline of Georgia rockcress (Schotz 2010, pp. 9–10; Moffett 2007, pp. 2–7; Alison 1995, pp. 7–18). Human-induced disturbance (quarrying, residential development, timber harvesting, road building, recreation and hydropower dam construction) has fragmented river bluff habitats and created conditions so that

these bluff habitats are receptive to invasion of nonnative species (Honu and Gibson 2006, pp. 263–264). Disturbance of 17 of the 18 known sites occupied by this species has provided opportunities for the invasion of aggressive, nonnative weeds, especially *Lonicera japonica* (Japanese honeysuckle). This species is a gap adaptor, that can easily invade disturbed areas to 90 meters (295 feet) into a forested habitat (Honu and Gibson 2006, p. 264). Other nonnatives include *Melia azedarach* (Chinaberry or bead-tree), *Pueraria montana* var. *lobata* (kudzu), *Albizia julibrissin* (mimosa), *Ligustrum japonica* (Japanese privet), *Ligustrum sinense* (Chinese privet), *Lygodium japonicum* (Japanese climbing fern), and *Microstegium vimineum* (Napalese browntop) (Alison 1995, pp. 18–29; Moffett 2007, p. 9; Schotz 2010, pp. 10, 19–57). While edge habitats are subject to invasion of nonnative species, a more limited group of nonnative plants can then invade closed-canopy habitats; furthermore, species with a rosette form (e.g., Georgia rockcress) are more susceptible to exclusion by some nonnatives (Meiners et al. 1999, p. 266). Georgia rockcress is not a strong competitor and is usually found in areas where growth of other plants is restrained due to the shallowness of the soils or the dynamic status of the site (e.g., eroding riverbanks) (Allison 1995, pp. 7–8; Moffett 2007, p. 4). However, nonnative species are effectively invading these riverbank sites, and the long-term survival of the at least five populations in the Coastal Plain province is questionable (Allison 1995, p. 11). This species is only able to avoid competition with nonnative species where the soil depth is limited (e.g., rocky bluffs) (Allison 1995, pp. 7–8; Moffett 2007, p. 4)

Competition from nonnative species, exacerbated by adjacent land use changes (Factor A), likely contributed to the loss of the population at the type locality in Stewart County, Georgia (Allison 1995, p. 28), and possibly to one of the Bibb County, Alabama, populations and several other sites in this general area (Allison 2002, pers. comm.; Alabama Natural Heritage Program 2004, p. 2). Additional populations are also currently being negatively affected by competition with nonnative plants. According to Moffett (2007, p. 3), most of the sites in Georgia are being impacted by the presence of invasive plant species, primarily Japanese honeysuckle, Chinese privet, and Napalese browntop. Japanese honeysuckle was observed growing on individual plants of Georgia rockcress at three sites visited by Allison in 1995. At a fourth site, plants growing in a mat of Nepalese browntop declined in number from 27 individuals in 1995 (Allison 1995, p. 19) to 3 in 2006 (Moffet 2007 p. 8). Allison (1995, pp. 18–28; Allison 1999, pp. 1–5) considered four other populations to be imminently threatened by the nearby presence of nonnative plants. Thus, approximately 40 percent of the populations visited by Allison in 1995 were reportedly threatened by nonnative species. By 2007, Moffett (2007, p. 3) reported all six of the Georgia rockcress populations in Georgia were threatened by nonnative species. By 2010, Schotz (2010, pp. 20–57) reported 9 of the 13 populations in Alabama were impacted by nonnative species. Currently 14 of the 18 extant populations are threatened by nonnatives.

Given the extremely small number of total plants (fewer than 5,000 in a given year; 12 of the 18 populations have fewer than 50 plants (Schotz 2010, p. iii; Elmore 2010, pp. 1–4; Moffett 2007, pp. 2–7; Alison 1999, pp. 1–5; Alison 1995, pp. 7–18)), and that the species is distributed as disjunct populations across five physiographic provinces (Schotz 2010, pp. 9–10; Moffett 2007, pp. 2–7; Alison 1995, pp. 7–18) in three major river systems, each population is important to the conservation of genetics for the species (Garcia 2012, pp. 30–36). Only the Goat Rock Dam and Fort Benning populations are sufficiently large (greater than 1,000 individuals) to preclude a genetic bottleneck (Schotz 2010, pp. 13–57; Moffett 2007, p. 8). A genetic bottleneck would result in reduced genetic diversity with mating between closely related individuals, which can lead to reduced fitness due to inbreeding depression (Ellstrand and Elam, pp. 217–237). This species is composed of three genetic groups: A North Georgia group, a Middle Georgia group, and an Alabama group (Garcia 2012, p 32). While the Middle Georgia genetic group contains the largest populations (Goat Rock Dam and Fort Benning) and is the most important to the conservation of this species, the smaller populations in the North Georgia and Alabama genetic groups are more vunerable to localized extirpation and represent an important conservation element for this species. Any threats that remove or further deteriorate populations can also have a detrimental effect on the existing genetic diversity of the species.

Determination

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to Georgia rockcress. Habitat degradation (Factor A) and the subsequent invasion of nonnative species (Factor E), more than outright habitat destruction, are the most serious threats to this species' continued existence. Disturbance, associated with timber harvesting, road building, and grazing, has created favorable conditions for the invasion of nonnative weeds, especially Japanese honeysuckle, in this species' habitat. Although the species is afforded some regulatory protection in Georgia, such protection is inadequate to reduce these threats, especially on private land (Factor D); furthermore, there are no such protections in Alabama. Because nearly all populations are currently or potentially threatened by the presence of nonnatives, we find that this species is warranted for listing throughout all its range, and, therefore, we find that it is unnecessary to analyze whether it is endangered or threatened in a significant portion of its range.

The riparian bluff habitat surrounding all 18 of the known populations has been adversely impacted in some way, and in some cases the habitat has suffered multiple impacts. The most imminent and severe threat to extant populations of Georgia rockcress is the ongoing invasion of nonnative species due to the degradation of its habitat. Disturbance (Factor A, in the form of quarrying, residential development, timber harvesting, road building, recreation, and hydropower dam construction) of most of the species' known sites has provided opportunities for the invasion of aggressive, nonnative weeds, especially Japanese honeysuckle. Additional populations are also currently being negatively affected by competition with nonnative plants. According to Moffett (2007, p. 3), most of the sites in Georgia are being impacted by the presence of invasive

plant species. At least 14 of the known populations are adversely impacted by nonnative species. Control of nonnative species will require active management, which is not provided for with current conservation efforts.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the Georgia rockcress is likely to become endangered throughout its entire range within the foreseeable future, based on the immediacy, severity, and scope of the threats described above. We do not find it to be endangered at this time because there are 18 sites spread across the geographic range; therefore the threats, while impacting all populations are not likely to eliminate all populations simultaneously, or even all populations within physiographic areas in the near future. Therefore, on the basis of the best available scientific and commercial information, we propose to list the Georgia rockcress (*Arabis georgiana*) as threatened in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed, preparation of a draft and final recovery plan, and revisions to the plan as significant new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that determine when a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (comprised of species experts, Federal and State agencies, nongovernment organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site (*http://www.fws.gov/endangered*), or from the U.S. Fish and Wildlife Service, Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribal, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Alabama and Georgia would be eligible for Federal funds to implement management actions that promote the protection and recovery of Georgia rockcress. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although Georgia rockcress is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the Department of Defense, U.S. Fish and Wildlife Service, and U.S. Forest Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; construction and management of gas pipeline and power line rights-of-way by the Federal Energy Regulatory Commission; and construction and maintenance of roads or highways by the Federal Highway Administration.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered and threatened plants. The prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61 for endangered plants and by 50 CFR 17.71 for threatened plants, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export,

transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, or remove and reduce the species to possession from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of such plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies. As discussed above (Factor D), this species is not listed in Alabama's State Wildlife Action conservation plan (Alabama Department of Conservation and Natural Resources 2005). Georgia lists the Georgia rockcress as a ''high priority species'' in its State Wildlife Action Plan (Georgia Department of Natural Resources 2005).

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.62 for endangered plants, and at 50 CFR 17.72 for threatened plants. With regard to threatened plants, a permit must be issued for the following reasons: scientific purposes, to enhance the propagation or survival of the species, economic hardship, botanical or horticultural exhibition, educational purposes, or other activities consistent with the purposes and policy of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of species proposed for listing. The following activity could potentially result in a violation of section 9 of the Act; this list is not comprehensive:

• Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the species, including import or export across State lines and international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**). Requests for copies of the regulations concerning listed animals and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, 105 West Park Drive, Suite D, Athens, GA 30606; telephone 706–613–9493; facsimile 706–613–6059.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with listing a species as endangered or threatened under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited in this rule is available on the Internet at *http://www.regulations.gov* or upon request from the Field Supervisor, Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT** section).

Authors

The primary authors of this proposed rule are the staff members of the Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

■ 2. In § 17.12(h), add an entry for ''*Arabis georgiana*'' to the List of Endangered and Threatened Plants in alphabetical order under FLOWERING PLANTS, to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*	*	
Arabis georgiana	Georgia rockcress ..	U.S.A. (GA and AL)	Brassicaceae	T	.....	NA	NA
*	*	*	*	*	*	*	

* * * * *

Dated: August 26, 2013.

Rowan W. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–22129 Filed 9–11–13; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register

Vol. 78, No. 177

Thursday, September 12, 2013

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

Forest Service

RIN 0596–AC82

Ecological Restoration Policy

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed directive; request for comment.

SUMMARY: The Forest Service proposes to issue a permanent Ecological Restoration Policy in Forest Service Manual (FSM) 2020. The proposed directive would provide broad direction for restoring National Forest System lands and associated resources to achieve sustainable management and ecological integrity. This policy would recognize the adaptive capacity of ecosystems, the role of natural disturbances, and uncertainty related to climate and other environmental change. On September 22, 2008, the Forest Service issued an interim directive, FSM 2020 Ecological Restoration and Resilience. The interim directive was reissued on March 3, 2010, a third time on August 30, 2011, and a fourth time on May 13, 2013, and is now proposed as permanent policy.

DATES: Comments must be received in writing by November 12, 2013.

ADDRESSES: Submit comments through the World Wide Web/Internet Web site *http://www.regulations.gov.* Alternately, submit written comments by addressing them to Forest Service Restoration Directive, c/o Jim Alegria, Forest Management Staff, USDA Forest Service, Mailstop 1103, 1400 Independence Avenue SW., Washington, DC 20250, or by facsimile to 202–205–1012. Please identify your written comments by including ''Restoration Directive'' on the cover sheet or first page. Electronic comments are preferred. For comments sent via U.S. Postal Service, please do not submit duplicate electronic or facsimile comments. Please confine comments to the proposed directive on the Ecological Restoration and Resilience Policy.

All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received on the internet at *http://www.fs.fed.us/restoration/index.shtml.*

FOR FURTHER INFORMATION CONTACT: Jim Alegria, Forest Management Staff, USDA Forest Service, Mailstop 1103, 1400 Independence Avenue SW., Washington, DC 20250, 202–205–1787. Individuals who use telecommunications devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background and Need for the Directive

The need for ecological restoration of many areas in the National Forest System is widely recognized, and the Forest Service has conducted restoration-related activities through many resource management programs for decades. However, an internal agency study (*http://www.fs.fed.us/restoration/documents/RestFramework_final_010606.pdf*) identified that the concept of ecological restoration has not been well understood nor consistently implemented within the agency. The Agency believes that a foundational, comprehensive policy and definitions would help it to use ecological restoration more effectively as a tool for achieving land management objectives on national forests and grasslands.

The Forest Service proposes to amend its directives by establishing a new title in the Forest Service Manual, FSM 2020: Ecological Restoration . The proposed directive would establish broad, foundational policy for restoration of National Forest System lands and resources. The intent is to provide a clear, comprehensive, and science-based restoration policy to guide achievement of sustainable management and ecological integrity under changing environmental conditions, such as those driven by a changing climate and increasing human uses.

Restoration is the process of assisting the recovery of ecosystems that have been damaged, degraded, or destroyed. Ecological restoration re-establishes the composition, structure, and/or ecological processes that support sustainable aquatic and terrestrial ecosystems. In order to identify an ecosystem in need of restoration, current conditions should be evaluated against: the natural range of variation as a reference to understand ecosystem function; the dynamic nature of ecosystems, associated natural and current disturbance regimes; and likely future environments resulting from climate change and increasing human uses. Although this proposal is to establish a restoration policy on National Forest System lands and resources, there may be some situations where ecosystems have been so degraded that restoration may not be feasible or economically possible.

The proposed directive applies to all National Forest System's resource management programs. For example, this directive would apply when there is an objective to restore watershed condition and function, control invasive species, re-create natural stream channel complexity, improve or reestablish habitat for threatened and endangered species, and restore natural fire regimes.

The Forest Service has a multiple-use mission and not all management activities on national forests and grasslands require a restoration objective. The Agency will continue to support management activities such as energy development, recreation use, grazing and timber production conducted in an ecologically sustainable manner to avoid the need for ecological restoration in the future. For example, vegetative treatments in the Wildland Urban Interface that are necessary to effectively reduce fire risk to communities may require a silvicultural treatment that would not be viewed as ecological restoration. Rather, the vegetative treatments would address the objective of reducing the risk of harm to people, property and forest resources due to wildfire. Water structures for range management will continue to be developed to sustain livestock and reduce risk to riparian systems. The directive would amend the Forest Service Manual to include a definition for the term *restoration,* or *ecological restoration.* The more generic term *restoration* has been used widely by the Forest Service and other agencies beginning with the National Fire Plan

Cohesive Strategy adopted in 2001, and the *10-Year Comprehensive Strategy and Implementation Plan.* The term *restoration* and associated concepts such as reforestation, resilience, and adaptation, are increasingly used by the Congress, media, stakeholders, general public, scientific community, and leaders, including the Secretary of Agriculture and the Chief of the Forest Service, in their public statements. The directive primarily serves to improve understanding of the term by Forest Service employees, partners, and the public, by clarifying the purpose behind it, as well as its scope and context. This improved understanding will allow the Forest Service to communicate ecological restoration needs more effectively at the local, regional, and national levels.

The policies and ecological principles in this proposed directive are consistent with those in the Forest Service's 2012 Land Management Planning Rule (planning rule). The proposed directive would reinforce the use of adaptive management, scientific information, and collaboration in agency planning and decision-making. The Forest Service twice asked for public comment on the concept and definition of restoration in developing the planning rule, with the release of the Notice of Intent to prepare an environmental impact statement (EIS) for a new rule (December 18, 2009) and again with release of the proposed rule (February 14, 2011). Some public comments stated that the term ''restoration'' needed to be defined. Most respondents who cited the Forest Service definition in the FSM 2020 interim directive generally agreed with it. Others did not agree with the Forest Service definition and offered new definitions. This proposed directive would adopt the definition of restoration from the 2012 planning rule (April 9, 2012) for FSM Chapter 2020—Ecological Restoration. Definitions for other terms proposed for FSM 2020.-5 are from the 2012 planning rule, Agency *National Environmental Policy Act* (NEPA) regulations, and other sources.

Interim Directive

In 2008, the Chief of the Forest Service determined that a national policy on ecological restoration was needed to ensure a consistent and cohesive approach to restoring the ecological integrity of forest and grassland ecosystems. Since then, the Forest Service has been using an interim directive that lays out an operational definition for ''ecological restoration.'' This interim directive has been in place since September 22, 2008, and was reissued on March 3, 2010. It was reissued a third time on August 30, 2011, and a fourth time on May 13, 2013. The interim directive expires on November 13, 2014.

Regulatory Certification

Environmental Impact

The proposed directive establishes broad, foundational policy for restoration of National Forest System lands and associated resources. The Agency procedure at 36 CFR 220.6(d)(2) excludes from documentation in an environmental assessment or environmental impact statement ''rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.'' This proposed directive constitutes a policy to establish Service-wide administrative procedures, program processes, or instructions consequently the Agency has concluded that the proposed directive falls within the category of actions in 36 CFR 220.6(d)(2) and that no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Regulatory Impact

This proposed directive has been reviewed under USDA procedures and *Executive Order 12866, Regulatory Planning and Review.* It has been determined that this is not an economically significant action. This action would not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor state or local governments. This action would not interfere with an action taken or planned by another agency. This action would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. However, because of the extensive interest in the management of National Forest System land, this proposed agency directive has been designated as significant and, therefore, is subject to Office of Management and Budget review under Executive Order 12866.

In accordance with OMB circular A–4, ''Regulatory Analysis,'' a cost/benefit analysis was conducted. The analysis compared the costs and benefits associated with the ''no action'' alternative of not having an agency policy and the alternative of adopting the proposed ecological restoration policy. Many benefits and costs associated with the proposed agency policy are not quantifiable. Benefits include providing consistent and uniform understanding and Service-wide application of restoration policies, principles, and terminology; increasing agency effectiveness when planning and implementing restoration activities; and fostering better understanding and collaboration among interests from local to national levels. It is anticipated that the proposed directive would reduce costs by providing clear policy, definitions, and principles of ecological restoration and reducing ad hoc or inconsistent interpretation of terminology and policy.

This directive has been reviewed in light of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*), and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by that Act. A threshold regulatory flexibility analysis is not required under the Regulatory Flexibility Act because this directive is broad agency policy that imposes no impacts or requirements on small or large entities. The directive will increase agency effectiveness when planning and implementing restoration activities at the local level.

Federalism

The Agency has considered this proposed directive under the requirements of *Executive Order 13132, Federalism.* The Agency has concluded that the proposed directive conforms with the federalism principles set out in this Executive order; will not impose any compliance costs on the States; and will not have substantial direct effects on the States or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has determined that no further assessment of federalism implications is necessary.

Consultation and Coordination with Indian Tribal Governments

Pursuant to *Executive Order 13175 of November 6, 2000, ''Consultation and Coordination with Indian Tribal Governments,''* Tribes were invited to consult on the proposed directive prior to review and comment by the general public. The consultation process was initiated through written instructions from the Deputy Chief for the National Forest System to the Regional Foresters and subsequently to the Forest Supervisors. Upon request from Tribes, formal consultation was conducted by the Forest Supervisors and/or District Rangers with assistance from staff. Tribal comments were submitted to the

Washington Office staff designated as lead for this proposed policy.

A limited number of responses were received during the course of the 120-day consultation period, and used in the formulation of policy or otherwise considered. Comments were in support of the directive. Some expressed the opinion that the directive did not represent any change from current Agency practices. One comment suggested that the ecological restoration policy should include identification and removal of stressors (often human uses) as part of any restoration activity. The suggestion was incorporated into the policy section at 2020.3.

Implementation of this directive primarily occurs at the local level (national forest or grassland unit) through land management planning and project-level planning and accomplishment. When local actions are initiated, another level of consultation would occur among Tribes and forest and grassland units because it is at that more local level that site-specific ecological restoration goals and objectives are established. Also, at that level the design and effects of restoration activities are most effectively managed in relation to the Agency's tribal trust responsibilities and Indian tribal treaty rights to assure Tribal interests are respected.

The proposed directive establisheses broad, foundational policy for ecological restoration of National Forest System (NFS) lands and associated resources but does not directly affect the occupancy and use of NFS land. The Agency has assessed the impact of this proposed directive on Indian Tribes through Tribal consultation and has determined that it does not have substantial direct or unique 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 Agency has also determined that this proposed directive does not impose substantial direct compliance costs on Indian tribal governments or preempt tribal law.

No Takings Implications

This proposed directive has been analyzed in accordance with the principles and criteria contained in *Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights,* and it has been determined that the proposed directive does not pose the risk of a taking of protected private property.

Civil Justice Reform

This proposed directive has been reviewed under *Executive Order 12988 ''Civil Justice Reform.''* After adoption of this proposed directive, (1) All state and local laws and regulations that conflict with this proposed directive or that would impede full implementation of this directive would be preempted; (2) no retroactive effect would be given to this proposed directive; and (3) the proposed directive would not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the Agency has assessed the effects of this proposed directive on State, local, and Tribal governments and the private sector. This proposed directive does not compel the annual expenditure of $100 million or more by any State, local, or Tribal government in the aggregate or by anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Energy Effects

This proposed directive has been reviewed under *Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* It has been determined that this proposed directive does not constitute a significant energy action as defined in the Executive order.

Controlling Paperwork Burdens on the Public

This proposed directive does not contain any additional record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law and already approved for use, and, therefore, imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Forest Service Manual

The Forest Service is seeking comment on the proposed policy being established in Forest Service Manual 2020 as follows:

Chapter 2020—Ecological Restoration

FSM 2020 provides foundational policy when ecological restoration is employed to manage National Forest System lands. This directive reaches across all program areas and activities applicable to management of National Forest System lands and resources so as to ensure integration and coordination at all levels and within all organizational units.

2020.1—Authority

The authority for restoring National Forest System lands derives from many laws enacted by Congress that define the purpose of national forests and grasslands. These are cited throughout the Forest Service Manual and Handbooks. FSM 1010 lists the most significant laws and provides guidance on where to obtain copies of them.

The history of Federal policies, treaties, statutes, court decisions, and Presidential direction regarding Indian Tribes and tribal rights and interests is extensive. FSM 1563.01a through 1563.01i set out the legal authorities relevant to Forest Service relationships with Tribes.

The President issued direction through several Executive orders relevant to protection of resources or restoration of ecosystem processes and functions. Also, numerous regulations governing the sustainable management and restoration of National Forest System lands are found in the Code of Federal Regulations under Title 36, Chapter II, Parts 200–299.

2020.11—Laws

The principal statutes governing the management and restoration of National Forest System lands include, but are not limited to, the following statutes. Except where specifically stated, these statutes apply to all National Forest System lands and resources.

1. *Organic Administration Act* (at 16 U.S.C. 475, 551). States the purpose of the national forests, and directs their control and administration to be in accord with such purpose, that is, ''[n]o national forest shall be established, except to improve and protect the forest within the boundaries, or for the purpose of securing favorable conditions of water flows, and to furnish a continuous supply of timber for the use and necessities of citizens of the United States.'' Authorizes the Secretary of Agriculture to ''make such rules and regulations . . . to preserve the [national] forests from destruction.''

2. *Weeks Act,* as amended (at 16 U.S.C. 515, 552). Authorizes the Secretary of Agriculture to enter into agreements with States for the purpose of conserving forests and water supply, and to acquire forested, cutover, or denuded lands within the watersheds of navigable streams to protect the flow of these streams or for the production of

timber, with the consent of the State in which the land lies.

3. *Knutson-Vandenberg Act* (16 U.S.C. at 576b). Specifies that the Secretary may require any purchaser of national forest timber to make deposits of money in addition to the payments for the timber, to cover costs incurred to the United States. These costs include planting, sowing with tree seeds, and cutting, destroying, or otherwise removing undesirable trees or other growth, on the national forest land cut over by the purchaser. The monies are used to improve the future stand of timber, or to protect and to improve the future productivity of the renewable resources of the forest land in such sale area.

4. *Anderson-Mansfield Reforestation and Revegetation Joint Resolution Act of 1949* (at 16 U.S.C. 581j and 581 j(note)). States the policy of the Congress to accelerate and provide a continuing basis for the needed reforestation and revegetation of national forest lands and other lands under Forest Service administration or control, for the purpose of obtaining stated benefits (timber, forage, watershed protection, and benefits to local communities) from the national forests.

5. *Granger-Thye Act* (16 U.S.C. at 580g–h). Section 12 authorizes the Secretary to use a portion of grazing fees for range improvement projects on NFS lands. Among the specific types of projects mentioned are artificial revegetation, including the collection or purchase of necessary seed and eradication of poisonous plants and noxious weeds, in order to protect or improve the future productivity of the range (16 USC 580h). Section 11 of the Act authorizes the use of funds for certain types of rangeland improvement projects outside of NFS lands under certain circumstances (16 USC 580g).

6. *Sikes Act* (16 U.S.C. at 670g). Section 201 directs the Secretary of Agriculture, in cooperation with State agencies, to plan, develop, maintain, coordinate, and implement programs for the conservation and rehabilitation of wildlife, fish, and game species. Such programs include specific habitat improvement projects on public land under the Secretary's jurisdiction.

7. *Multiple-Use Sustained-Yield Act of 1960* (16 U.S.C. 528–531). States that the National Forests are to be administered for outdoor recreation, range, timber, watershed, and wildlife and fish purposes, and adds that the establishment and maintenance of wilderness areas are consistent with this Act. This Act directs the Secretary to manage renewable surface resources of the national forests for multiple use and sustained yield of the several products and services obtained therefrom. Multiple use means the management of all the various renewable surface resources of the national forests in the combination that will best meet the needs of the American people; providing for periodic adjustments in use to conform to changing needs and conditions; and harmonious and coordinated management of the resources without impairment of the productivity of the land. Sustained yield of the several products and services means achieving and maintaining in perpetuity a high-level annual or regular periodic output of renewable resources without impairment of the productivity of the land.

8. *Wilderness Act* (16 U.S.C. 1131 et seq.). Requires the Secretary of Agriculture to administer certain congressionally designated National Forest System lands as wilderness. The Act directs the protection and preservation of wilderness areas in their natural state, primarily affected by nature and not man's actions. The Act allows certain management actions that would otherwise be prohibited in wilderness ''as necessary to meet minimum requirements for the administration of the area for the purpose of the Act,'' and also provides that ''such measures may be taken as may be necessary in the control of fire, insects, and diseases, subject to such conditions as the Secretary deems desirable.'' 16 U.S.C. 1133 (c),(d).

9. *Wild and Scenic Rivers Act* (16 U.S.C. 1271–1287). Establishes the National Wild and Scenic Rivers System, and policy for managing designated rivers and designating additions to the system. The Act prescribes for designated rivers and their immediate environments the protection and enhancement of their free-flowing character, water quality, and outstandingly remarkable scenic, recreational, geologic, fish and wildlife, historic, cultural, or other similar values. Streams eligible for inclusion in the system must be in free-flowing condition or have been restored to this condition. The Act authorizes the Secretary of Agriculture to plan for, protect, and manage river resources, and take such actions as necessary to protect rivers in accordance with the act, including cooperating with EPA and the appropriate State water pollution control agencies for the purpose of eliminating or diminishing the pollution of waters.

10. *National Environmental Policy Act of 1969 (NEPA)* (16 U.S.C. 4321 et seq.). Declares it is the policy of the Federal Government to encourage a ''productive and enjoyable harmony between humans and their environment,'' and fulfill the social, economic, and other requirements of present and future generations of Americans. The Act requires agencies proposing major federal actions significantly affecting the quality of the human environment to prepare a detailed statement on the environmental impacts of the proposed action, unavoidable adverse environmental impacts, alternatives to the action proposed, the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and any irreversible and irretrievable commitments of resources which would be involved if the proposed action is implemented. The Act also provides that for any proposal which involves unresolved conflicts concerning alternative uses of available resources, an agency must study, develop, and describe appropriate alternatives to recommended courses of action.

11. *Endangered Species Act of 1973* (16 U.S.C. 1531–1544, as amended). States its purposes are to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, and provide a program for the conservation of such endangered species and threatened species. Federal agencies are to use their authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of threatened and endangered species. Under the Act, ''conserve'' means to use methods and procedures necessary to bring any endangered or threatened species to the point at which the measures provided under the Endangered Species Act are no longer necessary. Federal agencies must also ensure that their actions are not likely to jeopardize threatened or endangered species or result in the destruction or adverse modification of critical habitat designated for them.

12. *Magnuson-Stevens Fishery Conservation and Management Act of 2006* (16 U.S.C. 1855, as amended). States each Federal agency shall consult with the Secretary of Commerce with respect to any action authorized, funded, or undertaken, or proposed to be authorized, funded or undertaken by such agency that may adversely affect essential fish habitat identified under this Act. Essential fish habitats are those waters and substrates necessary to federally managed fish for spawning, breeding, feeding, or growth to maturity.

13. *Forest and Rangeland Renewable Resources Planning Act (RPA) of 1974,* as amended by National Forest

Management Act (NFMA) of 1976 (16 U.S.C. 1600–1614, 472a). States that the development and administration of the renewable resources of the National Forest System are to be in full accord with the concepts for multiple use and sustained yield of products and services as set forth in the Multiple-Use Sustained-Yield Act of 1960. Establishes the policy of the Congress that all forested lands in the National Forest System be maintained in appropriate forest cover with species of trees, degree of stocking, rate of growth, and stand conditions designed to secure the maximum benefits of multiple use sustained yield management in accordance with land management plans. It sets forth the requirements for land and resource management plans for units of the National Forest System, including requiring guidelines to provide for the diversity of plant and animal communities based on the suitability and capability of the specific land area and within multiple use objectives.

14. *Clean Water Act* (33 U.S.C. 1251, 1254, 1323, 1324, 1329, 1342, 1344). Amends the Federal Water Pollution Control Act of 1972. The objective of the Act is to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'' Section 313 emphasizes Federal agency compliance with Federal, State, and local substantive and procedural requirements related to the control and abatement of pollution to the same extent as required of nongovernmental entities. (33 U.S.C. 1323.)

15. *Clean Air Act* (42 U.S.C. 7401, 7418, 7470. 7472, 7474, 7475, 7491, 7506, 7602). Section 169 A establishes a national goal to prevent any future, and remedy any existing, visibility impairment in certain wilderness areas the Forest Service manages (42 U.S.C. 7491). It also directs the Forest Service as a Federal land manager to protect air quality related values from man-made air pollution in these same areas. Section 118 obligates the Forest Service to comply with the Act's many provisions regarding abatement of air pollution to the same extent as any nongovernmental entity (42 U.S.C. 7418).

16. *North American Wetland Conservation Act* (16 U.S.C. 4401 (note), 4401–4413, 16 U.S.C. 669b (note)). Section 9 (U.S.C. 4408) directs Federal land managing agencies to cooperate with the Director of the U.S. Fish and Wildlife Service to restore, protect, and enhance the wetland ecosystems and other habitats for migratory birds, fish and wildlife within the lands and waters of each agency to the extent consistent with the mission of such agency and existing statutory authorities.

17. *Healthy Forests Restoration Act (HFRA) of 2003* (16 U.S.C. 6501–6591). Provides processes for developing and implementing hazardous fuel reduction projects on certain types of ''at-risk'' National Forest System and Bureau of Land Management (BLM) lands, and also provides other authorities and direction to help reduce hazardous fuels and protect, restore, and enhance healthy forest and rangeland ecosystems.

18. *Stewardship End Result Contracting Projects* (16 U.S.C. 2104 (note)). Grants the Bureau of Land Management (BLM) and the Forest Service ten-year authority (to September 30, 2013) to enter into stewardship contracts or agreements to achieve agency land management goals and meet community needs.

19. *Tribal Forest Protection Act of 2004* (25 U.S.C. 3115a). Authorizes the Secretary of Agriculture and the Secretary of the Interior to enter into an agreement or contract with Indian tribes meeting certain criteria to carry out projects to protect Indian forest land or rangeland, including projects to restore Federal land that borders on or is adjacent to Indian forest land or rangeland.

2020.12—Executive Orders

Principal Executive orders relevant to ecological restoration are listed below.

1. *Executive Order 11514* issued March 5, 1970, as amended by E.O. 11991, issued May 24, 1977. Protection and enhancement of environmental quality (35 FR 4247, March 7, 1970; 42 FR 26967, May 25, 1977). This order states that the Federal Government shall provide leadership in protecting and enhancing the quality of the Nation's environment to sustain and enrich human life. This order provides for monitoring, evaluation, and control on a continuing basis of the activities of each Federal agency so as to protect and enhance the quality of the environment.

2. *Executive Order 11644* issued February 8, 1972. Use of off-road vehicles on the public lands. (37 FR 2877, February 9, 1972). Amended by E.O. 11989 issued May 24, 1977 and E.O. 12608 issued September 9, 1987. These orders require Federal agencies to develop and implement procedures that will ensure that the use of off-road vehicles on public lands will be controlled and directed so as to protect the resources of those lands, to promote the safety of all users of those lands, and to minimize conflicts among the various uses of those lands.

3. *Executive Order 11988* issued May 24, 1977. Floodplain management (42 FR 26951 (May 25, 1977)). This order requires that each agency shall provide leadership and take action to:

a. Minimize adverse impacts associated with the occupancy and modification of flood plains and reduce risks of flood loss;

b. Minimize impact of floods on human safety, health, and welfare; and

c. Restore and preserve the natural and beneficial values served by floodplains.

4. *Executive Order 11990* issued May 24, 1977. Protection of wetlands. (42 FR 26961, May 25, 1977). This order requires each agency to take action to minimize destruction, loss, or degradation of wetlands and to preserve and enhance the natural and beneficial values of wetlands.

5. *Executive Order 13112* issued February 3, 1999. Invasive Species. (64 FR 6183 (February 8, 1999)). This order requires Federal agencies whose actions may affect the status of invasive species to, among other things, respond to and control populations of invasive species and provide for restoration of native species and habitat conditions in ecosystems that have been invaded by non-native invasive species.

2020.2—Objective

The objectives of the Forest Service Ecological Restoration policy are to:

1. Reestablish and retain ecological integrity of National Forest System ecosystems and associated resources to achieve ecological sustainability and provide a broad range of ecosystem services.

2. Restore and maintain resilient ecosystems that will have greater capacity to withstand stressors and recover from disturbances, especially those under changing and uncertain environmental conditions and extreme weather events.

2020.3—Policy

1. All resource management programs have a responsibility for ecological restoration including, but not limited to, management of vegetation, water, wildland fire, fish, wildlife, and recreation. Management activities may range from monitoring resource conditions to manipulating terrestrial and aquatic ecosystems to assist in their recovery from the impacts of human uses.

2. Strategic plans, including the Forest Service Strategic plan, land and resource management plans, and area plans should include ecological restoration goals and objectives to re-establish ecological integrity and

maintain the adaptive capacity of ecosystems. Goals and objectives must be established within the framework defined by laws; Indian treaties and Tribal values and desires; regulations; public values and desires; natural range of variation (NRV); current and likely future ecological capabilities; a range of climate and other environmental change projections; the best available scientific information; and technical and economic feasibility to achieve desired conditions for National Forest System lands. Guidance and procedures for assessing ecological integrity and establishing goals and objectives for ecological restoration are included in Forest Service Handbook 1909.12, chapter 40. The directives for implementing the 2012 Land and Resource Management Planning Rule are being revised to include direction for ecological restoration consistent with the new planning rule.

3. Ecological restoration activities should be planned, authorized, implemented, monitored, and evaluated within the context of the NRV, current and desired conditions, and the potential for future changes in environmental conditions due to climate change and human uses. Some ecosystems may be damaged to such an extent that restoration may not be ecologically or economically possible. Where an environment has been irreversibly altered, restoration goals and activities will need to be adjusted accordingly to management ecosystems so that they are sustainable.

4. Where appropriate, ecological restoration should be integrated into resource management programs and projects to achieve complementary or synergistic results. Primary elements of an integrated approach are identification and elimination or reduction of stressors that degrade or impair ecological integrity. An integrated approach includes, where appropriate, taking actions that ensure long-term resilience even though there may be localized short-term adverse effects.

5. Resource managers shall consider collaboration across ownerships and jurisdictions to develop and achieve landscape-scale restoration objectives. Collaboration must include public involvement and consultation with Indian Tribes to effectively achieve restoration objectives.

6. Within existing authorities, revenue from commercial uses of natural resources may be used to help fund restoration activities.

7. Adaptive management, monitoring, and evaluation are essential for effectively achieving ecological restoration goals.

2020.4—Responsibility

2020.41—Chief

The Chief:

1. Retains overall authority over and responsibility for establishing national policy for ecological restoration of disturbed sites and degraded ecosystems.

2. Promotes cooperation and coordination between the Forest Service and other Federal agencies; State, Tribal and local governments; industry; partners; and the public for the development of restoration objectives.

3. Provides leadership across deputy areas to ensure the application of restoration, climate change, and risk management science is integrated into all Forest Service program areas.

2020.42—Deputy Chief for National Forest System (NFS)

The Deputy Chief, NFS, is delegated the authority and responsibility for restoration of NFS lands in conformance with applicable Federal law, regulation, and policy. The Deputy Chief provides coordination across NFS program areas to ensure integrated and complementary program delivery. Authorities not delegated in the following sections to the regional foresters, forest and grassland supervisors, and district rangers are reserved to the Deputy Chief, NFS.

2020.43—Washington Office Staff Directors

All Washington Office staff directors are delegated authority by the Chief and deputy chiefs to plan, develop, administer, monitor, and evaluate assigned programs. In carrying out this authority as it relates to strategic planning, staff directors shall be responsible for developing, executing, monitoring, reporting, and overseeing their program and activity areas incorporating, where appropriate, specific integrated ecological restoration policies and principles consistent with the authorities described in detail in their specific program titles, chapters, and sections of the Forest Service Manual.

2020.44—Regional Forester

Regional foresters are responsible for:

1. Establishing regional policy for ecological restoration consistent with national policy.

2. Establishing direction and policy to ensure ecological restoration is integrated into regional programs and land management plans.

3. Coordinating with counterparts in other Federal agencies; State, county, and Tribal governments; private industry; and the public when developing and implementing ecological restoration programs and activities.

4. Delegating to forest and national grassland supervisors the authority to restore National Forest System lands.

2020.45—Forest and Grassland Supervisors

Forest and Grassland supervisors are responsible for:

1. Implementing forest and grassland programs consistent with national and regional policy for ecological restoration.

2. Ensuring ecological restoration is considered and integrated, as appropriate, into forest and grassland programs and the land management plan.

3. Coordinating with counterparts in other Federal agencies; State, county, and Tribal governments; private industry; and the public when planning and implementing ecological restoration programs.

2020.46—District Ranger

District rangers are responsible for development and approval of ecological restoration projects and to ensure they are consistent with national, regional, and forest policies.

2020.5—Definitions

Adaptive capacity. The ability of ecosystems to respond, cope or adapt to disturbances and stressors, including environmental change, to maintain options for future generations. Adaptation includes, but is not limited to, maintaining primary productivity and basic ecological functions such as hydrologic and nutrient cycling. Adaption occurs primarily by organisms altering their interactions with the physical environment and other organisms. As applied to ecological systems, adaptive capacity is determined by:

1. Genetic diversity within species in ecosystems, allowing for selection of individuals with traits adapted to changing environmental conditions.

2. Biodiversity within the ecosystem, both in terms of species richness and relative abundance, which contributes to functional redundancies.

3. The heterogeneity and integrity of ecosystems occurring as mosaics within broader-scaled landscapes or biomes, making it more likely that some areas will escape disturbance and serve as source areas for re-colonization.

Adaptive management. A system of management practices based on clearly identified intended outcomes and monitoring to determine if management actions are meeting those outcomes, and, if not, to facilitate management changes that will best ensure that those outcomes are met or re-evaluated. Adaptive management stems from the recognition that knowledge about natural resource systems is sometimes uncertain.

Disturbance. Any relatively discrete event in time that disrupts ecosystem, watershed, community, or species population structure and/or function and changes resources, substrate availability, or the physical environment.

Disturbance regime. A description of the characteristic types of disturbance on a given landscape; the frequency, severity, and size distribution of these characteristic disturbance types; and their interactions.

Ecological restoration. See Restoration.

Ecological Integrity. The quality or condition of an ecosystem when its dominant ecological characteristics (for example, composition, structure, function, connectivity, and species composition and diversity) occur within the NRV and can withstand and recover from most perturbations imposed by natural environmental dynamics or human influence.

Ecosystem. A spatially explicit, relatively homogeneous unit of the Earth that includes all interacting organisms and elements of the abiotic environment within its boundaries. An ecosystem is commonly described in terms of its:

(1) Composition. The biological elements within the different levels of biological organizations, from genes and species to communities and ecosystems.

(2) Structure. The organization and physical arrangement of biological elements such as snags and down woody debris, vertical and horizontal distribution of vegetation, stream habitat complexity, landscape pattern, and connectivity.

(3) Function. Ecological processes, such as energy flow; nutrient cycling and retention; soil development and retention; predation and herbivory; and natural disturbances such as wind, fire, and floods.

(4) Connectivity. Ecological conditions that exist at several spatial and temporal scales that provide landscape linkages that permit the exchange of flow, sediments, and nutrients; the daily and seasonal movements of animals within home ranges; the dispersal and genetic interchange between populations; and the long distance range shifts of species, such as in response to climate change.

Ecosystem services. Benefits people obtain from ecosystems, including:

Provisioning services—such as clean air and fresh water, as well as energy, fuel, forage, fiber, and minerals;

Regulating services—such as long-term storage of carbon; climate regulation; water filtration, purification, and storage;soil stabilization; flood control, and disease regulation;

Supporting services—such as pollination, seed dispersal, soil formation, and nutrient cycling; and

Cultural services—such as educational, aesthetic, spiritual, and cultural heritage values, recreational experiences, and tourism opportunities.

Landscape. A defined area irrespective of ownership or other artificial boundaries, such as a spatial mosaic of terrestrial and aquatic ecosystems, landforms, and plant communities, repeated in similar form throughout such a defined area.

Natural range of variation (NRV). Spatial and temporal variation in ecosystem characteristics under historic disturbance regimes during a reference period. The reference period considered should be sufficiently long to include the full range of variation produced by dominant natural disturbance regimes, often several centuries, for such disturbances as fire and flooding and should also include short-term variation and cycles in climate. ''Natural range of variation'' (NRV) is a term used synonymously with historic range of variation or range of natural variation. The NRV is a tool for assessing ecological integrity, and does not necessarily constitute a management target or desired condition. The NRV can help identify key structural, functional, compositional, and connectivity characteristics, for which plan components may be important for either maintenance or restoration of such ecological conditions.

Resilience. The capability of an ecosystem to endure disturbances and retain its structure and functions; the capacity of an ecosystem, which is subject to disturbance or change, to reorganize and renew itself.

Restoration. The process of assisting the recovery of an ecosystem that has been degraded, damaged, or destroyed. Ecological restoration focuses on reestablishing the composition, structure, pattern, and ecological processes necessary to facilitate terrestrial and aquatic ecosystem sustainability, resilience, and health under current and future conditions.

Stressors. Factors that may directly or indirectly degrade or impair ecosystem composition, ecosystem structure or ecological processes in a manner that may impair its ecological integrity, such as an invasive species, loss of connectivity, or the disruption of a natural disturbance regime.

Sustainability. The capability to meet the needs of the present generation without compromising the ability of future generations to meet their needs. Ecological sustainability refers to the capability of ecosystems to maintain ecological integrity.

Dated: September 6, 2013.

Thomas L. Tidwell,

Chief, Forest Service.

[FR Doc. 2013–22149 Filed 9–11–13; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, Department of Agriculture.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Cotton Ginning Survey. Revision to burden hours will be needed due to changes in the size of the target population, sampling design, and/or questionnaire length.

DATES: Comments on this notice must be received by November 12, 2013 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0220, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Fax:* (202) 720–6396.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building,

1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS Clearance Officer, at (202) 690–2388.

SUPPLEMENTARY INFORMATION:

Title: Cotton Ginning Survey.

OMB Control Number: 0535–0220.

Expiration Date of Approval: March 31, 2014.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture. The Cotton Ginning surveys provide cotton ginning statistics from August through February by State to aid in forecasting cotton production. Data collected consists of bales of cotton ginned to date, cotton to be ginned, lint cotton produced, cottonseed produced, cottonseed sold to oil mills, cottonseed used for other uses, number of gins by type, bales produced by county of origin, and cottonseed prices received by producers. The forecasting procedure involves calculating a weighted percent ginned to date as well as an allowance for cross-state movement and bale weight adjustments. Production by State allows adjustments for year-end State and county estimates. Total pounds of lint cotton produced, is used to derive an actual bale weight which increases the precision of production estimates.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501, et seq.) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33376.

Estimate of Burden: Public reporting burden for this collection of information is estimated to be between 10 to 15 minutes per respondent per survey.

Respondents: Active Cotton Gins.

Estimated Number of Respondents: 700.

Estimated Total Annual Burden on Respondents: 1,150 hours.

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 will have practical utility; (b) 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; (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 those who are to respond, including through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, August 22, 2013.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. 2013–22238 Filed 9–11–13; 8:45 am]

BILLING CODE 3410–20–P

BROADCASTING BOARD OF GOVERNORS

Sunshine Act Meeting Notice

DATE AND TIME: Wednesday, September 11, 2013, 11:30 a.m. EDT

PLACE: Broadcasting Board of Governors, Cohen Building, Room 3321, 330 Independence Ave. SW., Washington, DC 20237.

SUBJECT: Notice of Closed Meeting of the Broadcasting Board of Governors.

SUMMARY: The members of the Broadcasting Board of Governors (BBG) will meet in a special session, to be conducted telephonically, to discuss and approve a budget submission for Fiscal Year 2015. According to Office of Management and Budget (OMB) Circular A–11, Section 22.1, all agency budgetary materials and data are considered confidential prior to the President submitting a budget to Congress. In accordance with section 22.5 of Circular A–11, the BBG has determined that its meeting should be closed to public observation pursuant to 5 U.S.C. 552b(c)(9)(B). In accordance with the Government in the Sunshine Act and BBG policies, the meeting will be recorded and a transcript of the proceedings, subject to the redaction of information protected by 5 U.S.C. 552b(c)(9)(B), will be made available to the public. The publicly-releasable transcript will be available for download at *www.bbg.gov* within 21 days of the date of the meeting.

Information regarding member votes to close the meeting and expected attendees can also be found on the Agency's public Web site.

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Paul Kollmer-Dorsey at (202) 203–4545.

Paul Kollmer-Dorsey,

Deputy General Counsel.

[FR Doc. 2013–22284 Filed 9–10–13; 11:15 am]

BILLING CODE 8610–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–893]

Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results of Administrative Review; 2011–2012

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On March 12, 2013, the Department of Commerce (''Department'') published the *Preliminary Results* of the administrative review of the antidumping duty order on certain frozen warmwater shrimp (''shrimp'') from the People's Republic of China (''PRC''), covering the period of review (''POR'') from February 1, 2011, through January 31, 2012.[1] On May 20, 2013, the Department issued a post-preliminary analysis of Zhanjiang Regal Integrated Marine Resources Co., Ltd. (''Regal'') and preliminarily determined that Regal is eligible for a company-specific revocation.[2]

[1] *See Certain Frozen Warmwater Shrimp from the People's Republic of China: Preliminary Results of Administrative Review; 2011–2012,* 78 FR 15696 (March 12, 2013) (''*Preliminary Results*'').

[2] *See* Memorandum To: Paul Piquado, Assistant Secretary, Import Administration, From: Christian

Continued

The Department has determined to revoke the order with respect to Regal. Additionally, the Department continues to find that Hilltop International [3] and that Zhanjiang Newpro Foods Co., Ltd. (''Newpro'') are part of the PRC-wide entity. The final dumping margins are listed below in the ''Final Results of the Administrative Review'' section of this notice.

DATES: Effective Date: September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Josh Startup, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5260.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp. The product is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. The written description of the scope of the order is dispositive. A full description of the scope of the order is available in the accompanying Issues and Decision Memorandum.[4]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the Issues and Decision Memorandum. A list of the issues which parties raised, and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://www.trade.gov/ia/.* The signed Issues and Decision Memorandum and the electronic versions of the Decision Memorandum are identical in content.

Final Determination of No Shipments

In the *Preliminary Results* the Department found the following companies did not have any reviewable transactions during the POR: Allied Pacific Food (Dalian) Co., Ltd. and Allied Pacific Aquatic Products (Zhanjiang) Co., Ltd. (collectively ''Allied Pacific Group''); Shantou Yuexing Enterprise Company; and, Rizhao Smart Foods Co., Ltd.[5] We have not received any information to contradict this determination. Therefore, the Department is making the final determination that the above-named companies did not have any reviewable entries of subject merchandise during the POR, and will issue appropriate instructions that are consistent with our ''automatic assessment'' clarification, for these final results.

Verification

Pursuant to 19 CFR 351.307(b)(iii) and 19 CFR 351.222(f)(2)(ii), between June 3, 2013 and June 7, 2013, the Department conducted a verification of Regal's sales and factors of production, as well as information relevant to company-specific revocation.[6]

Changes Since the Preliminary Results

The Department has not made any changes to the margin calculations since the *Preliminary Results.*

Revocation In Part

In the Post-Prelim Analysis Memo, we determined that Regal met the regulatory criteria for revocation set forth in 19 CFR 351.222(b) (2011).[7] Following the verification of Regal, the Department continues to find that Regal has met all the criteria for revocation and, therefore, we will revoke the order with respect to Regal. Pursuant to 19 CFR 351.222(f)(3), this revocation applies to all entries of subject merchandise that are produced and exported by Regal, and are entered, or withdrawn from warehouse, for consumption on or after February 1, 2012 (*i.e.,* the first day after the period under review). The Department will order the suspension of liquidation lifted for all such entries and will instruct CBP to release any cash deposits or bonds. The Department will further instruct CBP to refund with interest any cash deposits on entries made on or after February 1, 2012.

Newpro's Separate Rate

In the Post-Prelim Analysis Memo, we preliminarily determined that Newpro had not met the necessary criteria to receive a separate rate.[8] We have not received any information since the issuance of the Post-Preliminary Analysis Memo that provides a basis for reconsidering this determination. Therefore, the Department continues to find that Newpro does not meet the criteria for a separate rate for the final results and Newpro will remain part of the PRC-wide entity.

Final Results of Review

The Department determines that the following weighted-average dumping margins exist.

Exporter	Weighted average dumping margin (in percent)
Zhanjiang Regal Integrated Marine Resources Co., Ltd.	0.00
PRC-Wide Entity [9]	112.81

Disclosure and Public Comment

Wewill disclose the calculations performed within five days of the date

Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Subject: 11/12 Antidumping Duty Administrative Review on Certain Frozen Warm water Shrimp from the People's Republic of China: Post-Preliminary Analysis for Zhanjiang Regal Integrated Marine Resources Co., Ltd., and Zhanjiang Newpro Foods Co., Ltd., dated May 20, 2013 (''Post-Prelim Analysis Memo'').

[3] As in past reviews, Hilltop reported in its Section A response that it is part of an affiliated group of companies that includes Yangjiang City Yelin Hoitat Quick Frozen Seafood Co., Ltd., Fuqing Yihua Aquatic Food Co., Ltd., Ocean Duke Corporation and Kingston Foods Corporation (collectively, ''Hilltop'').

[4] *See* Memorandum to paul Piquado, Assistant Secretary for Import Administration, From Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operation, Certain Frozen Warmwater Shrimp from the People's Republic of China: Issues and Decision Memorandum for the Final Results, (''Issues and Decision Memorandum'') dated concurrently with this notice.

[5] *See Preliminary Results,* 78 FR 15697.

[6] *See* Regal Verification Report.

[7] The Department recently modified the regulations concerning the revocation of antidumping and countervailing duty orders on a company specific basis, but that modification went into effect after the initiation of this administrative review. *See Modification to Regulation Concerning the Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 29875 (May 21, 2012).

[8] *See* Post-Preliminary Analysis Memo at 7.

[9] Aqua Foods (Qingdao) Co., Ltd., Asian Seafoods (Zhanjiang) Co., Ltd., Beihai Evergreen Aquatic Product Science And Technology Co Ltd, Dalian Hualian Foods Co., Ltd., Dalian Shanhai Seafood Co., Ltd., Dalian Taiyang Aquatic Products Co., Ltd. Dalian Z&H Seafood Co., Ltd., Fujian Chaohui International Trading, Fujian Dongshan County Shunfa Aquatic Product Co., Ltd., Fujian Rongjiang Import and Export Corp., Fuqing Minhua Trade Co., Ltd, Fuqing Yihua Aquatic Food Co., Ltd., Fuqing Yiyuan Trading Co., Ltd., Guangdong Jiahuang Foods Co., Ltd., Guangdong Jinhang Foods Co., Ltd., Guangdong Shunxin Sea Fishery Co. Ltd., Guangdong Wanya Foods Fty. Co., Ltd., Hai Li

of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rates

Upon issuance of these final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review.[10] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review.

We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review. Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[11]

The Department announced a refinement to its assessment practice in non-market economy cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, if the Department determines that an exporter had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate.[12]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Tariff Act of 1930, as amended (''Act''): (1) Because we have revoked the order with respect to subject merchandise produced and exported by Regal, we will instruct CBP to terminate the suspension of liquidation for imports of such merchandise entered, or withdrawn from warehouse, for consumption on or after February 1, 2012, and to refund all cash deposits collected; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: September 6, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix—List of Topics Discussed in the Final Decision Memorandum

1. Respondent Selection
2. India as the Surrogate Country for Regal's AR5 Analysis
3. Market Economy Purchases
4. Surrogate Value for Scrap
5. Regal's Reported Scrap Data
6. Revocation of Regal
7. Hilltop as Part of PRC-Wide Entity
8. Assignment of AFA to the PRC-Wide Entity

[FR Doc. 2013–22226 Filed 9–11–13; 8:45 a.m.]

BILLING CODE 3510–DS–P

Aquatic Co., Ltd., Hainan Brich Aquatic Products Co., Ltd., Hainan Hailisheng Food Co., Ltd., Hainan Xiangtai Fishery Co., Ltd., Haizhou Aquatic Products Co., Ltd., Hilltop International, Hua Yang (Dalian) International Transportation Service Co., Kingston Foods Corporation, Maoming Xinzhou Seafood Co., Ltd., Ocean Duke Corporation, Olanya (Germany) Ltd., Qingdao Yuanqiang Foods Co., Ltd., Rizhao Xinghe Foodstuff Co., Ltd., Rui'an Huasheng Aquatic Products Processing Factory, Savvy Seafood Inc., Sea Trade International Inc., Shandong Meijia Group Co., Ltd., Shanghai Linghai Fisheries Trading Co. Ltd., Shanghai Lingpu Aquatic Products Co., Shanghai Smiling Food Co., Ltd., Shanghai Zhoulian Foods Co., Ltd., Shantou Jiazhou Foods Industry, Shantou Jin Cheng Food Co., Ltd., Shantou Longsheng Aquatic Product Foodstuff Co., Ltd., Shantou Ruiyuan Industry Company Ltd., Shantou Wanya Foods Fty. Co., Ltd., Shenzen Allied Aquatic Produce Development Ltd., Shenzhen Yudayuan Trade Ltd., Thai Royal Frozen Food Zhanjiang Co., Ltd., Xiamen Granda Import & Export Co., Ltd., Yancheng Hi-king Agriculture Developing Co., Ltd., Yanfeng Aquatic Product Foodstuff, Yangjiang Anyang Food Co., Ltd., Yangjiang City Yelin Hoi Tat Quick Frozen Seafood Co., Ltd., Yangjiang Wanshida Seafood Co., Ltd., Yelin Enterprise Co., Ltd., Zhangzhou Xinwanya Aquatic Product, Zhangzhou Yanfeng Aquatic Product, Zhanjiang Evergreen Aquatic Product Science and Technology Co., Ltd., Zhanjiang Fuchang Aquatic Products Co., Ltd., Zhanjiang Go Harvest Aquatic Products Co., Ltd., Zhanjiang Haizhou Aquatic Product Co. Ltd., Zhanjiang Hengrun Aquatic Co, Ltd., Zhanjiang Jinguo Marine Foods Co., Ltd., Zhanjiang Join Wealth Aquatic Products Co., Ltd., Zhanjiang Longwei Aquatic Products Industry Co., Ltd., Zhanjiang Newpro Foods Co., Ltd., Zhanjiang Rainbow Aquatic Development, Zhanjiang Universal Seafood Corp., Zhejiang Daishan Baofa Aquatic Products Co., Ltd., Zhejiang Xinwang Foodstuffs Ltd., Zhejiang Zhoufu Food Co., Ltd., Zhoushan Corporation, and Zhoushan Haiwang Seafood Co., Ltd.

[10] *See* 19 CFR 351.212(b).

[11] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification for Reviews,* 77 FR 8101 (February 14, 2012).

[12] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review, 2011–2012

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On March 12, 2013, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the seventh administrative review of the antidumping duty *Order*[1] on certain

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp*

Continued

warmwater shrimp from the Socialist Republic of Vietnam (''Vietnam'').[2] Based upon our analysis of the comments and information received, we have determined that Minh Phu Group,[3] and Nha Trang Seafoods,[4] the two mandatory respondents, and Quoc Viet,[5] the voluntary respondent, have not sold subject merchandise at less than normal value during the period of review (''POR''), February 1, 2011, through January 31, 2012. Additionally, the Department has determined not to revoke the *Order* in part, with respect to Minh Phu Group and Nha Trang Seafoods.

DATES: *Effective Date:* September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Irene Gorelik, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–6905, respectively.

SUPPLEMENTARY INFORMATION: On March 12, 2013, the Department published the *Preliminary Results.* On May 22, 2013, the Department extended the time limit for these final results by 60 days. On April 15, 2013, Petitioner,[6] Minh Phu Group, and Nha Trang Seafoods, submitted additional surrogate value (''SV'') information. On April 25, 2013, Petitioner, Minh Phu Group and Nha Trang Seafoods submitted rebuttal SV comments.

We gave interested parties an opportunity to comment on the *Preliminary Results.* On May 31, 2013, Petitioner, Domestic Processors,[7] Quoc Viet, Minh Phu Group and Nha Trang Seafoods submitted case briefs. On June 5, 2013, Petitioner, Domestic Processors, Quoc Viet, Minh Phu Group and Nha Trang Seafoods submitted rebuttal briefs.

Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp. The product is currently classified under the following Harmonized Tariff Schedule of the United States item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. The written description of the scope of the order is dispositive. A full description of the scope of the order is available in the accompanying Issues and Decision Memorandum.[8]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the accompanying Issues and Decision Memorandum.[9] A list of the issues which parties raised, and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://www.trade.gov/ia/.* The signed Issues and Decision Memorandum and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Determination of No Shipments

In the *Preliminary Results,* the Department preliminarily determined the following companies did not have any reviewable transactions during the POR: Amanda Food (Vietnam) Ltd., Anvifish Joint Stock Company, Bien Dong Seafood Co., Ltd., Binh An Seafood Joint Stock Company, Camranh Seafoods, Thong Thuan Seafood Company, Vietnam Clean Seafood Corporation, and Vinh Hoan Corporation. We have not received any information to contradict this determination. Therefore, the Department has made the final determination that the above-named companies did not have any reviewable entries of subject merchandise during the POR, and will issue appropriate instructions that are consistent with our ''automatic assessment'' clarification, for these final results.

Verification

Pursuant to 19 CFR 351.307(b)(iv), the Department conducted a verification of Minh Phu Group's sales and factors of production between April 16, 2013 and April 26, 2013.[10] Based on Minh Phu Group's minor corrections presented to the Department and other findings, the Department requested Minh Phu Group submit revised data.[11] [12]

Changes Since the Preliminary Results

The Department has made changes to certain surrogate values and company-specific margin calculations since the *Preliminary Results.* Specifically, we changed the surrogate value for domestic cold storage warehousing and the surrogate values for certain export-related expenses incurred by Minh Phu Group and Nha Trang. The Department also made company-specific changes to the margin calculation programs resulting from verification in Minh Phu Group's case, and other programming changes for Minh Phu Group, Nha Trang, and Quoc Viet based on arguments made in case and rebuttal briefs. For detailed information, *see* the Issues and Decision Memorandum and the company-specific final results analysis memoranda.

From the Socialist Republic of Vietnam, 70 FR 5152 (February 1, 2005) (''*Order*'').

[2] *See Certain Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review. 2011–2012,* 78 FR 15699 (March 12, 2013) (''*Preliminary Results*''), and accompanying Preliminary Decision Memorandum.

[3] Minh Phu Seafood Export Import Corporation (and affiliated Minh Qui Seafood Co., Ltd. and Minh Phat Seafood Co., Ltd.); Minh Phu Seafood Corporation, Minh Phu Seafood Corp., Minh Qui Seafood Co., Ltd., Minh Qui Seafood, Minh Phat Seafood Co., Ltd., Minh Phat Seafood, and Minh Phu Hau Giang Seafood Co., Ltd. (collectively, the ''Minh Phu Group'').

[4] Nha Trang Seaproduct Company and its affiliates, NT Seafoods Corporation, Nhatrang Seafoods-F.89 Joint Stock Company, and NTSF Seafoods Joint Stock Company (collectively, the ''Nha Trang Seafoods'').

[5] Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd. (''Quoc Viet'').

[6] The Ad Hoc Shrimp Trade Action Committee (''Petitioner'').

[7] American Shrimp Processors Association (''Domestic Processors'').

[8] *See* Memorandum to Paul Piquado, Assistant Secretary for Import Administration, From Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Issues and Decision Memorandum for the Final Results, (''Issues and Decision Memorandum'') dated concurrently and hereby adopted by this notice.

[9] *See id.*

[10] *See* ''Memorandum to the File, though Catherine Bertrand, Program Manager, Office 9, from Irene Gorelik, Analyst, Office 9; re: Verification of the CEP Sales Response of the MPG in the 2011–2012 Administrative Review of Certain Warmwater Shrimp from the Socialist Republic of Vietnam,'' dated May 3, 2013; *see also* ''Memorandum to the File, though Catherine Bertrand, Program Manager, Office 9, from Irene Gorelik, Analyst, Office 9; re: Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Verification of Sales and Factors of Production for Minh Phu Seafood Corporation,'' dated May 16, 2013 (''Minh Phu Group Verification Report'')

[11] *See* Minh Phu Group's revised sales and factors of production data, dated May 23, 2013.

[12] The details of the changes to Minh Phu Group's margin calculation program are provided in ''Memorandum to the File through Catherine Bertrand, Program Manager, Office 9 from Irene Gorelik, Analyst, Office 9, re; Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Analysis for the Final Results of Minh Phu Group,'' dated concurrently with this notice.

Request for Revocation, In Part

In the *Preliminary Results,* we determined that Minh Phu Group and Nha Trang Seafoods have not met the regulatory criteria for revocation set forth in 19 CFR 351.222(b).[13] We have not received any further information following the issuance of the *Preliminary Results* that would warrant revocation of the order with regard to either Minh Phu Group or Nha Trang Seafoods.[14] Therefore, we will not revoke the *Order* with respect to Minh Phu Group and Nha Trang Seafoods because they have not met the regulatory criteria for revocation set forth in 19 CFR 351.222(b).[15]

Separate Rates

In the *Preliminary Results,* we determined that 30 companies [16] (''Separate Rate Respondents'') in addition to Minh Phu Group and Nha Trang Seafoods, and the voluntary respondent, Quoc Viet, met the criteria for separate rate status. We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsidering this preliminary determination. Therefore, the Department continues to find that these 33 companies meet the criteria for a separate rate for the final results.

Rate for Non-Selected Companies

For the final results, we continue to calculate zero rates for both mandatory respondents. Therefore, there is no change to the separate rate assigned to the Separate Rate Respondents for the final results of this review, and we continue to determine that a ''reasonable method for determining the weighted-average dumping margins for the non-selected respondents in this review is to average the weighted-average dumping margins calculated for the mandatory respondents,'' as noted in the *Preliminary Results.*[17] For a detailed discussion of the Department's separate rate calculation, *see* the Issues and Decision Memorandum at Comment 9.

Vietnam-Wide Entity

In the *Preliminary Results,* we determined that 41 companies failed to demonstrate their eligibility for a separate rate. In NME proceedings, '''rates' may consist of a single dumping margin applicable to all exporters and producers.'' [18] Therefore, we assignedthe Vietnam-wide entity a rate of 25.76 percent, the onlyrate ever determined for the Vietnam-wide entity in this proceeding. We have not received any information since the *Preliminary Results* that provides a basis for reconsidering this determination. We, therefore, continue to apply the Vietnam-wide entity rate of 25.76 percent to these 41 companies.[19]

Final Results of Review

The Department determines that the following final dumping margins exist:

Exporter	Margin (percent)
Minh Phu Group: [20]	
Minh Phu Seafood Corp., aka	
Minh Phu Seafood Corporation, aka	
Minh Phu Seafood Pte, aka	
Minh Phu Hau Giang Seafood Co., Ltd., aka	
Minh Phat Seafood Co., Ltd., aka	
Minh Qui Seafood Co., Ltd., aka	
Minh Qui Seafood	0.00
Nha Trang Seafoods: [21]	
Nha Trang Seaproducts Company, aka	
Nha Trang Seafoods, aka	
NT Seafoods Corporation, aka	
NT Seafoods, aka	
Nha Trang Seafoods—F.89 Joint Stock Company, aka	
Nha Trang Seafoods—F.89, aka	
NTSF Seafoods Joint Stock Company, aka	
NTSF Seafoods	0.00
Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd.[22]	0.00
Bac Lieu Fisheries Joint Stock Company, aka	
Bac Lieu Fisheries Company Limited, aka	
Bac Lieu Fisheries Co., Ltd., aka	
Bac Lieu Fisheries Limited Company, aka	

[13] *See Preliminary Results,* 78 FR at 15699–15700, and accompanying Preliminary Decision Memorandum at 5; *see also* ''Memorandum to Christian Marsh, Deputy Assistant Secretary, Import Administration, through Edward Yang, Senior Director, from James Doyle, Office Director, Office 9, re; Seventh Antidumping Duty Administrative Review of Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Addendum to the Preliminary Results Regarding the Minh Phu Group Revocation Request,'' dated April 4, 2013.

[14] *See* Issues and Decision Memorandum at Comment 12.

[15] The Department recently modified the section of its regulations concerning the revocation of antidumping and countervailing duty orders in whole or in part, but that modification does not apply to this administrative review. *See Modification to Regulation Concerning the Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 29875 (May 21, 2012). Reference to 19 CFR 351.222(b) thus refers to the Department's regulations prior to the modification.

[16] *See* Issues and Decision Memorandum at Appendix.

[17] *See Preliminary Results,* and accompanying Preliminary Decision Memorandum at 10–11.

[18] *See* 19 CFR 351.107(d).

[19] *See* Issues and Decision Memorandum at Appendix II for a list of the companies included in the Vietnam-Wide Entity.

[20] In *AR6 VN Shrimp,* the Department found the companies comprising Minh Phu Group are a single entity and, because the facts resulting in that determination have not changed, we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results of Administrative Review,* 77 FR 13547, 13549 (March 7, 2012), unchanged in *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 55800 (September 11, 2012) (''*AR6 VN Shrimp*'').

[21] In *AR5 VN Shrimp,* the Department found the companies comprising Nha Trang Seafoods are a single entity and, because there have been no changes to this determination since the fifth administrative review; we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results, Partial Rescission, and Request for Revocation, In Part, of the Fifth Administrative Review,* 76 FR 12054, 12056 (March 4, 2012), unchanged in *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 56158 (September 12, 2011) (''*AR5 VN Shrimp*'').

[22] The Department selected Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd. as a voluntary respondent in this review. *See Preliminary Results,* and accompanying Preliminary Decision Memorandum at 3.

Exporter	Margin (percent)
Bac Lieu Fis	0.00
BIM Seafood Joint Stock Company	0.00
Camau Frozen Seafood Processing Import Export Corporation, aka	
Camimex, aka	
Camau Seafood Factory No. 4, aka	
Camau Seafood Factory No. 5, aka	
Camau Frozen Seafood Processing Import Export Corp. (CAMIMEX–FAC 25), aka	
Frozen Factory No. 4	0.00
C.P. Vietnam Corporation, aka	
C.P. Vietnam Livestock Corporation, aka	
C.P. Vietnam Livestock Company Limited, aka	
C.P. Vietnam Livestock Co., Ltd., aka	
C.P. Vietnam	0.00
Cadovimex Seafood Import-Export and Processing Joint Stock Company, aka	
Cai Doi Vam Seafood Import-Export Company, aka	
Caidoivam Seafood Company, aka	
Cadovimex-Vietnam, aka	
Cadovimex	0.00
Cafatex Fishery Joint Stock Corporation, aka	
Cafatex Corporation, aka	
Cafatex Corp., aka	
Cafatex, aka	
Cantho Animal Fisheries Product Processing Export Enterprise (Cafatex), aka	
Cafatex, aka	
Taydo Seafood Enterprise, aka	
Xi Nghiep Che Bien Thuy Suc San Xuat Kau Cantho	0.00
Can Tho Import Export Fishery Limited Company, aka	
CAFISH	0.00
Coastal Fisheries Development Corporation, aka.	
COFIDEC, aka	
Coastal Fisheries Development Corp., aka	
Coastal Fisheries Development Co. aka	
Coastal Fisheries Development	0.00
Cuu Long Seaproducts Company, aka	
Cuu Long Seaproducts Limited, aka	
Cuulong Seapro aka	
Cuu Long Seapro	0.00
Danang Seaproducts Import Export Corporation, aka	
Danang Sea Products Import Export Corporation, aka	
Danang Seaproduct Import-Export Corporation, aka	
Danang Seaproducts Import Export, aka	
Tho Quang Seafood Processing & Export Company, aka	
Tho Quang Seafood Processing and Export Company, aka	
Tho Quang, aka	
Tho Quang Co., aka	
Seaprodex Danang	0.00
Viet I-Mei Frozen Foods Co., Ltd., aka	
Grobest & I-Mei Industrial (Vietnam) Co., Ltd., aka	
Grobest & I-Mei Industry (Vietnam) Co., Ltd., aka	
Grobest	0.00
Gallant Ocean (Vietnam) Co., Ltd., aka	
Gallant Ocean (Quang Ngai) Co., Ltd.	0.00
Investment Commerce Fisheries Corporation, aka	
Investment Commerce Fisheries Corp., aka	
Investment Commerce Fisheries, aka	
Incomfish, aka	
Incomfish Corp., aka	
Incomfish Corporation	0.00
Kim Anh Company Limited, aka	
Kim Anh Co, Ltd.	0.00
Minh Hai Export Frozen Seafood Processing Joint-Stock Company, aka	
Minh Hai Jostoco, aka	
Minh Hai Export Frozen Seafood Processing Joint Stock Company, aka	
Minh Hai Export Frozen Seafood Processing Joint-Stock Co., aka	
Minh-Hai Export Frozen Seafood Processing Joint-Stock Company	0.00
Minh Hai Joint-Stock Seafoods Processing Company, aka	
Seaprodex Minh Hai, aka	
Sea Minh Hai, aka	
Seaprodex Min Hai, aka	
Seaprodex Minh Hai-Factory No. 78, aka	
Seaprodex Minh Hai (Minh Hai Joint Stock Seafoods Processing Co.), aka	
Seaprodex Minh Hai (Workshop 1), aka	
Seaprodex Minh Hai Factory No. 69	0.00

Exporter	Margin (percent)
Minh Hai Sea Products Import Export Company, aka	
Ca Mau Seafood Joint Stock Company, aka	
Seaprimexco Vietnam aka	
Seaprimexco aka	
Minh Hai Seaproducts Co Ltd.	0.00
Ngoc Sinh Private Enterprise, aka	
Ngoc Sinh Private Enterprises, aka	
Ngoc Sinh Seafoods, aka	
Ngoc Sinh Seafoods Processing and Trading Enterprises, aka	
Ngoc Sinh Seafood Processing Company, aka	
Ngoc Sinh Seafoods (Private Enterprise), aka	
Ngoc Sinh Fisheries, aka	
Ngoc Sinh	0.00
Ngoc Tri Seafood Joint Stock Company	0.00
Nhat Duc Co., Ltd., aka	
Nhat Duc	0.00
Nha Trang Fisheries Joint Stock Company, aka	
Nha Trang Fisco aka	
Nhatrang Fisheries Joint Stock Company, aka	
Nhatrang Fisco, aka	
Nha Trang Fisheries, Joint Stock	0.00
Phu Cuong Jostoco Seafood Corporation, aka	
Phu Cuong Seafood Processing and Import-Export Co., Ltd., aka	
Phu Cuong Seafood Processing and Import Export Company Limited, aka	
Phu Cuong Jostoco Seafood Corp.	0.00
Phuong Nam Foodstuff Corp. aka	
Phuong Nam, aka	
Phuong Nam Co., Ltd., aka	
Western Seafood Processing and Exporting Factory, aka	
Western Seafood	0.00
Sao Ta Foods Joint Stock Company, aka	
Fimex VN aka	
Sao Ta Seafood Factory aka	
Saota Seafood Factory	0.00
Seavina Joint Stock Company, aka	
Seavina	0.00
Soc Trang Seafood Joint Stock Company, aka	
Stapimex, aka	
Soc Trang Aquatic Products and General Import Export Company, aka	
Stapimex Soc Trans Aquatic Products and General Import Export Company, aka	
Stapmex	0.00
Thuan Phuoc Seafoods and Trading Corporation, aka	
Thuan Phuoc Corp., aka	
Frozen Seafoods Factory No. 32, aka	
Seafoods and Foodstuff Factory, aka	
Seafoods and Foodstuff Factory Vietnam, aka	
My Son Seafoods Factory	0.00
UTXI Aquatic Products Processing Corporation, aka	
UT XI Aquatic Products Processing Corporation, aka	
UTXI Aquatic Products Processing Company, aka	
UT XI Aquatic Products Processing Company, aka	
UTXI Co. Ltd., aka	
UTXI, aka	
Hoang Phuong Seafood Factory, aka	
Hoang Phong Seafood Factory, aka	
UTXICO	0.00
Viet Foods Co., Ltd., aka	
Nam Hai Foodstuff and Export Company Ltd.	0.00
Viet Hai Seafood Co., Ltd., aka	
Vietnam Fish One Co., Ltd., aka	
Fish One	0.00
Vietnam-wide Entity [23]	25.76

Disclosure and Public Comment

We will disclose the calculations performed within five days of the date

[23] Agrex Saigon, Bentre Aquaproduct Import & Export Joint Stock Company, Can Tho Agricultural and Animal Products Import Export Company, aka Can Tho Agricultural Products, akaCan Tho Agricultural Products Imex Company, aka, CATACO, Can Tho Import Export Seafood Joint Stock Company, aka CASEAMEX, Cau Tre Enterprise (C.T.E.), CL Fish Co., Ltd. (Cuu Long Fish Company), Cautre Export Goods Processing Joint Stock Company, D & N Foods Processing (Danang Company Ltd.), Duy Dai Corporation, Gn Foods, Hai Thanh Food Company Ltd., Hai Viet Corporation (''HAVICO''), Hai Vuong Co., Ltd., Hoang Hai Company Ltd., Hua Heong Food Industries Vietnam Co. Ltd., Hoa Phat Aquatic Products Processing And Trading Service Co., Ltd., Interfood Shareholding Co., Kien Long Seafoods Co. Ltd., Luan Vo Fishery Co., Ltd., Lucky Shing Co.,

Continued

of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review. In these final results, the Department applied the assessment rate calculation method adopted in *Final Modification for Reviews, i.e.,* on the basis of monthly average-to-average comparisons using only the transactions associated with that importer with offsets being provided for non-dumped comparisons.[24]

Where we do not have entered values for all U.S. sales to a particular importer/customer, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[25] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer- (or customer-) specific *ad valorem* ratios based on the estimated entered value. Where either a respondent's weighted average dumping margin is zero or *de minimis,* or an importer- (or customer-) specific *ad valorem* rate is zero or above *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[26]

Additionally, pursuant to a refinement to its assessment practice in NME cases, if the Department continues to determine that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the NME-wide rate.[27]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above, which have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Vietnam and non-Vietnam exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Vietnam exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the Vietnam-wide entity; and (4) for all non-Vietnam exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Vietnam exporter that supplied that non-Vietnam exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: September 6, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

General Issues

Comment 1: Surrogate Country
A. Economic Comparability
B. Data Considerations
Comment 2: Financial Statements to Use When Selecting Indonesia as Surrogate Country
Comment 3: Market Economy Purchases
Comment 4: Whether the Surrogate Value For Export-Related Non-Market Economy Expenses Incurred is Double-Counted
Comment 5: Movement Expenses
Comment 6: Cold Storage Surrogate Value
Comment 7: Sauce Surrogate Value
Comment 8: Targeted Dumping
Comment 9: Calculation of the Separate Rate and Whether to Revise the Separate Rate Liquidation Instructions
Comment 10: Whether to Revise U.S. Customs and Border Patrol Liquidation and Cash Deposit Instructions
Comment 11: Whether to Include an Additional Company in Phu Cuong Jostoco' Separate Rate
Comment 12: Whether to Revoke From the Order Minh Phu Group and Nha Trang Seafoods

Company-Specific Issues

Minh Phu Group:
Comment 13: Whether Minh Phu Group's Reported Sample Sales Are Properly Excluded
Comment 14: Whether Certain Factors of Production Reported by Minh Phu Group are Properly Classified as Direct Materials
Comment 15: Whether the Department Applied an Incorrect Unit of Measure for Sauce
Comment 16: Whether the Department Incorrectly Applied Minh Phu Group's

Ltd., Minh Chau Imp. Exp. Seafood Processing Co., Ltd., Mp Consol Co., Ltd., Ngoc Chau Co., Ltd. and/or Ngoc Chau Seafood Processing Company, Nhat Du Co., Ltd., Quang Ninh Export Aquatic Products Factory aka Quang Ninh Seaproducts Factory, S.R.V. Freight Services Co., Ltd. Sea Product, Sustainable Seafood, Tan Thanh Loi Frozen Food Co., Ltd., Thanh Doan Seaproducts Import & Export Processing Joint-Stock Company (THADIMEXCO), Thanh Hung Frozen Seafood Processing Import Export Co., Ltd., Thanh Tri Seafood Processing Co. Ltd., Tho Quang Seafood Processing and Export Company, Tien Tien Garment Joint Stock Company, Tithi Co., Ltd., Trang Corporation, Vietnam Northern Viking Technologies Co., Ltd., Vinatex DanangViet Cuong Seafood Processing Import Export Joint-Stock Company, Viet Cuong Seafood Processing Import Export, Vinh Loi Import Export Company (''Vimexco''), aka Vinh Loi Import Export Company ''VIMEX''), aka VIMEXCO, aka VIMEX, aka Vinh Loi Import/Export Co., aka Vinhloi Import Export Company, aka Vinh Loi Import-Export Company, Vinh Loi Import Export Company (''Vimexco'') and/or Vinh Loi Import Export Company (''VIMEX'').

[24] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012) (''*Final Modification for Reviews*'').

[25] *See* 19 CFR 351.212(b)(1).

[26] *See* 19 CFR 351.106(c)(2); and *Final Modification for Reviews.*

[27] For a full discussion of this practice, see *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Reported Entered Value
Comment 17: Whether Minh Phu Group's Minor Corrections from Verification Are Properly Applied
Comment 18: Whether MPG's Indirect Selling Expenses Are Properly Calculated
Nha Trang Seafoods:
Comment 19: Whether to Adjust Electricity and Water Consumption
Comment 20: Whether Nha Trang Seafoods Included Transfer Costs between Factories
Quoc Viet:
Comment 21: Treatment of Sauce
Comment 22: Marine Insurance

[FR Doc. 2013–22228 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–856]

Steel Threaded Rod from India: Postponement of Preliminary Determination of Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce

DATES: *Effective Date:* September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Brooke Kennedy, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3818.

SUPPLEMENTARY INFORMATION:

Background

On July 17, 2013, the Department of Commerce (''the Department'') initiated a countervailing duty investigation on steel threaded rod from India.[1] The current deadline for the preliminary determination of this investigation is no later than September 20, 2013.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which the Department initiated the investigation. However, if the Department concludes that the parties concerned are cooperating and determines that the case is extraordinarily complicated and that additional time is necessary to make the preliminary determination, section 703(c)(1)(B) of the Act allows the Department to postpone making the preliminary determination until no later than 130 days after the date on which the administering authority initiated the investigation. We have concluded that the parties concerned are cooperating and that the case is extraordinarily complicated due to the complexity of the alleged subsidy programs, such that we need more time to make the preliminary determination. Specifically, the analysis of two of the alleged subsidy programs will involve not only the usual consideration of financial contribution and specificity, but will also involve the more complex consideration of whether the program has been terminated and, if so, whether there are any residual benefits. In addition, any analysis of the National Manufacturing Competitiveness Program—Marketing Assistance Scheme is likely to be complex as the program allegedly provides for a variety of subsidies including grants for rental space, freight charges, airfare and advertising. The deadline for completion of the preliminary determination is now November 25, 2013.[2]

We also note that, on September 3, 2013, All America Threaded Products Inc., Bay Standard Manufacturing Inc., and Vulcan Threaded Products Inc., the petitioners in this investigation, requested that the deadline for the preliminary determination be postponed to 130 days from the date of initiation in accordance with 19 CFR 351.205(b)(2). This notice is issued and published pursuant to section 703(c)(2) of the Act. [3]

September 6, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–22225 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Steel Threaded Rod From India: Initiation of Countervailing Duty Investigation,* 78 FR 44532 (July 24, 2013).

[2] As the actual due date of November 24, 2013 falls on a weekend, the preliminary determination is due the next business day, *i.e.,* November 25, 2013. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[3] We acknowledge that the Department inadvertently did not notify the parties to this investigation of this postponement within the timeframe provided in section 703(c)(2) of the Act.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC859

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fisheries of the Gulf of Mexico and Southern Atlantic States

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of an application for an exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from the Gulf and South Atlantic Fisheries Foundation, Inc (Foundation). If granted, the EFP would authorize the applicant, with certain conditions, to collect and retain limited numbers of specimens that would otherwise be prohibited from possession and retention. This study, to be conducted in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) and South Atlantic, is intended to characterize catch and bycatch within the shrimp fisheries of the Gulf and South Atlantic.

DATES: Comments must be received on or before October 15, 2013.

ADDRESSES: You may submit comments, identified by ''NOAA–NMFS–2013–0141'', 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-NMFS-2013-0141,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Susan Gerhart, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

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 NMFS. 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. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to

remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, 727–824–5305; email: *Susan.Gerhart@noaa.gov.*

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The applicant proposes research as part of the Cooperative Research Program, which is intended to involve commercial fishermen in the collection of fundamental fisheries information. The described research is part of a long-term observer program that began in 1992, and that can be expected to continue in the future. Resource collection efforts support the development and evaluation of fisheries management and regulatory options.

The EFP would exempt the activities described herein from regulations at 50 CFR part 622, as they affect fish and invertebrates managed by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils). The EFP covers these Council-managed species that may be taken during standard fishing activities of the commercial shrimp fishery of the southeast United States. The EFP would exempt personnel from the Foundation from fishery regulations such as bag limits, size limits, quotas, seasonal restrictions, and gear authorizations as specified in 50 CFR part 622, Subparts A through R for reef fish, red drum, coastal migratory pelagics, and spiny lobster in the Gulf of Mexico, and snapper-grouper, coastal migratory pelagics, dolphin and wahoo, and spiny lobster in the South Atlantic.

The EFP would authorize Foundation observers aboard commercial shrimp vessels to temporarily possess all necessary specimens from the catch for documentation and to permanently retain approximately 500 specimens of federally-managed finfishes and invertebrates that would otherwise be prohibited from possession and retention through December 31, 2018. The described research is part of a long-term observer program that began in 1992, and that can be expected to continue in the future, therefore, the 5-year time period for the EFP is appropriate for this research effort. Specimens would be collected from Federal waters of the Gulf and South Atlantic, and sampling would occur during normal fishing operations of the trawl gear component of the penaeid shrimp commercial sector. Sampling would occur year-round. These species would be retained only in the event of the need for subsequent shore-side identification or as documentation of quality assurance in the data collection process. Data collection for this study would support improved information about the catch, bycatch, discards, and the ability to reduce bycatch for species taken by the shrimp fisheries of the Gulf and South Atlantic. These data would provide insight on a stock's resilience to fishing, and would help improve estimates of long-term biological productivity of the stocks. Currently, these data are unavailable, and it is anticipated that project results will yield valuable data within these fisheries.

NMFS finds this application warrants further consideration. Based on a preliminary review, NMFS intends to issue an EFP. The limited sampling program and associated methodology listed in the EFP is not expected to impact the fishery stocks; the estimated 500 specimens to be retained through the duration of the EFP represents a small fraction of average annual landings.

Conditions the agency will impose on this permit, if it is granted, include but are not limited to, a prohibition of conducting research within marine protected areas, marine sanctuaries, or special management zones, without additional authorization. Additionally, NMFS will prohibit the possession of Nassau or goliath grouper, and require any sea turtles taken incidentally during the course of fishing or scientific research activities to be handled with due care to prevent injury to live specimens, observed for activity, and returned to the water. All Foundation-associated personnel who conduct onboard sampling activities have undergone formal sea turtle handling training through NMFS, and are considered NMFS-designated agents while conducting work under the identified Cooperative Agreements.

A final decision on issuance of the EFP will depend on a NMFS review of public comments received on the application, consultations with the affected states, the Councils, and the U.S. Coast Guard, and a determination that the EFP is consistent with all applicable laws.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 9, 2013.

James P. Burgess,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–22215 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC862

Marine Mammals; File No. 18171

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Wessley Merten, Marine Sciences Department, University of Puerto Rico, Mayagüez Campus, PO Box 9000, Mayagüez, PR 00682, has applied in due form for a permit to conduct commercial or educational photography of bottlenose dolphins (*Tursiops truncates*), spinner dolphins (*Stenella longirostris*), striped dolphins (*Stenella coeruleoalba*), False killer whales (*Pseudorca crassidens*), and killer whales (*Orcinus orca*) in waters off Puerto Rico.

DATES: Written, telefaxed, or email comments must be received on or before October 15, 2013.

ADDRESSES: These documents are available upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Rosa L. González or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216). Section 104(c)(6) provides for photography for educational or commercial purposes involving non-endangered and non-threatened marine mammals in the wild.

Wessley Merten requests a two-year photography permit to film and photograph bottlenose dolphins (*Tursiops truncates*), spinner dolphins (*Stenella longirostris*), striped dolphins (*Stenella coeruleoalba*), false killer whales (*Pseudorca crassidens*), and killer whales (*Orcinus orca*) in waters off Puerto Rico, specifically, out to 40 miles. Filming would be conducted underwater and from a small boat. Filming would occur throughout the year and be completed by July 2015. Footage would be used in a documentary of offshore sport fishing in Puerto Rico, endorsed by the Puerto Rico Sea Grant Program, and which would be distributed to schools and the public throughout Puerto Rico. In addition, footage would be used in a documentary about Puerto Rico's marine mammal and marine mammal program.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: September 6, 2013.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–22186 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC100

Marine Mammals; File No. 17115

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that a major amendment to Permit No. 17115–00 has been issued to James Lloyd-Smith, Ph.D., Department of Ecology and Evolutionary Biology, University of California, Los Angeles, 610 Charles E. Young Dr. South, Box 723905, Los Angeles, CA 90095–7239.

ADDRESSES: The permit amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Tammy Adams, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On July 15, 2013, notice was published in the **Federal Register** (78 FR 42041) that a request for an amendment Permit No. 17115–00 to conduct research on California sea lions (*Zalophus californianus*) had been submitted by the above-named applicant. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 17115–01 authorizes the permit holder to study the prevalence of leptospirosis in wild California sea lions in California. The amendment expands the scope of the study to include (1) two additional study sites, Monterey Bay and San Nicolas Island, in addition to Año Nuevo Island; (2) disentangling sea lions; (3) disturbance from collecting environmental samples to study transmission of leptospirosis; and (4) collecting fur and blood to study contaminants. Sea lions may be captured (including restraint and anesthesia); marked and measured; sampled (blood, urine, vibrissae, fur); and released. A limited number of non-target sea lions may be captured and released without sampling. California sea lions, northern elephant seals (*Mirounga angustirostris*), and harbor seals (*Phoca vitulina*) may be taken by incidental disturbance. Four unintentional mortalities of California sea lions are authorized annually, not to exceed eight over the duration of the permit. The permit expires September 30, 2017.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: September 6, 2013.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–22182 Filed 9–11–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the National Commission on the Structure of the Air Force

AGENCY: Director of Administration and Management, DoD.

ACTION: Notice of advisory committee meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the National Commission on the Structure of the Air Force (''the Commission'') will take place.

DATES: *Date of Open Meeting, including Hearing and Commission Discussion:* Tuesday, October 1, 2013, from 1:00 p.m. to 5:00 p.m. Registration will begin at 12:30 p.m.

ADDRESSES: Bossier Civic Center, Bodcau Room, at 620 Benton Road, Bossier City, LA 71111.

FOR FURTHER INFORMATION CONTACT: Mrs. Marcia Moore, Designated Federal Officer, National Commission on the Structure of the Air Force, 1950 Defense Pentagon, Room 3A874, Washington, DC 20301–1950. Email: *dfoafstrucomm@osd.mil.* Desk (703) 545–9113. Facsimile (703) 692–5625.

SUPPLEMENTARY INFORMATION:

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of Meeting: The members of the Commission will hear testimony from individual witnesses and then will discuss the information presented at the hearings.

Agenda: On the morning of October 1, 2013, a subset of members from the Commission will tour units located at the Barksdale Air Force Base.

The hearing and meeting on October 1, 2013 is expected to include testimony from representatives from the state of Louisiana and possibly neighboring states, as well as military leadership from bases and units in the area who have been asked to testify and address the evaluation factors under consideration by the Commission for a U.S. Air Force structure that—(a) Meets current and anticipated requirements of the combatant commands; (b) achieves an appropriate balance between the regular and reserve components of the Air Force, taking advantage of the unique strengths and capabilities of each; (c) ensures that the regular and reserve components of the Air Force have the capacity needed to support current and anticipated homeland defense and disaster assistance missions in the United States; (d) provides for sufficient numbers of regular members of the Air Force to provide a base of trained personnel from which the personnel of the reserve components of the Air Force could be recruited; (e) maintains a peacetime rotation force to support operational tempo goals of 1:2 for regular members of the Air Forces and 1:5 for members of the reserve components of the Air Force; and (f) maximizes and appropriately balances affordability, efficiency, effectiveness, capability, and readiness. Individual Commissioners will also report their activities, information collection, and analyses to the full Commission.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and the availability of space, the meeting is open to the public. The building is fully handicap accessible. Several public parking facilities are nearby. Photography and videography is permitted, but must be previously arranged through the Commission's staff. All contact information may be found in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments to the Commission in response to the stated agenda of the open meeting or the Commission's mission. The Designated Federal Officer (DFO) will review all submitted written statements. Written comments should be submitted to Mrs. Marcia Moore, DFO, via facsimile or electronic mail, the preferred modes of submission. Each page of the comment must include the author's name, title or affiliation, address, and daytime phone number. All contact information may be found in the **FOR FURTHER INFORMATION CONTACT** section.

Oral Comments: In addition to written statements, one hour will be reserved for individuals or interested groups to address the Commission on Tuesday, October 1, 2013. Interested oral commenters must summarize their oral statement in writing and submit with their registration. The Commission's staff will assign time to oral commenters at the meeting, for no more than 5 minutes each. While requests to make an oral presentation to the Commission will be honored on a first come, first served basis, other opportunities for oral comments will be provided at future meetings.

Registration: Individuals who wish to attend the public hearing and meeting on Tuesday, October 1, 2013 are encouraged to register for the event in advance with the Designated Federal Officer, using the electronic mail and facsimile contact information found in **FOR FURTHER INFORMATION CONTACT.** The communication should include the registrant's full name, title, affiliation or employer, email address, and daytime phone number. If applicable, include written comments and a request to speak during the oral comment session. (Oral comment requests must be accompanied by a summary of your presentation.) Registrations and written comments must be typed.

Background: The National Commission on the Structure of the Air Force was established by the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239). The Department of Defense sponsor for the Commission is the Director of Administration and Management, Office of the Secretary of Defense. The Commission is tasked to submit a report, containing a comprehensive study and recommendations, by February 1, 2014 to the President of the United States and the Congressional defense committees. The report will contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for such legislation and administrative actions it may consider appropriate in light of the results of the study. The comprehensive study of the structure of the U.S. Air Force will determine whether, and how, the structure should be modified to best fulfill current and anticipated mission requirements for the U.S. Air Force in a manner consistent with available resources.

Dated: September 9, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–22209 Filed 9–11–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2013–0029]

Proposed Collection; Comment Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army (OAA–AAHS), DoD.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. 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 of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) 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 November 12, 2013.

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:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

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 U.S. Army Cadet Command Junior ROTC, Bldg. 6573, 394 2nd Dragoon Road, Fort Knox, Kentucky 40121, ATTN: ATCC–JRI (Billy Smith), or call Department of the Army Reports Clearance Officer at (703) 428–6440.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application and Contract for Establishment of a Junior Reserve Officers' Training Corps Unit, DA Form 3126; OMB Control Number 0702–0021.

Needs and Uses: The program provides unique educational opportunities for young citizens through their participation in a federally sponsored curriculum while pursuing their civilian education. Students develop citizenship, leadership, communications skills, an understanding of the role of the U.S. Army in support of national objectives, and an appreciation for the importance of physical fitness.

Affected Public: Not for Profit Institutions.

Annual Burden Hours: 70.

Number of Respondents: 70.

Responses per Respondent: 1.

Average Burden per Response: 1 hour.

Frequency: On occasion.

Data provided on the DA Form 3126 is used to determine which schools are invited to host a unit, to establish a fair and equitable distribution of units throughout the Nation, and to identify selection criteria such as enrollment potential, capacity of the institution to conduct the program, educational accreditation, and the ability of the school to comply with statutory and contractual obligations.

Dated: September 8, 2013.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2013–22202 Filed 9–11–13; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2013–0030]

Proposed Collection; Comment Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army, (OAA-RPA), DoD.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. 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 of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) 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 November 12, 2013.

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:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

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 Department of the Army, Military Surface Deployment and Distribution Command, (AMSSD–SB), 1 Soldier Way, Scott Air Force Base, Illinois 62225–5006, ATTN: Mr. Kim Morrison, or call Department of the Army Reports Clearance Officer at (703) 428–6440.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Signature and Tally Record, DD Form 1907, OMB Control Number 0702–0027.

Needs and Uses: Signature and Tally Records (STR) is an integral part of the Defense Transportation System and is used for commercial movements of all sensitive and classified material. The STR provides continuous responsibility for the custody of shipments in transit and requires each person responsible for the proper handling of the cargo to sign their name at the time they assume responsibility for the shipment, from point of origin, and at specified stages until delivery at destination. A copy of the STR, along with other transportation documentation is forwarded by the carrier to the appropriate finance center for payment.

Affected Public: Business or other for profit.

Annual Burden Hours: 3,750.

Number of Respondents: 130.

Responses per Respondent: 577.

Average Burden per Response: 3 minutes.

Frequency: On occasion.

The destination transportation officer uses the DD Form 1907 to assure that the carriers utilize the STR and provide the transportation service as requested by origin shipper. A copy of the STR, along with other transportation documentation, is forwarded by the carrier to the appropriate finance center for payment. The DD Form 1907 verifies the protected services requested in Bill of Lading that was provided.

Dated: September 9, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–22206 Filed 9–11–13; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2013–ICCD–0121]

Agency Information Collection Activities; Comment Request; Highly Qualified Teachers Clearance

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), 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 new information collection.

DATES: Interested persons are invited to submit comments on or before November 12, 2013.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0121 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 2E103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For questions related to collection activities or burden, please call Kathy Axt 540–776–7742 or electronically mail *ICDocketMgr@ed.gov.* Please do not send comments here.

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: Highly Qualified Teachers Clearance

OMB Control Number: 1875–NEW

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, or Tribal Governments

Total Estimated Number of Annual Responses: 17,053

Total Estimated Number of Annual Burden Hours: 115,000

Abstract: As set forth in Section 145(b) of H.J. Res. 117, the Fiscal Year 2013 Continuing Resolution (CR) Congress directed the U.S. Department of Education (ED) to submit a report to Congress on December 31, 2013, regarding the degree to which certain populations of students (students with disabilities, English language learners, rural students, and economically disadvantaged students) are taught by teachers participating in an alternative route to certification program. State educational agencies (SEAs) and local educational agencies (LEAs) have not been required to collect nor report this information. The requisite data must be reported from schools to LEAs to SEAs. ED respectfully seeks clearance to collect this information required to answer Congress's directive. It is anticipated that the collection is needed for one year only; hence, SEAs are not likely to alter their data collection and reporting systems to meet this data reporting requirement.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013–22196 Filed 9–11–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3106–001]

New York Power Authority; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Surrender of Conduit Exemption.

b. *Project No.:* 3106–001.

c. *Date filed:* December 11, 2012.

d. *Applicant:* New York Power Authority (NYPA).

e. *Name of Project and Location:* The Kensico Hydroelectric Project is located within the headworks of the Kensico Reservoir—City of New York Aqueduct, lower part of the Catskill Water Distribution System, which is owned and operated by the City of New York.

f. *Filed Pursuant to:* 18 CFR 4.95.

g. *Applicant Contact:* Robert J. Knowlton, P.E., Vice President Engineering Operations, New York Power Authority. (914) 681–6424. *Robert.Knowlton@nypa.gov.*

h. *FERC Contact:* Krista Sakallaris, (202) 502–6302, *Krista.Sakallaris@ferc.gov.*

i. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice. All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments.

Please include the project number (P–3106–001) on any comments, motions, or protests filed.

j. *Description of Project Facilities:* Three turbine generator units each with a rated capacity of 1,000 kilowatts installed in the existing bays within the lower aqueduct effluent chamber.

k. *Description of Request:* The applicant received notification from the

New York City Department of Environmental Protection (NYDEP) stating its intent to cease the delivery of water through a portion of the Catskill Aqueduct required by the NYPA's Kensico Hydroelectric Project. Due to the lack of water, the project is now inoperable. The NYDEP has asked NYPA to remove the turbines and appurtenant facilities that are located in the Catskill Lower Effluent Chamber.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208- 3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described proceeding. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

Dated: September 5, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–22152 Filed 9–11–13; 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: ER13–298–001.
Applicants: New York Independent System Operator, Inc.
Description: NYISO compliance filing re: Ancillary Services Mitigation step increase to be effective 9/25/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5229.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–1346–000.
Applicants: Mesa Wind Power Corporation.
Description: Mesa Wind Refund Report to be effective 9/4/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5173.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–2277–000.
Applicants: Avista Corporation.
Description: Avista Corp FERC Rate Schedule No. 184 to be effective 10/1/2013.
Filed Date: 8/29/13.
Accession Number: 20130829–5000.
Comments Due: 5 p.m. ET 9/19/13.

Docket Numbers: ER13–2322–000.
Applicants: Duke Energy Progress, Inc.
Description: MBR Name Change to be effective 10/25/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5105.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–2323–000.
Applicants: Duke Energy Progress, Inc.
Description: Cancellation of Duke Energy Progress' MBR Tariff database to be effective 11/4/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5109.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–2324–000.
Applicants: Southern California Edison Company.
Description: GIA and Distribution Service Agmt with AP North Lake Solar LP to be effective 9/6/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5136.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–2325–000.
Applicants: CES Placerita, Incorporated.
Description: Change in Status Filing to be effective 9/30/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5165.
Comments Due: 5 p.m. ET 9/26/13.

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: September 5, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–22198 Filed 9–11–13; 8:45 am].

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4050–002.
Applicants: Cogentrix of Alamosa, LLC.
Description: Notice of Non-Material Change in Status of Cogentrix of Alamosa, LLC.
Filed Date: 9/4/13.
Accession Number: 20130904–5196.
Comments Due: 5 p.m. ET 9/25/13.

Docket Numbers: ER13–1980–001.
Applicants: Golden Spread Electric Cooperative, Inc.
Description: Revised Wholesale Power Contracts Filing to be effective 9/13/2013.
Filed Date: 9/5/13.
Accession Number: 20130905–5033.
Comments Due: 5 p.m. ET 9/26/13.

Docket Numbers: ER13–2102–001.
Applicants: ReEnergy Black River LLC.
Description: ReEnergy Black River Amended Notice of Succession and MBR Tariff Revisions to be effective 9/5/2013.
Filed Date: 9/4/13.
Accession Number: 20130904–5165.
Comments Due: 5 p.m. ET 9/25/13.

Docket Numbers: ER13–2320–000.
Applicants: ReEnergy Black River LLC.
Description: Notice of Cancellation of Market-Based Rate Tariff for Black River Generation to be effective 9/5/2013.
Filed Date: 9/4/13.
Accession Number: 20130904–5168.
Comments Due: 5 p.m. ET 9/25/13.

Docket Numbers: ER13–2321–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2013–09–04 Cost Deferral for non-Entergy Entities to be effective 11/3/2013.
Filed Date: 9/4/13.
Accession Number: 20130904–5188.
Comments Due: 5 p.m. ET 9/25/13.

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: September 5, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–22197 Filed 9–11–13; 8:45 am].

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

September 6, 2013.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP11–2473–000
Applicants: Gulf South Pipeline Company, LP
Description: 2012 CICO Filing to be effective N/A
Filed Date: 9/3/13
Accession Number: 20130903–5108
Comments Due: 5 p.m. ET 9/16/13

Docket Numbers: RP11–2474–000
Applicants: Gulf Crossing Pipeline Company LLC
Description: 2012 CICO Report to be effective N/A
Filed Date: 9/3/13
Accession Number: 20130903–5107
Comments Due: 5 p.m. ET 9/16/13

Docket Numbers: RP13–1314–000
Applicants: Millennium Pipeline Company, LLC
Description: Negotiated Rate & Non-Conforming Agreement—Carrizo, DTE, SW to be effective 9/5/2013
Filed Date: 9/5/13
Accession Number: 20130905–5220
Comments Due: 5 p.m. ET 9/17/13

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.

Filings in Existing Proceedings

Docket Numbers: CP11–56–003
Applicants: Texas Eastern Transmission, LP and Algonquin Gas Transmission, LLC
Description: Abbreviated Application of Texas Eastern Transmission, LP and Algonquin Gas Transmission, LLC for Limited Amendment of Certificates of Public Convenience and Necessity
Filed Date: 9/4/13
Accession Number: 20130904–5206
Comments Due: 5 p.m. ET 9/13/13

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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.

Nathaniel J. Davis, Sr.,

Deputy Secretary

[FR Doc. 2013–22199 Filed 9–11–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3401–049]

Hydro Nelson, Ltd.; Hydro-WM, LLC; Notice of Transfer of Exemption

1. By documentation filed July 8, 2013 and supplemented on September 4, 2013, Hydro-WM, LLC informed the Commission that the exemption from licensing for the Walker Mill Dam Project, FERC No. 3401, originally issued March 26, 1982,[1] has been transferred to Hydro-WM, LLC. The project is located on the Rockfish River in Nelson County, Virginia. The transfer of an exemption does not require Commission approval.

2. Hydro-WM, LLC is now the exemptee of the Walker Mill Dam Project, FERC No. 3401. All correspondence should be forwarded to Mr. Frederic Reveiz, President/Owner, Hydro-WM, LLC, 5272 River Road, Suite 100, Bethesda, MD 20816.

[1] 18 FERC ¶ 62,525, Order Granting Exemption From Licensing of a Small Hydroelectric Project of 5 Megawatts or Less.

Dated: September 5, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–22153 Filed 9–11–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0341; FRL–9536–2]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Plywood and Composite Products (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Plywood and Composite Products (40 CFR Part 63, Subpart DDDD) (Renewal)'' (EPA ICR No. 1984.05, OMB Control No. 2060–0552), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) This is a proposed extension of the ICR, which is currently approved through October 31, 2013. Public comments were previously requested via the **Federal Register** (78 *FR* 33409) on June 4, 2013 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2013.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0341, to: (1) EPA online, using *www.regulations.gov* (our preferred method), by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The NESHAP for Plywood and Composite Products covers both new and existing plywood and composite wood products (PCWP) facilities. Plywood and composite products include, but are not limited to plywood, veneer, particleboard, oriented strand board, hardboard, fiberboard, medium density fiberboard, laminated strand lumber, laminated veneer lumber, wood I-joists, kiln-dried lumber and glue-laminated beams.

Owners/operators of plywood and composite products facilities are required to submit an initial notification report, performance tests, and compliance status reports. Also, respondents are required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Semiannual reports are required.

Form Numbers: None.

Respondents/affected entities: Plywood and composite product manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart DDDD).

Estimated number of respondents: 228 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 11,687 hours (per year). ''Burden'' is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,159,112 (per year), includes $15,960 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the respondent burden from the most-recently approved ICR. This is not due to any program changes. The adjustment increase is the result of a labor rate increase and a rounding correction. The previous ICR rounded the number of hours required to record continuous parameter information. This ICR uses a more-accurate estimate in calculating this burden.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–22221 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2011–1036; FRL—9536–4]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Soil Fumigant Risk Mitigation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has submitted the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: ''Soil Fumigant Risk Mitigation'' (EPA ICR No. 2451.01, OMB Control No. 2070-New). This is a request for approval of a new collection. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs. Copies of the ICR and related documents are available in the docket.

DATES: Additional comments may be submitted on or before October 15, 2013.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OPP–2011–1036, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats,

information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Ryne Yarger, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (703) 605–1193; fax number: (703) 305–5884; email address: *yarger.ryne@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA submitted the following ICR to OMB for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), and the procedures in 5 CFR 1320.12.

Prior Public Notice: Pursuant to 5 CFR 1320.8(d), EPA announced and provided a 60-day public comment period on the information collection activities as described in this ICR (77 FR 39699, July 5, 2012). EPA did not receive any public comments. This notice allows for an additional 30 days for public comments.

ICR Status: This is a new ICR. Under the PRA, an Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register,** are listed in 40 CFR part 9 and are included on the related collection instrument or form, if applicable.

Abstract: EPA will use the information collected under this new ICR to ensure that the identified risk mitigation measures necessary for reregistration eligibility for certain soil fumigant chemicals are adequately implemented. Under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pesticide registrants must generate and submit data to the Agency when such data are needed to maintain an existing registration of a pesticide.

In June 2009, after an extensive public review process, EPA completed Reregistration Eligibility Decisions (REDs) for a group of soil fumigant chemicals that takes into account the best available information on the potential risks and benefits of soil fumigant use. As discussed in the RED, the Agency determined that certain uses of the soil fumigants are eligible for reregistration, provided that the risk mitigation measures outlined in the REDs are adopted. This ICR estimates the burden on respondents related to the implementation of these risk mitigation measures.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this ICR are certified applicators and agricultural pesticide handlers, soil fumigant registrants, state and tribal lead agencies, and EPA.

Respondent's obligation to respond: Responses to this collection of information are required to obtain or retain a benefit (i.e., registration of the soil fumigant uses identified).

Estimated number of respondents: 17,853.

Frequency of response: On occasion.

Total estimated annual burden: 197,646 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated annual cost: $7,243,472, includes $808,800 in annual capital or operation & maintenance costs.

Changes in the Estimates: This is a new ICR.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–22216 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0119; FRL 9532–6]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Motor Vehicle and Engine Compliance Program Fees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), Motor Vehicle and Engine Compliance Program Fees (Renewal) (EPA ICR No.2080.05, OMB Control No. 2060–0545, to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2013. Public comments were previously requested via the **Federal Register** (78 FR 15010) on March 8, 2013 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2013.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2013–0019 to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Lynn Sohacki, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number: 734–214–4851; fax number 734–214–4869; email address: *sohacki.lynn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: As required by the Clean Air Act, EPA has regulations establishing emission standards and other requirements for various classes of vehicles, engines, and evaporative emissions. These regulations require that compliance be demonstrated prior to EPA granting a ''Certificate of Conformity.'' EPA charges fees for

administering this certification program. In 2004, the fees program was expanded to include non-road categories of vehicles and engines, such as several categories of marine engines, locomotives, non-road recreational vehicles, and many non-road compression-ignition and spark-ignition engines. In 2008, the fees program was further expanded to include fees for certification of evaporative system components (primarily fuel lines and fuel tanks). Manufacturers and importers of covered vehicles, engines and components are required to pay the applicable certification fees prior to their certification applications being reviewed. Under section 208 of the Clean Air Act (42 U.S.C. 7542(c)) all information, other than trade secret processes or methods, must be publicly available. Information about fee payments is treated as confidential information prior to certification.

Form Numbers: EPA Forms 3520–29.

Respondents/affected entities: Manufacturers or importers of passenger cars, motorcycles, light trucks, heavy duty truck engines, non-road vehicles or engines, and evaporative emissions components required to receive a certificate of conformity from EPA prior to selling or introducing these products into commerce in the U.S.

Respondent's obligation to respond: Required to obtain or retain a benefit (40 CFR Part 1027)

Estimated number of respondents: 583 (total).

Frequency of response: Yearly and Occasionally.

Total estimated burden: 1,513 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: $112,873 (per year), which includes $24,623 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is increase of 306 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to an adjustment of the estimate entirely due to the increased number of fee forms received from an increased number of manufacturers.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–22220 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2013–0254; FRL–9397–7]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the pesticide applicant, Robert I. Rose, Ph.D., on behalf of James Mains, Ph.D., Mosquito Mate, Inc. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0254, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. EUP

EPA has issued the following EUP:

89668–EUP–1. Issuance. Robert I. Rose, Ph.D., on behalf of James Mains, Ph.D., Mosquito Mate, Inc., 1122 Oak Hill Drive, Lexington, KY 40505–3322. This EUP allows the weekly release for a 6-month period of 100,000 male *Aedes albopictus* mosquitoes containing a total of 38.4 mg *Wolbachia pipientis* ZAP strain over the entire EUP between July 29, 2013, and July 29, 2016. Releases will total over 4,118 acres in certain areas of California, Florida, Kentucky, and New York as described in the amended Section G in the docket. These releases are intended to suppress the population of the naturally occurring *Aedes albopictus* mosquitoes that, on mating, are expected to produce non-viable eggs. Mosquito population and eggs will be monitored during the EUP in annual reports to EPA. One comment urging approval of the research trials was submitted in response to the Notice of Receipt of the EUP application.

Authority: 7 U.S.C. 136c.

List of Subjects

Environmental protection, Experimental use permits.

Dated: September 5, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–22223 Filed 9–11–13; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

[Public Notice: 2013–0045]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088162XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before October 7, 2013 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2013–0045 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2013–0045 on any attached document.

Reference: AP088162XX.

Purpose and Use:

Brief description of the purpose of the transaction:

To support the export of U.S.-manufactured commercial aircraft to China.

Brief non-proprietary description of the anticipated use of the items being exported:

To provide airline service in China and between China and various regional and international destinations.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported may be used to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: The Boeing Company

Obligor: China Southern Airlines

Guarantor(s): N/A

Description of Items Being Exported:

Boeing 787 aircraft and possibly other wide-body, long haul-aircraft.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Cristopolis Dieguez,

Program Specialist, Office of the General Counsel.

[FR Doc. 2013–22192 Filed 9–11–13; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Determination of Insufficient Assets To Satisfy Claims Against Financial Institution in Receivership

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice.

SUMMARY: The FDIC has determined that insufficient assets exist in the receivership of Hillcrest Bank, Overland Park, Kansas, to make any distribution on general unsecured claims, and therefore such claims will recover nothing and have no value.

DATES: The FDIC made its determination on August 29, 2013.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding this notice, you may contact an FDIC Claims Agent at (972) 761–8677. Written correspondence may also be mailed to FDIC as Receiver of Hillcrest Bank, Attention: Claims Agent, 1601 Bryan Street, Dallas, Texas 75201.

SUPPLEMENTARY INFORMATION: On October 22, 2010, Hillcrest Bank, Overland Park, Kansas, (FIN #10302) was closed by the Office of the State Bank Commissioner of Kansas, and the Federal Deposit Insurance Corporation (''FDIC'') was appointed as its receiver (''Receiver''). In complying with its statutory duty to resolve the institution in the method that is least costly to the deposit insurance fund (see 12 U.S.C. 1823(c)(4)), the FDIC facilitated a transaction with Hillcrest Bank, National Association, (''Hillcrest Bank, N.A.''), Overland Park, Kansas, to assume all of the deposits (excluding brokered deposits) and most of the assets of the failed institution.

Section 11(d)(11)(A) of the FDI Act, 12 U.S.C. 1821(d)(11)(A), sets forth the order of priority for distribution of amounts realized from the liquidation or other resolution of an insured depository institution to pay claims. Under the statutory order of priority, administrative expenses and deposit liabilities must be paid in full before any distribution may be made to general unsecured creditors or any lower priority claims.

As of June 30, 2013, the maximum value of assets that could be available for distribution by the Receiver, together with maximum possible recoveries on tax refund claims was $126,154,744. As of the same date, administrative expenses and depositor liabilities equaled $391,321,173, exceeding available assets and potential recoveries by $265,166,429. Accordingly, the FDIC has determined that insufficient assets exist to make any distribution on general unsecured creditor claims (and any lower priority claims) and therefore all such claims, asserted or unasserted, will recover nothing and have no value.

Dated: September 9, 2013.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013–22201 Filed 9–11–13; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting Notice

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors met in open session at 10:00 a.m. on Tuesday, September 10, 2013, to consider the following matters:

SUMMARY AGENDA:

Disposition of minutes of previous Board of Directors' Meetings.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

DISCUSSION AGENDA:

Memorandum and resolution re: Final Rule on Definition of Insured Deposit.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Jeremiah O. Norton (Appointive), concurred in by Director Thomas J. Curry (Comptroller of the Currency), Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters on less than seven days' notice to the public; and that no earlier notice of the meeting than that previously provided on September 5, 2013, was practicable.

The meeting was held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

Dated: September 10, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013–22342 Filed 9–10–13; 4:15 pm]

BILLING CODE P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting Notice

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:16 a.m. on Tuesday, September 10, 2013, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Jeremiah O. Norton (Appointive), concurred in by Director Richard Cordray (Director, Consumer Financial Protection Bureau), Director Thomas J. Curry (Comptroller of the Currency), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street NW., Washington, D. C.

Dated: September 10, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013–22341 Filed 9–10–13; 4:15 pm]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov*.

ATS Logistics, LLC (NVO & OFF), 19747 Highway 59 N, Suite 261, Humble, TX 77338, Officers: Lydia R. Ramos, Secretary (QI), Amit K. Gandhi, President, Application Type: New NVO & OFF License

C Auto Group Inc. (OFF), 13224 Valley Blvd., La Puente, CA 91746, Officers: Lida Mov, Secretary (QI), Cindy P. Tang, CEO, Application Type: New OFF License

DSX-Port, Inc. (NVO), 1450 W. Thorndale Avenue, Itasca, IL 60143, Officers: Jeff Aguilar, Vice President (QI), Michael Butterfield, President, Application Type: QI Change

Eastern Logistics Services, Inc. (NVO & OFF), One Cross Island Plaza, Suite 111, Rosedale, NY 11422, Officer: Jimmy Wong, Director (QI), Application Type: New NVO & OFF License

International Cargo Consolidators, Corp. (OFF), 10049 NW 89th Avenue, Bay 3, Medley, FL 33178, Officer: Maria (aka Teri) T. Rodriguez-Olivero, President (QI), Application Type: New OFF License

Popi Trading, Inc. dba Liner American Services N.A. (NVO & OFF), 225 Broadway, Suite 2701, New York, NY 10007, Officers: Cristina Rodriguez, Treasurer (QI), Pablo J. Silva, President, Application Type: New NVO & OFF License

Seascape Lines, Inc. (NVO), 15 Forbush Road, Dublin, NH 03444, Officers: Renee G. Rebolledo, President (QI), C. Wilson Sullivan, Secretary, Application Type: QI Change

World Link Transport, Inc. (NVO & OFF), 1220 Kona Drive, Compton, CA 90220, Officers: Michael M. Goto, President (QI), Nanette Victoriano, Corporate Secretary, Application Type: New NVO & OFF License

By the Commission.

Dated: September 6, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–22133 Filed 9–11–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations and Terminations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked or terminated for the reason shown pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 004306N.
Name: International Transport Services, Inc.
Address: 19987 Commerce Parkway, Cleveland, OH 44130.
Date Revoked: August 9, 2013.
Reason: Failed to maintain a valid bond.

License No.: 004436NF.
Name: Wimpex, Inc.
Address: 1001 La Bore International Ct., Suite C, Vadnais Heights, MN 55110.
Date Revoked: July 29, 2013.
Reason: Voluntary Surrender of License.

License No.: 020272NF.
Name: CCT Corporation dba CCT Marine dba CCT Global Logistics.
Address: 11250 NW 25th Street, Suite 114, Miami, FL 33172.
Date Revoked: August 1, 2013.
Reason: Failed to maintain valid bonds.

License No.: 022827F.
Name: Stella Maris International Trading, Inc. dba OP Shipping.
Address: 1601 Sahlman Drive, Tampa, FL 33605.
Date Revoked: July 24, 2013.
Reason: Failed to maintain a valid bond.

License No.: 023333NF.
Name: Base Ventures International, Inc. dba Base Ventures Shipping
Address: 160 1st Street, SE., Suite 201, New Brighton, MN 55112.
Date Revoked: July 24, 2013.
Reason: Failed to maintain valid bonds.

License No.: 024023F.
Name: OES Logistics, Inc
Address: 10900 E. 183rd Street, #130, Cerritos, CA 90703.
Date Revoked: July 16, 2013.
Reason: Failed to maintain a valid bond.

James A. Nussbaumer,

Deputy Director, Bureau of Certification and Licensing.

[FR Doc. 2013–22131 Filed 9–11–13; 8:45 am]

BILLING CODE 6730–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–00XX; Docket No. 2013–0001; Sequence 7]

Information Collection; DigitalGov Customer Satisfaction Survey

AGENCY: Office of Citizen Services and Innovative Technologies (OCSIT), General Services Administration (GSA).

ACTION: Notice of request for comments regarding a new request for an OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), the Regulatory Secretariat will submit to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding the DigitalGov Web site Customer Satisfaction Survey.

DATES: Submit comments on or before November 12, 2013.

ADDRESSES: Submit comments identified by Information Collection 3090–00xx; DigitalGov Customer Satisfaction Survey by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal for ''Information Collection 3090–00xx; DigitalGov Customer Satisfaction Survey''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–00xx; DigitalGov Customer Satisfaction Survey''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–00xx; DigitalGov Customer Satisfaction Survey'' on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Hada Flowers/IC 3090–00xx; DigitalGov Customer Satisfaction Survey.

Instructions: Please submit comments only and cite ''Information Collection 3090–00XX; DigitalGov Customer Satisfaction Survey'' in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Rachel Flagg, Program Analyst, Center for Excellence in Digital Government, GSA, via email at *rachel.flagg@gsa.gov* or by phone 509–850–5654.

SUPPLEMENTARY INFORMATION:

A. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

B. Purpose

The Digital Government Strategy (May 2012) requires federal agencies to measure performance and customer satisfaction to improve service delivery. Since the Web is a primary channel for agencies to deliver government information and services to the American public, this collection will provide actionable data to help agencies improve their Web sites; enable agency compliance with the Digital Government Strategy; and streamline the PRA review process for Web site surveys, for both OMB and agencies.

Online surveys are an industry best practice, and one of the most efficient ways for agencies to measure customer satisfaction. A random selection of visitors to government Web sites will be given the opportunity to complete a survey. Participation is voluntary and anonymous. Survey questions are documented on *HowTo.gov.* The data gathered will be used internally by agencies to improve service to government customers.

C. Annual Reporting Burden

(Note, this burden is calculated only for GSA's *HowTo.gov* Web site.)

The estimated annual burden:

Respondents: 1800.

Responses Per Respondent: 1.

Total Annual Responses: 1800.

Hours Per Response: .03.

Total Burden Hours: 54.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 3090–XXXX, DigitalGov Customer Satisfaction Survey, in all correspondence.

Dated: September 5, 2013.

Casey Coleman,

Chief Information Officer.

[FR Doc. 2013–22191 Filed 9–11–13; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0161; Docket 2013–0077; Sequence 12]

Federal Acquisition Regulation; Information Collection; Reporting Purchases From Sources Outside the United States

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension, with changes, to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning reporting purchases from sources outside the United States.

DATES: Submit comments on or before November 12, 2013.

ADDRESSES: Submit comments identified by IC 9000–0161 by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''9000–0161; Reporting of Purchases from Outside the United States''. Select the link ''Submit a Comment'' that corresponds with ''9000–0161; Reporting of Purchases from Outside the United States''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and 9000–0161; Reporting of Purchases from Outside the United States'' on your attached document.

• *Fax:* 202–501–4067.

• *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., 2nd floor, Washington, DC 20405–0001. ATTN: Hada Flowers/IC 9000–0161.

Instructions: Please submit comments only and cite IC 9000–0161, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Program Analyst, at

202–219–0202. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755.

SUPPLEMENTARY INFORMATION:

A. Purpose

The information on place of manufacture was formerly used by each Federal agency to prepare a report to Congress required by 41 U.S.C. 8302(b)(1) for FY 2009 through 2011 on acquisitions of articles, materials, or supplies that are manufactured outside the United States. However, the data is still necessary for analysis of the application of the Buy American statue and the trade agreements and for other reports to Congress. Additionally, contracting officers require this data as the basis for entry into the Federal Procurement Data System for further data on the rationale for purchasing foreign manufactured items.

B. Annual Reporting Burden

Based on a Federal Procurement Data System (FPDS) report of Government-wide acquisition of manufactured end products in FY 2012, a total of 427,055 contracts were awarded. Since this is a solicitation provision, we estimate an average of 4 responses per solicitation resulting in approximately 1,708,220 offers (427,055 x 4 (rounded)). Of the approximately 1,708,220 offers, the Government estimates that an average of 10 responses annually will be received from 170,822 unique vendors (1,708,220/10). Consequently, it was determined that the FY 2012 FPDS data identifying 170,822 unique vendors was a sufficient baseline for estimating the number of respondents. It is therefore estimated that approximately 170,822 respondents would need to comply with this information collection. The time required to read and prepare information is estimated at .01 hour (less than one minute) per completion. Recordkeeping will be integrated into systems already established by offerors.

Estimated number of respondents: 170,822.

Est. number of responses per respondent per year: x 10.

Total annual responses (rounded): 1,708,220.

Estimated hours per response: 0.1.

Total response burden hours: 17,082.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd floor, Washington, DC 20405–0001, telephone 202–501–4755. Please cite OMB Control Number 9000–0161, Reporting Purchases from Sources Outside the United States, in all correspondence.

Dated: September 6, 2013.

Karlos Morgan, Sr.,

Acting Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2013–22193 Filed 9–11–13; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice-GTAC–2013–03; Docket No. 2013–0002; Sequence 30]

Government-Wide Travel Advisory Committee (GTAC); Public Advisory Committee Meeting

AGENCY: Office of Government-Wide Policy, General Services Administration (GSA).

ACTION: Notice.

SUMMARY: The Government-wide Travel Advisory Committee (GTAC) (the Committee), is a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App 2. This notice provides the public meeting dates for the remainder of the 2013 calendar year for the GTAC: November 7, 2013 and December 10, 2013. The meetings are open to the public via teleconference.

DATES: The meetings will be held on Thursday, November 7, 2013, beginning at 9:00 a.m. Eastern Standard Time, and ending no later than 4:00 p.m. Eastern Standard Time and Tuesday, December 10, 2013, beginning at 9:00 a.m. Eastern Standard Time, and ending no later than 4:00 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Ms. Marcerto Barr, Designated Federal Officer (DFO), Government-wide Travel Advisory Committee (GTAC), Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, 202–208–7654 or by email to: *gtac@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Authority: The GSA Office of Asset and Transportation Management, Travel and Relocation Division, establishes policy that governs travel by Federal civilian employees and others authorized to travel at Government expense on temporary duty travel through the Federal Travel Regulation (FTR).

Agenda: The Committee will continue to discuss the FTR per diem for lodging as well as Meals and Incidental Expenditures allowances. The Committee may discuss other topics to be determined at a later date associated with the FTR.

Meeting Access: The meeting is open to the public via teleconference. Members of the public wishing to listen in on the GTAC discussion are recommended to visit the GTAC Web site at: *www.gsa.gov/gtac* to obtain registration details. Members of the public will not have the opportunity to ask questions or otherwise participate in the meeting. However, members of the public wishing to comment on the discussion or topics outlined in the agenda should follow the steps detailed in Procedures for Providing Public Comments.

Availability of Materials for the Meeting: Please see the GTAC Web site *www.gsa.gov/gtac* for any available materials and detailed meeting notes after the meeting.

Procedures for Providing Public Comments: In general, public comments will be posted to *www.gsa.gov/gtac.* Non-electronic documents will be made available for public inspection and copying at GSA, 1800 F Street NW., Washington, DC 20405, on official business days between the hours of 10:00 a.m. Eastern Standard Time and 4:00 p.m. Eastern Standard Time. The public can make an appointment to inspect comments by telephoning the DFO at 202–208–7654. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure. Any comments submitted in connection with the GTAC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

The public is invited to submit written comments within 7 business days after each meeting by either of the following methods and cite Meeting Notice-GTAC–2013–03.

Electronic or Paper Comments: (1) Submit electronic comments to *gtac@gsa.gov;* or

(2) submit paper comments to the attention of Ms. Marcerto Barr at GSA, 1800 F Street NW., Washington, DC 20405.

Dated: September 6, 2013.

Carolyn Austin-Diggs,

Acting Deputy Associate Administrator, Office of Asset and Transportation Management, Office of Government-wide Policy.

[FR Doc. 2013–22190 Filed 9–11–13; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier HHS–OS–20296–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0945–0003 scheduled to expire on 12/31/2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 15, 2013.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0945–0003 and document identifier HHS–OS–20296–30D for reference.

Information Collection Request Title: Standards for Privacy of Individually Identifiable Health Information, Security Standards for the Protection of Electronic Protected Health Information, and Supporting Regulations Contained in 45 CFR Parts 160 and 164

OMB No.: 0945–0003.

Abstract: The Office for Civil Rights (OCR) is notifying the public of revisions to a previously approved OCR data collection. The revisions reflect certain regulatory modifications to the HIPAA Privacy and Security Rules, pursuant to the Health Information for Economic and Clinical Health (HITECH) Act and the Genetic Information Nondiscrimination Act (GINA), that were finalized in the Omnibus HIPAA Final Rule published on January 25, 2013 (78 FR 5566). These modifications strengthen privacy and security protections for individually identifiable health information used or disclosed by business associates and enhance the rights of individuals with respect to their identifiable health information.

Need and Proposed Use of the Information: The information collection addresses HIPAA requirements related to the use, disclosure, and safeguarding of individually identifiable health information by covered entities affected by the HIPAA Rules. The information is routinely used by covered entities and business associates for treatment, payment, and health care operations. In addition, the information is used for specified public policy purposes, including research, public health, and as required by other laws. The Privacy Rule also ensures that the individuals are able to exercise certain rights with respect to their information, including the rights to access and seek amendments to their health records and to receive a Notice of Privacy Practices (NPP) from their direct treatment providers and health plans.

Likely Respondents: Respondents include HIPAA covered entities and their business associates, as well as members of the public.

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 to 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 tables below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

[New burdens associated with the final rule]

Section	Type of respondent	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
164.316	Documentation of Security Rule Policies and Procedures and Administrative Safeguards (business associates).	300,000	1	70/60	350,000
164.504	Business Associates Needing to Establish or Modify Business Associate Agreements with Subcontractors.	375,000*	1	20/60	125,000
164.520	Revision of Notice of Privacy Practices for Protected Health Information (drafting revised language) (health plans).	1,500	1	.111	167

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

[New burdens associated with the final rule]

Section	Type of respondent	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
164.520	Dissemination of Notice of Privacy Practices for Protected Health Information (health plans).	20,000,000	1	.00333335	66,667
164.520	Revision of Notice of Privacy Practices (providers).	697,000	1	.11111	77,444
Total					619,278

ONGOING ANNUAL BURDENS OF COMPLIANCE WITH THE RULES

Section	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
160.204	Process for Requesting Exception Determinations (states or persons).	1	1	16	16
164.504	Uses and Disclosures—Organizational Requirements	700,000	1	5/60	58,333
164.508	Uses and Disclosures for Which Individual authorization is required.	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes	113,524	1	5/60	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail).	100,000,000	1	0.25	416667
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail).	100,000,000	1	0.167	278333
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement).	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information.	150,000	1	3/60	7,500
164.524	Access of Individuals to Protected Health Information (disclosures).	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (requests)	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (denials)	50,000	1	3/60	2,500
164.528	Accounting for Disclosures of Protected Health Information.	70,000	1	3/60	5,833
Total					32,143,642

Total Hours: 32,762,920.

Darius Taylor,

Deputy Information Collection Clearance Officer.

[FR Doc. 2013–22148 Filed 9–11–13; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

National Foundation on Fitness, Sports, and Nutrition Establishment Act; Delegation of Authority; Office of the Assistant Secretary for Health

Notice is hereby given that I have delegated to the Assistant Secretary for Health authority under Section 5 of the National Foundation on Fitness, Sports, and Nutrition Establishment Act, Public Law 111–332 (Dec. 22, 2010). The delegation excludes the authorities to issue regulations and to submit reports to the Congress. This authority may be re-delegated.

I hereby affirm and ratify any actions taken by the Assistant Secretary for Health, or his subordinates, which involved the exercise of this authority delegated herein prior to the effective date of this delegation of authority.

This delegation is effective upon date of signature.

Dated: September 6, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–22235 Filed 9–11–13; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the

SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.*

DATES: The meeting will be held on Thursday, October 3, 2013 from 8:30 a.m. until 5:00 p.m. and Friday, October 4, 2013 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Hubert H. Humphrey Building, Room 800, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; fax: 240–453–6909; email address: *Julia.Gorey@hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., Thursday, October 3. Following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subcommittee on Harmonization (SOH) will give their report.

SOH was established by SACHRP at its July 2009 meeting and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

Following opening remarks on the morning of October 4, the Subpart A Subcommittee (SAS) will give their report. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business September 30, 2013.

Dated: September 5, 2013.

Jerry Menikoff,

Director, Office for Human Research Protections,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2013–22236 Filed 9–11–13; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Multi-Agency Informational Meeting Concerning Compliance with the Select Agent Regulations; Public Webcast

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webcast.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces a public webcast for all interested parties, including individuals and entities possessing, using, or transferring biological agents and toxins. The purpose of the webcast is to provide guidance related to the select agent regulations established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The webcast is being organized by the U.S. Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS), HHS/CDC, and the Department of Justice's Federal Bureau of Investigation (FBI), Criminal Justice Information Services. Changes to Section 11(Security) of the select agent regulations including information security, physical security, and personnel suitability will be discussed. Topics will focus on additional requirements for entities possessing select agents and toxins designated as Tier 1 agents.

DATES: The webcast will be held on Friday, November 15, 2013 from 10 a.m. to 4 p.m. EST. All who wish to join the webcast must register by October 18, 2013. Registration instructions can be found on the Web site *http://www.selectagents.gov.*

ADDRESSES: The webcast will be broadcast from the APHIS facility, 4700 River Road, Unit 2, Riverdale, MD 20737.

FOR FURTHER INFORMATION CONTACT:

APHIS: Dr. Keith Wiggins, APHIS Select Agent Program, 4700 River Road, Unit 2, Riverdale, MD 20737; 301–851–3300 option 1 (voice only); *ASAP@aphis.usda.gov.*

CDC: Diane Martin, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, CDC, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30333; (404) 718–2000; lrsat@cdc.gov.

SUPPLEMENTARY INFORMATION: Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, ''Enhancing Controls on Dangerous Biological Agents and Toxins'' (sections 201 through 221), provides for the regulation of certain biological agents and toxins by HHS (subtitle A, sections 201–204) and USDA (subtitle B, sections 211–213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). HHS/CDC regulates the possession, use or transfer biological agents and toxins that have the potential to pose a severe threat to public health and safety. The HHS/CDC select agent regulations can be found at 42 CFR part 73.

USDA/APHIS has a parallel program that regulates the possession, use or transfer biological agents that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The USDA/APHIS select agent regulations can be found at 7 CFR part 331 and 9 CFR part 121.

The Criminal Justice Information Service (CJIS) in the Federal Bureau of Investigation (FBI) conducts security risk assessments of all individuals and nongovernmental entities that require access to select agents and toxins.

The webcast announced here is an opportunity for the regulated community (i.e., registered entity responsible officials, alternate responsible officials, and entity owners) and other interested individuals to obtain specific regulatory guidance and information on standards concerning security issues related to the select agent regulations. Representatives from HHS/CDC, USDA/APHIS, and the FBI will be present during the webcast to address questions from and concerns of the web participants.

Changes to Section 11 (Security) of the select agent regulations including

information security, physical security, and personnel suitability will be discussed. Presenters will focus on the additional requirements for entities possessing select agents and toxins designated as Tier 1 agents or toxins. A question and answer session will follow each presentation.

Registration instructions can be found on the Web site *http://www.selectagents.gov*. Registration must be completed by October 18, 2013. Registration is required for participation to the webcast. This is a 100% webcast; therefore, in person participation cannot be accommodated.

Participants will be able to submit questions during the webcast at *selectagentwkshp@cdc.gov*. Closed-captioning services will be provided during the webcast.

Dated: September 4, 2013.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2013–21985 Filed 9–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response, (BSC, OPHPR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Dates and Times: October 16, 2013 8:00 a.m.–5:00 p.m., October 17, 2013 8:00 a.m.–12:00 p.m.

Place: Centers for Disease Control and Prevention (CDC), Global Communications Center, Building 19, Room 247/248, 1600 Clifton Road NE., Atlanta, Georgia 303333.

Status: Open to the public limited only by the space available. The meeting room will accommodate up to 30 people. Public participants should pre-register for the meeting as described in Additional Information for Public Participants.

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review of OPHPR scientific programs. For additional information about the Board, please visit: *http://www.cdc.gov/phpr/science/counselors.htm*

Matters To Be Discussed: Agenda items for this 2-day meeting include: (1) Briefings and BSC deliberation on the following topics: Program response to recommendations made in the Joint Report from the National Biodefense Science Board and the OPHPR BSC; program response to recommendations made in the peer review of the Career Epidemiology Field Officer Program; Hurricane Sandy Research; emergency preparedness and response communication challenges; development of an emergency risk communication research framework; community approaches to healthcare preparedness; National Health Security Preparedness Index Update; systems thinking in disaster management; assessing CDC's Emergency Management Program through accreditation; (2) BSC liaison representative updates to the Board highlighting organizational activities relevant to the OPHPR mission.

Agenda items are subject to change as priorities dictate.

Additional Information for Public Participants: Members of the public that wish to attend this meeting should pre-register by submitting the following information by email, facsimile, or phone (see Contact Person for More Information) no later than 12:00 noon (EDT) on Tuesday, October 8, 2013:

- Full Name,
- Organizational Affiliation,
- Complete Mailing Address,
- Citizenship, and
- Phone Number or Email Address

Contact Person for More Information: Marquita Black, Office of Science and Public Health Practice, Executive Assistant, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D–44, Atlanta, Georgia 30333, Telephone: (404) 639–7325; Facsimile: (404)639–7977; Email: *OPHPR.BSC.Questions@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–22177 Filed 9–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:00 p.m., October 16, 2013 (Closed). 8:00 a.m.–5:00 p.m., October 17, 2013 (Closed).

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314, Telephone: (703) 684–5900, Fax: (703) 684–0653.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications.

These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345, Telephone: (404) 498–2511, Fax: (404) 498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and

other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–22179 Filed 9–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns NIOSH Member Conflict Review, PA 07–318, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and date: 1:00 p.m.–4:00 p.m., October 31, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''NIOSH Member Conflict Review, PA 07–318''.

Contact Person for More Information: Nina Turner, Ph.D., Scientific Review Officer, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5976.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–22178 Filed 9–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: TANF Quarterly Financial Report ACF–196R.

OMB No.: New.

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for approval to create the ACF–196R form for quarterly financial reporting under the Temporary Assistance for Needy Families (TANF) program. Implementation of these changes will entail new costs to ACF, and thus, final adoption will depend upon funding availability. States participating in the TANF program are required by statute to report financial data on a quarterly basis. The forms meet the legal standard and provide essential data on the use of federal TANF funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions and annual reports required by Congress. Financial reporting under the TANF program is governed by 45 CFR Part 265.

Approval of the ACF–196R would result in two basic changes to TANF quarterly financial reports. The first is to require respondents to allocate annual expenditures among an expanded list of categories on the ACF–196R; these categories better reflect the wide range of activities on which states are expending TANF funds. The second change is to the accounting method used to report expenditures made in a fiscal year and monitor cumulative expenditures by grant year award. Specifically, effective FY 2015, with each open grant year award, respondents will be required to report actual expenditures made in a fiscal year rather than updating cumulative totals, using the ACF–196R. If a respondent needs to adjust an expenditure reported in a prior year, it will revise the report for the fiscal year in which that expenditure occurred, rather than the current year's report.

We will maintain the ACF–196 form (Approved OMB No 0970–0247), only for revisions to historical data. Specifically, if a respondent needs to adjust or correct an expenditure submitted in a fiscal year prior to FY 2015, the respondent will revise the ACF–196 pertaining to the relevant grant year for expenditures cumulative through FY 2014. Thus, the reporting burden associated with the ACF–196 is greatly reduced.

Respondents: State agencies administering the TANF program

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196R	51	4	14	2856
Estimated Total Annual Burden Hours:				2856

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Comments may be sent in writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer or emailed to: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection. Interested parties can also request copies of the proposed collection of information (instructions and forms) at the above address or by accessing the Information Memorandum TANF–ACF–IM–2013–03 on the Policy page of the OFA Web site, available at *http://www.acf.hhs.gov/programs/ofa/programs/tanf/policy.*

ACF specifically requests comments on: (a) Whether the proposed collection of information is critical to 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 proposed collection of information; (c) 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 automated collection techniques or other forms of information technology; (e) ability of respondents to categorize and allocate expenditures in the more detailed manner that the new categories listed on the ACF–196R would require; (f) whether definitions for categories are clear, or whether any of the definitions should be revised to prevent confusion over how to report an expenditure; (g) whether any additional or alternative categories of expenditure reporting should be included in order to improve understanding of how TANF and maintenance-of-effort (MOE) funds are being used; (h) length of time it will take for respondents to adapt to the new accounting method, specifically, whether a state would be able to accurately report expenditures according to the new accounting methodology by February 14, 2016 (the date the first quarter FY 2015 report is due), and if not, what transition time would be needed in order to report in accordance with the revised forms and procedures; (h) any complications that may result from the transition to a new accounting method, and if so, how to minimize the potential for complications; (i) whether there will be costs involved with transitioning to reporting in new expenditure categories and accounting method, and if so, what would be the anticipated extent of such costs. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–22180 Filed 9–11–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Block Grant Reporting Requirements—ACF–700.

OMB No.: 0970–0430.

Description: The Child Care and Development Fund (CCDF) report requests annual Tribal aggregate information on services provided through the CCDF, which is required by the CCDF Final Rule (45 FR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services. The CCDF statute and regulations also require TLAs to submit a supplemental narrative as part of the ACF–700 report. This narrative describes child care activities and actions in the TLA's service area. Information from the ACF–700 and supplemental narrative report will be included in the Secretary's Report to Congress, as appropriate, and will be shared with all TLAs to inform them of CCDF-funded activities in other Tribal programs.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700 Report	260	1	38	9,880
Estimated Total Annual Burden Hours:				9,880

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–22222 Filed 9–11–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health was renewed for an additional two-year period on August 15 2013.

It is determined that the Advisory Committee to the Deputy Director for Intramural Research, National Institutes of Health, is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *spaethj@od.nih.gov.*

Dated: September 6, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22173 Filed 9–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; 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: National Center for Complementary and Alternative Medicine Special Emphasis Panel; ZAT1 PK28: PAR 10–163 R34 Clinical trial planning grants and other clinical applications.

Date: October 16, 2013.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter Kozel, Ph.D., Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–5475, 301–496–8004, *kozelp@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: September 6, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22175 Filed 9–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 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 materials, 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: National Institute on Drug Abuse Special Emphasis Panel Multisite Clinical Trials.

Date: September 25, 2013.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Scott A. Chen, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4234, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892–9550, 301–443–9511, *chensc@mail.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.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; I/START Review R03 (PAR12–066).

Date: October 29, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Minna Liang, Ph.D., Scientific Review Officer, Grants Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4226, MSC 9550, Bethesda, MD 20892–9550, 301–435–1432, *liangm@nida.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Advancing Exceptional Research on HIV/AIDS (R01).

Date: November 18, 2013.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, *rogersn2@nida.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 6, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22171 Filed 9–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: September 16, 2013.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: The Advisory Committee to the Director, NIH (ACD) is holding a public conference to discuss the findings of two of its working groups: the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) working group and the HeLa Genome Data Access working group. The BRAIN working group presentation and discussion will focus on the working group's interim report which identifies high priority areas for funding in Fiscal Year 2014.The HeLa Genome Data Access working group presentation will include an overview of the working group's scope and a summary of its review of requests for accessing genome sequence data from HeLa cell lines. Materials related to this meeting will be posted when available on the ACD Web site (*http://acd.od.nih.gov*).

To sign up for the public comment, please submit you name and affiliation to the Contact Person listed by 11:00 a.m. ET on September 16, 2013. Sign up will be restricted to one sign up per email. In the event that time does not allow for all those interested to present or a comments, anyone may file written comments with the committee through the Contact Person listed below. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person. The toll free number to participate in the teleconference is 800–779–1423. Indicate to the conference operator that your participant pass code is ''ACD.''

Place: (Telephone conference call), National Institutes of Health, One Center Drive, Building 1, Room 116, Bethesda, Maryland 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Immediate Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, Telephone: 301–496–4272, *woodgs@od.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to conflicts in finalizing the agenda and scheduling events.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

Dated: September 6, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22174 Filed 9–11–13; 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Molecular and Cellular. Endocrinology Study Section

Date: October 8, 2013.

Time: 8:00 am to 6:30 pm.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814,

Contact Person: John Bleasdale, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170 MSC 7892, Bethesda, MD 20892, 301–435–4514. *bleasdaleje@csr.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 10–11, 2013.

Time: 7:45 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico, Boulevard, Santa Monica, CA 90405

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, MSC, Bethesda, MD 20892, 301–435–1047, *dennis.hlasta@nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

Date: October 10–11, 2013.

Time: 8:00 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place:

Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Priscah Mujuru, RN, DRPH, COHNS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *mujurup@mail.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Nutrition and Metabolic Processes Study Section.

Date: October 10, 2013.

Time: 8:00 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701, Rockledge Drive, Room 6164 MSC 7892, Bethesda, MD 20892, 301–435–1044, *campdm@mail.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Chemo/Dietary Prevention Study Section.

Date: October 10, 2013.

Time: 8:00 am to 7:00 pm..

Agenda: To review and evaluate grant applications.

Place: Holiday Inn San Francisco Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

Contact Person: Sally A Mulhern, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 408–9724, *mulherns@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section

Date: October 10–11, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place:

Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: October 10, 2013.

Time: 8:00 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: Samuel C Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetics of Health and Disease Study Section.

Date: October 10–11, 2013.

Time: 8:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Avenue Hotel Chicago, 160 E. Huron Street, Chicago, IL 60611.

Contact Person: Cheryl M Corsaro, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435–1045, *corsaroc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Language and Communication.

Date: October 11, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005.

Contact Person: Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@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: September 6, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22172 Filed 9–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of 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 open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Further Investigation into the Causes of Stillbirth

Date: September 30, 2013

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To provide concept review of proposed concept review

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Rockville, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 6, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–22176 Filed 9–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0079]

Agency Information Collection Activities: Application for Replacement/Initial Nonimmigrant Arrival-Departure Document, Form I–102; Revision of a Currently Approved Collection; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information or new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 12, 2013.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0079 in the subject box, the agency name and Docket ID USCIS–2007–0011. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *www.regulations.gov* under e-Docket ID number USCIS–2007–0011;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) 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;

(2) 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;

(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 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) *Title of the Form/Collection:* Application for Replacement/Initial Nonimmigrant Arrival-Departure Document.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–102; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Nonimmigrants temporarily residing in the United States use this

form to request a replacement of their arrival evidence document.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 6,782 responses. 3,987 responses (paper-format) at .50 hours per response; and 2,795 responses (electronic filing) at .416 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,156.22 annual burden hours.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

Dated: September 4, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013–22217 Filed 9–11–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0095]

Agency Information Collection Activities:

Notice of Appeal or Motion, Form I–290B; Revision of a Currently Approved Collection

ACTION: 30-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on March 22, 2013, at 78 FR17701, allowing for a 60-day public comment period. USCIS received comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until October 15, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* The comments submitted to the OMB USCIS Desk Officer may also be submitted to DHS via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0027 or via email at *uscisfrcomment@uscis.dhs.gov.* All submissions received must include the agency name and the OMB Control Number 1615–0095.

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) 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;

(2) 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;

(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 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 Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Notice of Appeal or Motion.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–290B; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households, employers, private entities and organizations, businesses, non-profit institutions/organizations, and attorneys. Form I–290B is necessary in order for USCIS to make a determination that the appeal or motion to reopen or reconsider meets the eligibility requirements, and for USCIS to adjudicate the merits of the appeal or motion to reopen or reconsider.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 25,465 responses: 18,844 responses (paper-format) at 1.5 hours (90 minutes) per response; and 6,621 electronic filing responses at 1.33 hours (80 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 37,072 annual burden hours.

If you need a copy of the information collection instrument with supplementary documents, or need additional information, please visit *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140; Telephone 202–272–8377.

Dated: September 4, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013–22208 Filed 9–11–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Prior Disclosure

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning Prior Disclosure. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before November 12, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street, NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (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 estimates 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 including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Prior Disclosure.

OMB Number: 1651–0074.

Form Number: None.

Abstract: The Prior Disclosure program establishes a method for a potential violator to disclose to CBP that they have committed an error or a violation with respect to the legal requirements of entering merchandise into the United States, such as underpaid tariffs or duties, or misclassified merchandise. The procedure for making a prior disclosure is set forth in 19 CFR 162.74 which requires that respondents submit information about the merchandise involved, a specification of the false statements or omissions, and what the true and accurate information should be. A valid prior disclosure will entitle the disclosing party to the reduced penalties pursuant to 19 U.S.C. 1592(c)(4).

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 3,500.

Estimated Number of Annual Responses: 3,500.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 3,500.

Dated: September 9, 2013.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2013–22224 Filed 9–11–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDT000000.L11200000.DD0000.241A.00]

Notice of Public Meetings, Twin Falls District Resource Advisory Council, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA), the Federal Advisory Committee Act of 1972 (FACA, the U.S. Department of the Interior, Bureau of Land Management (BLM) Twin Falls District Resource Advisory Council (RAC) will meet as indicated below.

DATES: On September 26, 2013, the Twin Falls District RAC members will meet at the Best Western Sawtooth Inn at 2653 S. Lincoln Street, Jerome, Idaho. The meeting will begin at 9:00 a.m. and end no later than 4:00 p.m. The public comment period for the RAC meeting will take place 9:10 a.m. to 9:40 a.m.

FOR FURTHER INFORMATION CONTACT: Heather Tiel-Nelson, Twin Falls District, Idaho, 2536 Kimberly Road, Twin Falls, Idaho, 83301, (208) 736–2352.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Idaho. During the September 26th meeting, there will be an update on the Craters of the Moon National Monument Resource Management Plan (RMP) Amendment, and updates on both the Jarbidge RMP as well as the BLM's National Greater Sage-Grouse Planning Strategy.

Additional topics may be added and will be included in local media announcements. More information is available at *www.blm.gov/id/st/en/res/resource_advisory.3.html.* RAC meetings are open to the public. For further information about the meeting, please contact Heather Tiel-Nelson, Public Affairs Specialist for the Twin Falls District, BLM at (208) 736–2352.

Dated: August 26, 2013.

Mel M. Meier,

District Manager .

[FR Doc. 2013–22183 Filed 9–11–13; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00560 L58530000 EU0000 241A; N–78190 et al.; 13–08807; MO# 4500053642; TAS: 14X5232]

Notice of Realty Action: Competitive Sale of 28 Parcels of Public Land in Clark County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM) proposes to offer 28 parcels of public land totaling approximately 440.42 acres in the Las Vegas Valley by competitive sale, at not less than the appraised fair market

values (FMV). The sale parcels would be offered for sale pursuant to the Southern Nevada Public Land Management Act of 1998 (SNPLMA), as amended. The sale would be subject to the applicable provisions of Sections 203 of the Federal Land Policy and Management Act of 1976 (FLPMA), and BLM land sale regulations.

DATES: Interested parties may submit written comments regarding the proposed sale, until October 28, 2013. The sale by sealed bid and oral public auction will be held on January 16, 2014, at the BLM Las Vegas Field Office at 10 a.m., Pacific Time. The FMV for the parcels will be available 30 days prior to the sale. The BLM will accept sealed bids beginning December 30, 2013. Sealed bids must be received by the BLM Las Vegas Field Office no later than 4:30 p.m. Pacific Time, on January 10, 2014. The BLM will open sealed bids on the day of the sale just prior to oral bidding.

ADDRESSES: Mail written comments and submit sealed bids to the BLM Las Vegas Field Office, Assistant Field Manager, 4701 N. Torrey Pines Drive, Las Vegas, NV 89130.

FOR FURTHER INFORMATION CONTACT: Manuela Johnson at email: *manuela_johnson@blm.gov* or telephone: 702–515–5224. For general information on previous BLM public land sales, go to: *http://www.blm.gov/nv/st/en/snplma/Land_Auctions.html*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM proposes to offer 28 parcels of public land throughout various locations of the Las Vegas Valley. The parcels are positioned between the following locations: Hollywood Boulevard and Los Feliz Street, Warbonnet Way and Redwood Street north of Blue Diamond Road, Hualapai Way and Durango Drive south of Blue Diamond Road, Grand Canyon and Tee Pee Lane north of Alexander Road, and the northwest corner of Volunteer Boulevard and Executive Airport Drive. The subject public lands are described as:

Mount Diablo Meridian

N–91842, 17.50 acres: T. 20 S., R. 60 E., Sec. 6, NW¼SW¼SE¼, W½NE¼SW¼SE¼, NE¼NE¼SW¼SE¼.

N–78190, 2.50 acres: T. 22 S., R. 60 E., Sec. 14, NW¼SW¼NW¼SW¼.

N–91783, 5.00 acres: T. 22 S., R. 60 E., Sec. 14, S½SW¼SW¼SW¼.

N–91794, 10.00 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NE¼NE¼SW¼, E½NW¼NE¼SW¼, SW¼NW¼NE¼SW¼.

N–91795, 3.75 acres: T. 22 S., R. 60 E., Sec. 15, W½NE¼NW¼SE¼SW¼, NW¼NW¼SE¼SW¼.

N–81899, 2.50 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NE¼NW¼SW¼.

N–91796, 10.00 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NW¼NW¼SW¼, N½SW¼NW¼SW¼, SE¼SW¼NW¼SW¼.

N–91797, 17.50 acres: T. 22 S., R. 60 E., Sec. 15, S½SW¼SW¼SW¼, NW¼SW¼SW¼SW¼, W½SW¼SE¼SW¼, S½SE¼SW¼SW¼.

N–91786, 10.00 acres: T. 22 S., R. 60 E., Sec. 15, SW¼SW¼NE¼.

N–91806, 2.50 acres: T. 22 S., R. 60 E., Sec. 15, SE¼SE¼NE¼SE¼.

N–91807, 20.00 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NE¼NW¼SE¼, SE¼NW¼NW¼SE¼, N½SW¼NW¼SE¼, E½SE¼NE¼SW¼, W½NW¼SW¼SE¼.

N–91808, 7.50 acres: T. 22 S., R. 60 E., Sec. 15, W½NW¼NE¼SE¼, SE¼NW¼NE¼SE¼.

N–91787, 2.50 acres: T. 22 S., R. 60 E., Sec. 15, SE¼SW¼NE¼SE¼.

N–91809, 5.00 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NW¼SE¼SE¼, NW¼SW¼SE¼SE¼.

N–91788, 2.50 acres: T. 22 S., R. 60 E., Sec. 15, SW¼NE¼SW¼SE¼.

N–91789, 5.00 acres: T. 22 S., R. 60 E., Sec. 15, E½NE¼SE¼SE¼.

N–91810, 10.00 acres: T. 22 S., R. 60 E., Sec. 16, W½NE¼SE¼NE¼, E½SE¼SE¼NE¼.

N–91812, 12.50 acres: T. 22 S., R. 60 E., Sec. 16, SE¼NE¼NE¼SE¼, N½SE¼NE¼SE¼, SE¼SE¼NE¼SE¼, NE¼NE¼SE¼SE¼.

N–91782, 2.08 acres: T. 22 S., R. 60 E., Sec. 19, lots 17 and 74.

N–91815, 3.15 acres: T. 22 S., R. 60 E., Sec. 19, lots 70, 72.

N–79534, 16.25 acres: T. 22 S., R. 60 E., Sec. 19, W½SW¼SE¼NW¼, NE¼SW¼SE¼NW¼, W½SE¼SE¼NW¼, SW¼NE¼SE¼NW¼, S½NW¼NE¼SE¼NW¼.

N–91790, 2.50 acres: T. 22 S., R. 60 E., Sec. 19, SE¼SE¼SE¼NE¼.

N–91791, 5.00 acres: T. 22 S., R. 60 E., Sec. 20, S½SE¼SW¼NW¼.

N–91793, 7.50 acres: T. 22 S., R. 60 E., Sec. 20, S½SE¼SE¼NW¼, SW¼SW¼SW¼NE¼.

N–91792, 2.50 acres: T. 22 S., R. 60 E., Sec. 23, SE¼NE¼SW¼SW¼.

N–91827, 2.50 acres: T. 22 S., R. 60 E., Sec. 23, SE¼SW¼SW¼SW¼.

N–91844, 5.00 acres: T. 23 S., R. 61 E., Sec. 10, N½SW¼NE¼SE¼.

**N–91124, 247.59 acres:* T. 20 S., R. 62 E., Sec. 14, lots 1, 2, E½NW¼, N½SW¼.

The areas described contain 440.42 acres, more or less, in Clark County.

A sales matrix is available on the BLM Web site at: *http://www.blm.gov/snplma*. The sale matrix provides information specific to each sale parcel such as: legal description, physical location, encumbrances, acreage and fair market values.

**Sale parcel N–91124* consists of split-estate lands. The parcel of approximately 247.59 acres overlies privately-owned sand and gravel deposits patented out of Federal ownership pursuant to Private Law 96–67 signed on December 5, 1980, for the relief of two mining claimants. The patent provides for the private ownership and use of the sand and gravel deposits and such use of the surface that is reasonably required for mining. The northern portion of sale parcel N–91124 is near the southern boundary of Nellis Air Force Base near the Live Ordnance Loading Area. The existing explosion evacuation arcs extend onto the northern portion of the sale parcel.

This proposed competitive sale is in conformance with the BLM Las Vegas Resource Management Plan (RMP) and decision LD–1, approved by Record of Decision on October 5, 1998, and is in compliance with Section 203 of FLPMA. The proposed sale parcels were analyzed in the Las Vegas Valley Disposal Boundary Environmental Impact Statement and approved by Record of Decision on December 23, 2004, and a site specific Determination of National Environmental Policy Act Adequacy document numbered DOI–BLM–NV–S010–2013–0093–DNA approved on June 27, 2013.

Submit comments to the address in the **ADDRESSES** section. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including any personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. In addition to this Notice, notice of this sale will also be published once a week for 3 weeks in the *Las Vegas Review-Journal.*

Sale procedures: The public sale auction would be through sealed and oral bids. Sealed bids would be opened and recorded on the sale date to determine the high bids among the qualified bids received. Sealed bids above the FMV would set the starting point for oral bidding on a parcel. Parcels that receive no qualified sealed bids will begin at the established FMV.

Sealed-bid envelopes must be clearly marked on the lower front left corner with the parcel number and name of the sale, for example: ''N–XXXXX, 28-parcel SNPLMA Sale 2013.'' Sealed bids for the sale must also include a certified check, postal money order, bank draft, or cashier's check made payable to the ''Department of the Interior-Bureau of Land Management'' in an amount not less than 20 percent of the total amount bid. Personal or company checks will not be accepted. The sealed-bid envelope must contain the 20 percent bid deposit, and a completed and signed ''Certificate of Eligibility'' form stating the name, mailing address, and telephone number of the entity or person submitting the bid. Certificate of Eligibility forms are available at the BLM Las Vegas Field Office at the address listed in the **ADDRESSES** section and on the BLM Web site at: *http://www.blm.gov/nv/st/en/snplma/Land_Auctions.html.* Pursuant to 43 CFR 2711.3–1(c), if two or more sealed-bid envelopes containing valid bids of the same amount are received, oral bidding would start at the sealed-bid amount. If there are no oral bids on the parcel, the authorized office will determine the winning bidder. Bids for less than the federally approved FMV will not be qualified. The BLM will send the successful bidder(s) a high bidder letter with detailed information for full payment.

All funds submitted with unsuccessful bids will be returned to the bidders or their authorized representative upon presentation of acceptable photo identification at the BLM Las Vegas Field Office or by certified mail. If a bidder purchases a parcel and defaults, the BLM may retain the bid deposit and cancel the sale of that parcel. If the high bidder is unable to consummate the transaction for any other reasons, the second highest bid may be considered. If there are no acceptable bids, the parcels may remain available for sale at a future date in accordance with competitive sale procedures without further legal notice.

Federal law requires that bidders must be: (1) A citizen of the United States 18 years of age or over; (2) A corporation subject to the laws of any State or of the United States; (3) A State, State instrumentality or political subdivision authorized to hold property; and (4) An entity legally capable of conveying and holding lands or interests therein under the laws of the State within which the lands to be conveyed are located. United States citizenship is evidenced by presenting a birth certificate, passport, or naturalization papers. Failure to submit the above requested documents to the BLM within 30 days from receipt of the high-bidder letter shall result in cancellation of the sale and forfeiture of the bid deposit. The successful bidder would be allowed 180 days from the date of the sale to submit the remainder of the full purchase price.

Publication of this notice in the **Federal Register** segregates the subject lands from all forms of appropriation under the public land laws, including the mining laws. Any subsequent application will not be accepted, will not be considered as filed, and will be returned to the applicant if the notice segregates from the use applied for in the application. The segregative effect of this notice terminates upon issuance of a patent or other document of conveyance to such lands; publication in the **Federal Register** of a termination of the segregation; or 2 years after the date of this publication, whichever occurs first. The segregation period may not exceed 2 years unless extended by the BLM State Director, Nevada, in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

Terms and Conditions: All minerals for the sale parcels, except sale parcel N–91124, will be reserved to the United States. The patents, when issued, will contain a mineral reservation to the United States for all minerals, except sale parcel N–91124.

The parcels are subject to limitations prescribed by law and regulation, and certain encumbrances in favor of third parties. Prior to patent issuance, a holder of any right-of-way within the sale parcels will be given the opportunity to amend the right-of-way for conversion to a new term, including perpetuity, if applicable, or conversion to an easement. The BLM will notify valid existing right-of-way holders of record of their ability to convert their compliant rights-of-way to perpetual rights-of-way or easement. In accordance with Federal regulations at 43 CFR 2807.15, once notified, each valid holder may apply for the conversion of their current authorization.

The following numbered terms and conditions will appear on the conveyance documents for the sale parcels:

1. All minerals deposits in the lands so patented, and to it, or persons authorized by it, the right to prospect for, mine, and remove such deposits from the same under applicable law and regulations to be established by the Secretary of the Interior are reserved to the United States, together with all necessary access and exit rights. Note: Sale parcel N–91124 will not include this mineral reservation because the mineral estate of this parcel is held by a private party.

2. A right-of-way is reserved for ditches and canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C. 945);

3. A right-of-way for Federal aid highway (Blue Diamond Road) purposes reserved to the Federal Aid Highway Administration, its successors and assigns, by right-of-way

No. Nev-012728, pursuant to the Act of August 27, 1958 (23 U.S.C. 107(D)) within parcels N–91782, N–91815, N–79534, N–91791 and N–91793;

4. The parcels are subject to valid existing rights;

5. The parcels are subject to reservations for road, public utilities and flood control purposes, both existing and proposed, in accordance with the local governing entities' transportation plans;

6. An appropriate indemnification clause protecting the United States from claims arising out of the lessees/patentee's use, occupancy, or occupations on the leased/patented lands.

Pursuant to the requirements established by Section 120(h) of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9620(h) (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1988, 100 Stat. 1670, notice is hereby given that the described lands have been examined and no evidence was found to indicate that any hazardous substances have been stored for 1 year or more, nor had any hazardous substances been disposed of or released on the subject property.

No warranty of any kind, express or implied, is given by the United States as to the title, whether or to what extent the land may be developed, its physical condition, future uses, or any other circumstance or condition. The conveyance of a parcel will not be on a contingency basis. However, to the extent required by law, the parcel is subject to the requirements of Section 120(h) of the CERCLA.

Unless other satisfactory arrangements are approved in advance by the BLM authorized officer, conveyance of title shall be through the use of escrow. Designation of the escrow agent shall be through mutual agreement between the BLM and the prospective patentee, and costs of escrow shall be borne by the prospective patentee.

Requests for all escrow instructions must be received by the BLM Las Vegas Field Office prior to 30 days before the

prospective patentee's scheduled closing date. There are no exceptions.

All name changes and supporting documentation must be received at the BLM Las Vegas Field Office 30 days from the date on the high-bidder letter by 4:30 p.m., Pacific Time. Name changes will not be accepted after that date. To submit a name change, the apparent high bidder must submit the name change in writing on the Certificate of Eligibility form to the BLM Las Vegas Field Office.

The remainder of the full bid price for the parcel must be received no later than 4:30 p.m., Pacific Time, within 180 days following the day of the sale. Payment must be submitted in the form of a certified check, U.S. postal money order, bank draft, cashier's check, or made available by electronic fund transfer made payable in U.S. dollars to the ''Department of the Interior—Bureau of Land Management'' to the BLM Las Vegas Field Office. Personal or company checks will not be accepted.

Arrangements for electronic fund transfer to the BLM for payment of the balance due must be made a minimum of 2 weeks prior to the payment date. Failure to pay the full bid price prior to the expiration of the 180th day will disqualify the high bidder and cause the entire 20 percent bid deposit to be forfeited to the BLM. Forfeiture of the 20 percent bid deposit is in accordance with 43 CFR 2711.3–1(d). No exceptions will be made. The BLM cannot accept the remainder of the bid price after the 180th day of the sale date.

The BLM will not sign any documents related to 1031 Exchange transactions. The timing for completion of such an exchange is the bidder's responsibility. The BLM cannot be a party to any 1031 Exchange.

In accordance with 43 CFR 2711.3–1(f), within 30 days the BLM may accept or reject any or all offers to purchase, or withdraw any parcel of land or interest therein from sale, if, in the opinion of a BLM authorized officer, consummation of the sale would be inconsistent with any law, or for other reasons as may be provided by applicable law or regulations. No contractual or other rights against the United States may accrue until the BLM officially accepts the offer to purchase and the full bid price is paid.

Upon the publication of this Notice and until the completion of this sale, the BLM is no longer accepting land use applications affecting the parcel identified for sale. However, land use applications may be considered after sale if the parcel is not sold. The parcel may be subject to land use applications received prior to publication of this Notice if processing the application would have no adverse effect on the marketability of title, or the FMV of the parcel. Information concerning the sale, encumbrances of record, appraisals, reservations, procedures and conditions, CERCLA, and other environmental documents that may appear in the BLM public files for the proposed sale parcels are available for review during business hours, 7:30 a.m. to 4:30 p.m., Pacific Time, Monday through Friday, at the BLM Las Vegas Field Office, except during Federal holidays.

In order to determine the FMV through appraisal, certain extraordinary assumptions and hypothetical conditions may have been made concerning the attributes and limitations of the lands and potential effects of local regulations and policies on potential future land uses. Through publication of this Notice, the BLM advises that these assumptions may not be endorsed or approved by units of local government.

It is the buyer's responsibility to be aware of all applicable Federal, State, and local government laws, regulations and policies that may affect the subject lands, including any required dedication of lands for public uses. It is also the buyer's responsibility to be aware of existing or prospective uses of nearby properties. When conveyed out of Federal ownership, the lands will be subject to any applicable laws, regulations, and policies of the applicable local government for proposed future uses. It is the responsibility of the purchaser to be aware through due diligence of those laws, regulations, and policies, and to seek any required local approvals for future uses. Buyers should also make themselves aware of any Federal or State law or regulation that may impact the future use of the property. Any land lacking access from a public road or highway will be conveyed as such, and future access acquisition will be the responsibility of the buyer.

Any comments regarding the proposed sale will be reviewed by the BLM Nevada State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action in response to such comments. In the absence of any comments, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2711.1–2.

Vanessa L. Hice,

Assistant Field Manager, Division of Lands.

[FR Doc. 2013–22210 Filed 9–11–13; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–853]

Certain Wireless Consumer Electronics Devices and Components Thereof; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge has issued a Final Initial Determination and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, specifically a limited exclusion order against certain wireless consumer electronics devices and components thereof imported by respondents Acer, Inc. of Taipei, Taiwan; Acer America Corporation of San Jose, California; Amazon.com, Inc. of Seattle, Washington; Barnes and Noble, Inc. of New York, New York; Garmin Ltd of Schaffhausen, Switzerland; Garmin International, Inc. of Olathe, Kansas; Garmin USA, Inc. of Olathe, Kansas; HTC Corporation of New Taipei City, Taiwan; HTC America of Bellevue, Washington; Huawei Technologies Co, Ltd. of Shenzhen, China; Huawei Device Co., Ltd. of Shenzhen, China; Huawei Device USA Inc. of Plano, Texas; and Futurewei Technologies, Inc. d/b/a Huawei Technologies (USA) of Plano, Texas; Kyocera Corporation of Kyoto, Japan; Kyocera Communications, Inc. of San Diego, California; LG Electronics, Inc. of Seoul, Korea; LG Electronics U.S.A., Inc. of Englewood Cliffs, New Jersey; Nintendo Co. Ltd. of Kyoto, Japan; Nintendo of America, Inc. of Redmond, Washington; Novatel Wireless, Inc. of San Diego, California; Samsung Electronics Co., Ltd., of Seoul, Korea; Samsung Electronics America, Inc. of Ridgefield Park, New Jersey; ZTE Corporation of Shenzhen, China; and ZTE (USA) Inc. of Richardson, Texas. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS)

at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on September 6, 2013. Comments should address whether issuance of a limited exclusion order and cease and desist orders in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the limited exclusion order and cease and desist orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on October 7, 2013.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–853'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

Issued: September 9, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–22189 Filed 9–11–13; 8:45 am]

BILLING CODE 7020–02–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 13–113]

NASA Advisory Council; Science Committee; Planetary Science Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Tuesday, October 1, 2013, 8:30 a.m. to 4:30 p.m., and Wednesday, October 2, 2013, 8:30 a.m. to 3:30 p.m., Local Time.

ADDRESSES: This meeting will take place at NASA Headquarters, Room 9H40, 300 E Street SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Ann Delo, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0750, fax (202) 358–3092, or *ann.b.delo@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The meeting will also be available telephonically and by WebEx. Any interested person may call the USA toll free conference call number 800–857–7040, pass code PSS, to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/* the meeting number on October 1 is 997 670 187, password PSS@Oct1; the meeting number on October 2 is 990 912 672, password PSS@Oct2. The agenda for the meeting includes the following topics:

—Planetary Science Division Update
—Mars Exploration Program Update
—Government Performance and Results Act Presentation and Scoring
—Assessment Group Updates

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals

attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Ann Delo via email at *ann.b.delo@nasa.gov* or by fax at (202) 358–3092. U.S. citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation 3 working days prior to the meeting to Ann Delo.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2013–22219 Filed 9–11–13; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL LABOR RELATIONS BOARD

Notice of Sunshine Act Meetings: September 2013

TIME AND DATES: All meetings are held at 2:00 p.m.

Tuesday, September 10;
Wednesday, September 11;
Thursday, September 12;
Tuesday, September 17;
Wednesday, September 18;
Thursday, September 19;
Tuesday, September 24;
Wednesday, September 25;
Thursday, September 26.

PLACE: Board Agenda Room, No. 11820, 1099 14th St, NW., Washington, DC 20570.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Pursuant to § 102.139(a) of the Board's Rules and Regulations, the Board or a panel thereof will consider ''the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct, or disposition . . . of particular representation or unfair labor practice proceedings under section 8, 9, or 10 of the [National Labor Relations] Act, or any court proceedings collateral or ancillary thereto.'' See also 5 U.S.C. 552b(c)(10).

CONTACT PERSON FOR MORE INFORMATION: Henry Breiteneicher, Associate Executive Secretary, (202) 273–2917

Dated: September 10, 2013.

William B. Cowen,

Solicitor.

[FR Doc. 2013–22366 Filed 9–10–13; 4:15 pm]

BILLING CODE 7545–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by October 15, 2013. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Adrian Dahood, ACA Permit Officer, at the above address or *ACApermits@nsf.gov* or (703) 292–7149.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

1. Applicant

Permit Application: 2014–016
Zicheng Yu
Department of Earth and Environmental Science
Lehigh University
Bethlehem, PA

Activity for Which Permit Is Requested

ASPA Entry; The applicant requests access to ASPA 113 Litchfield Island to collect small samples of moss and peat and to deploy small data loggers and sensors for the duration of the permit . Litchfield Island has thriving and pristine peat moss bank communities. Samples could be gathered easily without significantly impacting the moss populations. All loggers and sensors would be removed before the permit expires. Data gathered from this research will advance the understanding of peat moss banks to climate change during the last 50–1000 years.

Location

ASPA 113 Litchfield Island.

Dates

November 1, 2013 to April 15, 2014.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2013–22194 Filed 9–11–13; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0206]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 314, Certificate of Disposition of Materials.

2. *Current OMB approval number:* 3150–0028.

3. *How often the collection is required:* This form is submitted once, when a licensee terminates its license.

4. *Who is required or asked to report:* Persons holding an NRC license for the

possession and use of radioactive byproduct, source, or special nuclear material who are ceasing licensed activities and terminating the license.

5. *The number of annual respondents:* 136.

6. *The number of hours needed annually to complete the requirement or request:* 68.

7. *Abstract:* The NRC Form 314 furnishes information to the NRC regarding transfer or other disposition of radioactive material by licensees who wish to terminate their licenses. The information is used by the NRC as part of the basis for its determination that the facility has been cleared of radioactive material before the facility is released for unrestricted use.

Submit, by November 12, 2013, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC's home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2013–0206. You may submit your comments by any of the following methods: Electronic comments go to: *http://www.regulations.gov* and search for Docket No. NRC–2013–0206. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 6th day of September 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–22109 Filed 9–11–13; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting Notice; Cancellation of September 11, 2013 Public Hearing

OPIC's Sunshine Act notice of its Public Hearing in Conjunction with each Board meeting was published in the **Federal Register** (Volume 78, Number 139, Pages 43244 and 43245) on July 19, 2013. No requests were received to provide testimony or submit written statements for the record; therefore, OPIC's public hearing scheduled for 2 p.m., September 11, 2013 in conjunction with OPIC's September 19, 2013 Board of Directors meeting has been cancelled.

CONTACT PERSON FOR INFORMATION: Information on the hearing cancellation may be obtained from Connie M. Downs at (202) 336–8438, or via email at *Connie.Downs@opic.gov.*

Dated: September 6, 2013.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2013–22287 Filed 9–10–13; 11:15 am]

BILLING CODE P

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 30, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 7 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2013–59, CP2013–80.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–22144 Filed 9–11–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 12, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 30, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 14 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2013–58, CP2013–79.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–22146 Filed 9–11–13; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70339; File No. SR–BX–2013–051]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Fees Assessed for Connectivity to the Exchange Under Rule 7015 and Amend the Fees Assessed and Credits Paid Under Exchange Rule 7018(a)

September 6, 2013.

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 August 28, 2013, NASDAQ OMX BX, Inc. (''BX'' or ''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 a rule change to amend fees assessed for connectivity to the Exchange under Rule 7015. The Exchange is also amending the fees assessed and credits paid under Exchange Rule 7018(a) for executing certain trades that either add liquidity to or remove liquidity from the Exchange's order book in securities priced at $1 per share or greater. The text of the proposed rule change is also available on the Exchange's Web site at *http://nasdaqomxbx.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to modify two sets of fees: (1) Connectivity fees assessed under Exchange Rule 7015, and (2) execution fees and credits assessed or granted under Exchange Rule 7018(a) with respect to securities priced at $1 per share or greater.

Connectivity Fees. The Exchange is proposing to increase the fee assessed for use of TCP ITCH data feed pairs to connect to the BX System. TCP ITCH data feed pairs are a type of port pair [3] that firms may subscribe to receive market data through a private (*i.e.,* not shared) connection to BX. By contrast, a firm may subscribe to a Multicast ITCH data feed pair,[4] which provides access to a shared distribution of market data that is distributed to all subscribers simultaneously. BX assesses a fee of $400 per month for each port pair used to connect to BX using protocols other than Multicast ITCH. Currently, subscription to a TCP ITCH data feed pair is covered by this fee. Unlike Multicast ITCH data, TCP ITCH data requires substantially greater hardware infrastructure to support subscribers because BX must support each individual TCP ITCH connection, including the transmission of the large volume of market data through each port. By contrast, BX transmits market data for Multicast ITCH through a single point, which is accessed by all subscribers. In light of increased costs resulting from a need to support the hardware and support demands of the service, the Exchange is proposing to increase the fees for subscription to a TCP ITCH data port from $400 per month, per port pair to $750 per month, per port pair.

BX is also proposing to increase the $400 monthly fee assessed under Rule 7015 for port pairs used to enter orders in Exchange trading systems to $500 per month. The change does not affect ports used to receive market data, to enter quotes, or to enter trade reports into the FINRA/NASDAQ Trade Reporting Facility. The change applies both to members that obtain ports for direct access, and non-member service bureaus that act as a conduit for orders entered by BX members that are their customers.

[3] BX uses the term ''data feed pair'' herein and in the rule as a more precise description of the intended use and functionality of the port pair.

[4] For a fee of $1,000 per month for software-based TotalView-ITCH or $2,500 per month for combined software- and hardware-based TotalView-ITCH.

BX notes that it has not increased the $400 fee since its adoption in January 2009.[5] When the Exchange initially adopted its fees, it set its fee levels appropriate to the start-up nature of the Exchange's new equities trading platform and in manner designed to attract order flow to the Exchange. Since that time, the BX has matured as a market, resulting in higher volumes. As a consequence, the Exchange has experienced greater hardware demands and costs associated with offering connectivity options. Accordingly, BX believes that an increase in access services fees is now warranted to help ensure that its market data technology continues to perform at a high level of responsiveness and efficiency.

Execution Fees and Credits. The Exchange proposes to amend four fees and credits governed by Rule 7018(a), which applies to securities priced at $1 per share or greater. The first three adjustments apply to credits the Exchange offers members for entering order that accesses liquidity in the NASDAQ OMX BX Equities System. The first applies to order entered by a member through a BX Equities System Market Participant Identifier (''MPID'') through which the member (i) accesses an average daily volume of 3.5 million or more shares of liquidity, or (ii) provides an average daily volume of 1 million or more shares of liquidity during the month (excluding an order that executes against a midpoint pegged order). Currently, the credit pays $0.0014 per share executed. BX is lowering that credit to $0.0013 per share executed.

The second adjustment applies to order entered by a member through a BX Equities System MPID through which the member provides an average daily volume of at least 25,000, but less than 1 million, shares of liquidity during the month (excluding an order that executes against a midpoint pegged order). Currently, the credit offered is $0.0010 per share executed, and BX proposes to increase that credit to $0.0011 per share executed.

The third adjustment is an increase from $0.0004 to $0.0007 in credit per share executed for all orders entered in securities priced at $1 per share or greater that accesses liquidity in the NASDAQ OMX BX Equities System. This increase is a ''catch-all'' that applies to all other orders that access liquidity in securities priced $1 per share or greater that are not specified elsewhere in Rule 7018(a) (*i.e.,* not in

[5] Securities Exchange Act Release No. 61595 (Feb. 2, 2009), 74 FR 6441 (Feb. 9, 2009) (SR–BX–2009–004).

the liquidity program described in the preceding two paragraphs, not midpoint peg orders, and not any of the multiple order types otherwise specified).

The fourth adjustment to the fee schedule for the BX Equities Market is an decrease from $0.0015 to $0.0014 per share executed in the charge for providing liquidity through the NASDAQ OMX BX Equities System for Displayed order entered by a Qualified Liquidity Provider through a Qualified MPID. The Exchange charges a reduced fee for members providing liquidity if they meet the criteria of a ''Qualified Liquidity Provider.'' These criteria (which BX is not modifying) include requirements that the member access and provide volumes of liquidity in excess of certain levels, expressed as a percentage of Consolidated Volume.[6] BX is now proposing to further reduce the fee changed under that program from $0.0015 to $0.0014 per share executed.

2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and Section 6(b)(4) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that the Exchange operates or controls, and it does not unfairly discriminate between customers, issuers, brokers or dealers.

The proposed connectivity fee increases are reasonable because they reflect the increased costs associated with offering connectivity options on BX. The proposed fees are equitable and not unfairly discriminatory because the Exchange is assessing the fees equally among subscribers to the service. Moreover, the proposed fees are not unfairly discriminatory as it enables the Exchange to allocate the increased costs of connectivity to the Exchange to those who subscribe to the service. The Exchange believes that the increased fees will enable it to cover its costs and earn an appropriate return on its investment in market technology and services.

With respect to execution fees under Exchange Rule 7018(a), the Exchange believes that the minor fee modifications provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which BX operates or controls, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, with respect to the credits offered for orders executed that access liquidity on BX in securities priced at $1 or greater, the Exchange notes that decreasing the credit paid to members qualifying for the highest volume tier and increasing the credit for members qualifying for the lower tier or for no tier (as is the case with the ''catch-all'' rate), will encourage more members to access liquidity from BX. BX expects that small and medium-sized member firms will benefit most from the proposed changes. Additionally, by increasing the overall quantities of executed orders that access liquidity, as BX believes will occur, BX expects to also increase total liquidity available on its market, increase total order interaction on its order book, and improve overall execution quality for all members.

With respect to the decrease from $0.0015 to $0.0014 per share executed in the charge for providing liquidity through the NASDAQ OMX BX Equities System for Displayed order entered by a Qualified Liquidity Provider through a Qualified MPID, the Exchange believes that the proposed modification provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which BX operates or controls, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, the Exchange first notes the proposed changes do not modify the requirements with respect to the current $0.0015 per share executed rate for Displayed orders that provide liquidity. The current Liquidity Provider program has itself been accepted as consistent with the Exchange Act.

Additionally, the decrease in the applicable rate for such Displayed orders is reasonable because it will further encourage members to qualify for the program, and increase the total volume of orders displayed on the Exchange. Increased display of liquidity on the Exchange will benefit all members, as described above. Moreover, the Exchange continues to offer an even more favorable charge to members using midpoint pegged orders, which may be used by all members, regardless of volume.

The proposed fee reduction is consistent with an equitable allocation of fees because it is consistent with the established practice at a number of national securities exchanges of providing more favorable fee economics to members that contribute to market quality and the Exchange's market share by achieving certain volume requirements. A member that provides and displays a comparatively large volume of liquidity is demonstrating its commitment to the viability of BX's market model by posting orders at prices that attract members seeking liquidity. Accordingly, BX believes that it is equitable for the fees charged to such a member to be more favorable than the fees charged to members providing lower volumes of liquidity. The Exchange further believes that the change is not unfairly discriminatory because the associated volume requirements are not very high and because the Exchange provides an alternative means of paying a lower fee for orders that provide liquidity.

The Exchange notes that it operates in a highly competitive market, in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. Accordingly, if the Exchange's proposed fee is deemed excessive, a market participant currently subscribed to the data service may elect to cancel its subscription and either subscribe to another connectivity option or route its order flow to another competitor exchange with lower fees.

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. BX notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, BX must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, BX believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the increased subscription fee is reflective of the increased costs associated with offering the associated connectivity options. As

[6] ''Consolidated Volume'' is the consolidated volume of shares reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month.

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

such, the fees are targeted to apply to only those that subscribe to, and derive benefit from, subscription to the connectivity options. In terms of TCP ITCH data feed fee, the Exchange will continue to offer other data connectivity options and firms may seek out third party providers of such data as well, should the firms determine that the cost of subscribing to the TCP ITCH data feed is excessive.

With respect to the execution fees and credits, the minor modifications described herein are a direct response to competition, which should be viewed as a positive signal that a competitive market exists. If the changes are unattractive to market participants, it is likely that BX will lose market share as a result. Accordingly, BX does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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 foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act.

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–BX–2013–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–BX–2013–051.* 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 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–BX–2013–051* and should be submitted on or before October 3, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M O'Neill,

Deputy Secretary.

[FR Doc. 2013–22165 Filed 9–11–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70345; File No. SR–FINRA–2013–029]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Granting Approval of Proposed Rule Change Relating to the Dissemination of Transactions in TRACE-Eligible Securities That Are Effected Pursuant to Securities Act Rule 144A

September 6, 2013.

I. *Introduction*

On July 17, 2013, the Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 relating to dissemination of transactions in TRACE-Eligible Securities [3] that are effected pursuant to Rule 144A [4] under the Securities Act of 1933 (''Securities Act'').[5] The proposed rule change was published for comment in the **Federal Register** on July 25, 2013.[6] The Commission received two comments on the proposal.[7] This order approves the proposed rule change.

II. Description of the Proposal

Historically, FINRA has utilized the Trade Reporting and Compliance Engine (''TRACE'') to collect from its members and publicly disseminate information on secondary over-the-counter transactions in corporate debt securities and Agency Debt Securities [8] and certain primary market transactions. For certain other asset types, FINRA has utilized TRACE to collect transaction information but has not reported such information publicly.[9] Information

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''TRACE-Eligible Security'' is defined in FINRA Rule 6710(a).

[4] 17 CFR 230.144A.

[5] 15 U.S.C. 77a *et seq.*

[6] *See* Securities Exchange Act Release No. 70009 (July 19, 2013), 78 FR 44997 (''Notice'').

[7] *See* letters to Elizabeth M. Murphy, Secretary, Commission, from: Dorothy Donohue, Deputy General Counsel—Securities Regulation, Investment Company Institute, dated August 15, 2013 (''ICI Letter''); and Ari Gabinet, Executive Vice President and General Counsel, OFI Global Asset Management, dated August 15, 2013 (''OFI Letter'').

[8] The term ''Agency Debt Security'' is defined in FINRA Rule 6710(*l*).

[9] Recently, however, FINRA has expanded TRACE's functionality to include public dissemination of transaction information for certain Asset-Backed Securities, which information FINRA

Continued

regarding transactions in TRACE-Eligible Securities that are effected pursuant to Rule 144A under the Securities Act (''Rule 144A transactions'') falls into this category, as it is currently collected through TRACE but not disseminated publicly.

As FINRA notes, Section 201 of the Jumpstart Our Business Startups Act (the ''JOBS Act'') [10] directed the Commission to eliminate the long-standing prohibition against general solicitation and general advertising in offerings of securities pursuant to Securities Act Rule 144A and in certain other private placements.[11] According to FINRA, up to this point Rule 144A transactions reported to TRACE have not been disseminated in part to avoid concerns about soliciting persons other than qualified institutional buyers (''QIBs'') for such transactions.[12] As a result, price information regarding Rule 144A transactions has been limited, which has made it difficult for market participants to assess the quality of executions of Rule 144A securities or to compare them to executions of similar publicly traded securities of the same issuer or similarly-rated issuers.

FINRA now has proposed to provide for public dissemination of Rule 144A transactions and to make certain related changes to its rules, as described below.

Dissemination of Rule 144A Transaction Information

Currently, FINRA Rule 6750(b)(1) states that FINRA will not disseminate information on a transaction in a TRACE-Eligible Security that is effected pursuant to Rule 144A. FINRA has proposed to remove that language from FINRA Rule 6750(b)(1) and amend FINRA Rule 6750(a) to include Rule 144A transactions among the transactions for which FINRA disseminates information immediately upon receipt of the transaction report, provided that the asset type involved in the Rule 144A transaction is currently subject to dissemination under FINRA Rule 6750.[13] Consequently, only Rule 144A transactions in corporate bonds will be newly disseminated as a result of the proposed rule change. The proposed rule change will not otherwise expand TRACE dissemination at this time.[14]

Dissemination Caps

Currently, there are dissemination caps in place for disseminated TRACE data, such that the actual size of a transaction over a certain par value is not displayed. FINRA has proposed that Rule 144A transactions be disseminated subject to the same dissemination caps that are currently in effect for a non-Rule 144A transaction in the applicable security.[15] Accordingly, the dissemination caps currently in effect for non-Rule 144A corporate bond transactions—$5 million (''$5MM'') for Investment Grade corporate bonds and $1 million (''$1MM'') for Non-Investment Grade corporate bonds [16]—would apply to the Rule 144A corporate bond transactions disseminated as result of this proposal. As a result, the size of a Rule 144A Investment Grade corporate bond transaction in excess of $5MM would be displayed as ''$5MM+'' and the size of a Rule 144A Non-Investment Grade corporate bond transaction in excess of $1MM would be displayed as ''$1MM+.''

Market Data

FINRA has proposed to amend Rule 7730(c) to establish a real-time market data set for Rule 144A transactions (''Rule 144A Data Set'')—similar to the data sets for corporate bonds, Agency Debt Securities, and Asset-Backed Securities—which would consist of information disseminated immediately upon receipt of a transaction report for a Rule 144A transaction. FINRA also has proposed to amend Rule 7730(d) to establish a historic data set for Rule 144A transactions (''Historic Rule 144A Data Set''), also similar to the existing historic data sets for corporate bonds, Agency Debt Securities, and Asset-Backed Securities.[17]

Relatedly, FINRA would amend the definition of ''Historic TRACE Data'' in Rule 7730(f)(4) to reference the three existing data sets and the proposed Historic Rule 144A Data Set and to clarify that the Historic Rule 144A Data Set would include all historic Rule 144A transactions reported to TRACE, except transactions involving a type of TRACE-Eligible Security that is not subject to real-time dissemination under FINRA Rule 6750. FINRA would further amend Rule 7730(f)(4) to define the existing historic data sets for corporate bonds, Agency Debt Securities, and Asset-Backed Securities, and to clarify, as applicable, that they do not contain historic Rule 144A transactions.

In addition, FINRA has proposed minor revisions to the TRACE fee table in the beginning of Rule 7730, and also to Rules 7730(c) and 7730(d), to clarify that the fees set forth therein apply only to the existing real-time and historic data sets for corporate bonds, Agency Debt Securities, and Asset-Backed Securities. FINRA has stated that it plans to file a separate proposal to address market data fees for the Rule 144A Data Set and the Historic Rule 144A Data Set.[18] FINRA also has proposed to make a minor, technical revision to Rule 7730(d) to clarify that the 2012 Historic ABS Data Set includes the 2011 Historic ABS Data Set.

Effective Date of Proposed Rule Change

FINRA has stated that it would announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval, and that the effective date be no later than 270 days following publication of that *Regulatory Notice.*

III. Comment Summary

The Commission received two comment letters on the proposal.[19] Both commenters supported the proposal. One commenter stated that ''[t]he Rule 144A market has, over time, become a more mature and liquid market with no corresponding enhancement in its transparency,'' and that requiring information regarding Rule 144A transactions to be disseminated to the same extent as comparable non-Rule 144A transactions ''will provide enhanced transparency in a manner that addresses the potential negative impact

previously collected but did not disseminate. *See* Securities Exchange Act Release No. 61566 (February 22, 2010), 75 FR 9262 (March 1, 2010) (approving SR–FINRA–2009–065); *see also* Securities Exchange Act Release No. 66829 (April 18, 2012), 77 FR 24748 (April 25, 2012) (approving SR–FINRA–2012–020); Securities Exchange Act Release No. 68084 (October 23, 2012), 77 FR 65436 (October 26, 2012) (approving SR–FINRA–2012–042). The term ''Asset-Backed Security'' is defined in FINRA Rule 6710(m).

[10] Public Law 112–106, 126 Stat. 306.

[11] *See* Notice, 78 FR at 44998.

[12] *See id.*

[13] Equity securities transactions effected pursuant to Rule 144A are not reported to TRACE and are not the subject of FINRA's proposal.

[14] *See* Notice, 78 FR at 44999 n.24. As mentioned above, transactions in Agency Debt Securities and certain Asset-Backed Securities are currently disseminated. But there would be no additional transactions in such securities disseminated as a result of the proposal because Rule 144A is not used to effect transactions in such securities. There are also certain Asset-Backed Security transactions that are not currently subject to dissemination, which would preclude them from dissemination under the proposal at this time.

[15] *See* Notice, 78 FR at 44999.

[16] The terms ''Investment Grade'' and ''Non-Investment Grade'' are defined in FINRA Rules 6710(h) and 6710(i), respectively.

[17] The Historic Rule 144A Data Set would include Rule 144A transactions in securities subject to dissemination, effected as of or after July 1, 2002, and, among other things, would include uncapped volume information. However, like all other Historic TRACE Data, Rule 144A transaction data included in the Historic Rule 144A Data Set would be released subject to a delay of approximately 18 months from the date of the transaction. *See* Notice, 78 FR at 44999.

[18] *See* Notice, 78 FR at 45000 n.29.

[19] *See supra* note 7.

that such dissemination could have on liquidity.'' [20] The other commenter asserted that dissemination of Rule 144A transactions would be in keeping with TRACE's goal of improving transparency in the corporate debt market.[21] This commenter also stated that the proposed rule change would enhance pre-trade price discovery, foster more competitive pricing within the Rule 144A market, and significantly improve the ability of market participants to conduct analyses of Rule 144A transactions and assess the quality of their executions.[22]

IV. 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 association.[23] In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act,[24] which requires, among other things, that FINRA's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission notes that the only two entities that submitted comments supported the proposal.

In approving the original TRACE rules, the Commission stated that price transparency plays a fundamental role in promoting the fairness and efficiency of U.S. capital markets.[25] To further the goal of increasing price transparency in the debt markets in general and the market for Rule 144A securities in particular, the Commission now believes that it is reasonable and consistent with the Act for FINRA to extend post-trade price transparency to Rule 144A transactions. Real-time dissemination of last-sale information could aid dealers in deriving better quotations, because they would know the prices at which other market participants had recently transacted in the same or similar instruments. This information could aid all market participants in evaluating current quotations, because they could inquire why dealer quotations might differ from the prices of recently executed transactions. Furthermore, post-trade transparency affords market participants a means of testing whether dealer quotations before the last sale were close to the price at which the last sale was executed. In this manner, post-trade transparency can promote price competition between dealers and more efficient price discovery, and ultimately lower transaction costs in the market for Rule 144A securities.

Although the market for Rule 144A securities remains restricted to QIBs, the Commission believes that non-QIB market participants could still benefit from post-trade transparency in the Rule 144A market. Certain Rule 144A securities are issued by the same entity as, or are otherwise similar to, corporate debt securities not issued pursuant to Rule 144A, which securities may be purchased and sold by non-QIBs. Some academic research suggests that post-trade transparency in one market can have ''spillover benefits'' in a related market.[26]

In addition, the Commission believes that the proposed dissemination caps are reasonable and consistent with the Act. The caps to be employed for Rule 144A debt securities will be the same as those for other corporate debt securities, which were previously approved by the Commission.[27] The Commission notes that, in its Regulatory Notice 12–39, FINRA requested comment on the existing dissemination caps for transactions in corporate bonds, Agency Debt Securities, and Asset-Backed Securities, although FINRA determined not to propose changes to any of the current dissemination caps at this time. The Commission expects FINRA to periodically re-evaluate whether the dissemination caps, including the caps for Rule 144A transactions being approved today, continue to be appropriate.

The Commission further believes that establishing real-time and historic market data products for Rule 144A securities in the manner described in the proposal is reasonable and consistent with the Act. The new data sets are similar to the data sets for corporate bonds, Agency Debt Securities, and Asset-Backed Securities, which products have previously been approved by the Commission.[28] The Commission notes FINRA's representation that it will submit a separate rule filing to address the market data fees for the Rule 144A Data Set and the Historic Rule 144A Data Set. Finally, the Commission believes that the minor revisions to certain of FINRA's market data rules are consistent with the Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[29] that the proposed rule change (SR–FINRA–2013–029) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–22167 Filed 9–11–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70335; File No. SR–ISE–2013–47]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to $0.50 and $1 Strike Price Intervals for Classes in the Short Term Option Series Program

September 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

[20] ICI Letter at 2.

[21] *See* OFI Letter at 2.

[22] *See id.*

[23] 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).

[24] 15 U.S.C. 78*o*-3(b)(6).

[25] *See* Securities Exchange Act Release No. 43873 (January 23, 2001), 66 FR 8131, 8136 (January 29, 2001) (approving SR–NASD–99–65) (''2001 TRACE Order'').

[26] *See* Henrik Bessembinder, William Maxwell, and Kumar Venkataraman, ''Market Transparency, Liquidity Externalities, and Institutional Trading Costs in Corporate Bonds'' (2005), available at *http://home.business.utah.edu/hank.bessembinder/publications/bondtransparency.pdf* (presenting a model implying and finding empirical evidence in TRACE data for what the authors term a ''liquidity externality,'' *i.e.,* improved market quality in certain securities that were not yet TRACE-eligible, when related securities had become subject to TRACE post-trade transparency).

[27] *See* 2001 TRACE Order, 66 FR at 8132.

[28] *See id.* (approving real-time dissemination of reported corporate bond transactions as part of approval of original TRACE rules); *see also* Securities Exchange Act Release No. 60726 (September 28, 2009), 74 FR 50991 (October 2, 2009) (approving SR–FINRA–2009–010, which expanded TRACE to include real-time dissemination of Agency-Debt Security transactions and most primary market transactions, and to create separate corporate bond and Agency-Debt Security market data sets); Securities Exchange Act Release No. 61012 (November 16, 2009), 74 FR 61189 (November 23, 2009) (approving SR–FINRA–2007–006, which established the historic TRACE market data sets for corporate bond and Agency-Debt Security transactions); Securities Exchange Act Release No. 66829 (April 18, 2012), 77 FR 24748 (April 25, 2012) (approving SR–FINRA–2012–020, which established real-time and historic market data sets for certain Asset-Backed Securities traded ''To Be Announced''); Securities Exchange Act Release No. 68084 (October 23, 2012), 77 FR 65436 (October 26, 2012) (approving SR–FINRA–2012–042, which established real-time and historic market data sets for certain other Asset-Backed Securities).

[29] 15 U.S.C. 78s(b)(2).

[30] 17 CFR 200.30–3(a)(12).

(''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on August 28, 2013, International Securities Exchange, LLC (the ''Exchange'' or ''ISE'') filed with the Securities and Exchange Commission (''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 give the Exchange the ability to initiate strike prices in more granular intervals for Short Term Options (''STOs'') in the same manner as on other options exchanges.

The text of the proposed rule change is available on the Exchange's Internet Web site at *http://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 self-regulatory organization 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

The Commission recently approved the Exchange's proposal regarding strike price intervals for certain STOs, permitting ISE to list $0.50 strike price intervals for STOs for options classes that trade in one dollar increments and are in the Short Term Option Series Program (''STOS Program''),[3] and simultaneously approved a NASDAQ OMX PHLX, LLC (''PHLX'') filing regarding $0.50 and $1 strike price intervals for certain STOs that used a different methodology than ISE for STO pricing.[4] Subsequent to the approval of these two competing methodologies, the Chicago Board Options Exchange, Inc. (''CBOE''), PHLX, NYSE Arca, Inc. (''Arca''), NYSE MKT LLC (''MKT''), and MIAX Options Exchange (''MIAX'') filed immediately effective rule changes that integrated the two prior methodologies for establishing strike price intervals for STOs.[5] In order to remain competitive, the Exchange is now proposing to adopt a consolidated methodology for STO strike price intervals as currently employed by these other options exchanges.

The STOS Program is codified in ISE Rules 504 and 2009. These rules state that after an option class has been approved for listing and trading on the Exchange, the Exchange may open for trading on any Thursday or Friday that is a business day, series of options on no more than thirty option classes that expire on each of the next five consecutive Fridays that are business days. In addition to the thirty option class limitation, there is also a limitation that no more than twenty series for each expiration date in those classes may be opened for trading.[6] Furthermore, the strike price of each STO series has to be fixed with approximately the same number of strike prices being opened above and below the value of the underlying security at about the time that the STOs are initially opened for trading on the Exchange, and with strike prices being within thirty percent (30%) above or below the closing price of the underlying security from the preceding day. The Exchange does not propose any changes to the current program limitations. The Exchange only proposes to amend Supplementary Material .12 to ISE Rule 504 (Series of Options Contracts Open for Trading) and Supplementary Material .05 to ISE Rule 2009 (Terms of Index Options Contracts) to specify that the strike price interval for STOs may be $0.50 or greater where the strike price is less than $75, and $1 or greater where the strike price is between $75 and $150. Like the other options exchanges, ISE rules will also continue to permit strike price intervals of $0.50 for option classes that trade in one dollar increments and are in the STOS Program.

The Exchange notes that while it believes that there is substantial overlap between the two strike price interval setting parameters, the Exchange believes there are gaps that would enable one of the options exchanges listed above to initiate a series that ISE would not be able to initiate.[7] Since strict inter-exchange rule uniformity is not required for the STOS Programs that have been adopted by the various options exchanges, the Exchange proposes to revise its strike price intervals setting parameters so that it has the ability to initiate strike prices in the same manner (i.e., intervals) as CBOE, PHLX, Arca, MKT, and MIAX. Accordingly, the Exchange proposes to adopt rule text language substantially similar in all material respects to that adopted by the other exchanges, and in this way consolidate the two different approaches regarding strike price intervals for STOs.

The principal reason for the proposed expansion is in response to market and customer demand to list actively traded products in more granular strike price intervals, and to provide Exchange members and their customers increased trading opportunities in the STOS Program, which is one of the most popular and quickly-expanding options

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67754 (August 29, 2012), 77 FR 54629 (September 5, 2012) (SR–ISE–2012–33).

[4] *See* Securities Exchange Act Release No. 67753 (August 29, 2012) 77 FR 54635 (September 5, 2012) (SR–Phlx–2012–78).

[5] *See* Securities Exchange Act Release Nos. 68074 (October 19, 2012), 77 FR 65241 (October 25, 2012) (SR–CBOE–2012–92); 69633 (May 23, 2013), 78 FR 32498 (May 30, 2013) (SR–Phlx–2013–55); 68194 (November 8, 2012), 77 FR 68172 (November 15, 2012) (SR–NYSEArca–2012–114); 68193 (November 8, 2012), 77 FR 68177 (November 15, 2012) (NYSEMKT–2012–53); 69809 (June 20, 2013), 78 FR 38416 (June 26, 2013) (SR–MIAX–2013–30).

[6] However, if the Exchange opens less than twenty (20) short term options for a Short Term Option Expiration Date, additional series may be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. Any additional strike prices listed by the Exchange shall be within thirty percent (30%) above or below the current price of the underlying security. The Exchange may also open additional strike prices of STO series that are more than 30% above or below the current price of the underlying security provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate or individual customers or their brokers (market-makers trading for their own account shall not be considered when determining customer interest under this provision). Supplementary Material .02(d) to Rule 504 and Supplementary Material .01(d) to Rule 2009.

[7] The Exchange is making a distinction between initiating series and cloning series. The Exchange and the majority, if not all, of the other options exchanges that have adopted a STOS Program have a rule similar to the Exchange's that permits the listing of series that are opened by other exchanges. *See* Supplementary Material .02 to Rule 504 and Supplementary Material .01 to Rule 2009. This filing is concerned with the ability to initiate series. If a class is selected to participate in the STOS Program but does not trade in dollar increments, the Exchange would not be permitted to initiate $0.50 strikes on that class even though other options exchanges may be permitted to do so based on the strike price.

expiration programs. The Exchange has observed increased demand for STO classes and/or series, particularly when market moving events such as significant market volatility, corporate events, or large market, sector, or individual issue price swings have occurred. There are substantial benefits to market participants in the ability to trade eligible option classes at more granular strike price intervals. The Exchange notes that the STOS Program has been well-received by market participants, in particular by retail investors. The Exchange believes that the current proposed revisions to the STOS Program will permit the Exchange to meet increased customer demand for more granular strike prices.

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle any potential additional traffic associated with this current amendment to the STOS Program. The Exchange believes that its members will not have a capacity issue as a result of this proposal. The Exchange represents that it will monitor the trading volume associated with the additional options series listed as a result of this proposal and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder, including the requirements of Section 6(b) of the Act.[8] In particular, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that giving it the ability to initiate strike prices in $0.50 and $1 intervals for STO options, as provided for in the proposed rule text, is reasonable because it will benefit investors by providing them with the flexibility to more closely tailor their investment and hedging decisions. While the proposed rule change may generate additional quote traffic, the Exchange does not believe that any increased traffic will become unmanageable since the proposal remains limited to a fixed number of classes. The Exchange also believes that the proposed rule change will ensure competition because it will allow the Exchange to initiate series in the same strike intervals as other options exchanges, including CBOE, PHLX, Arca, MKT, and MIAX.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. To the contrary, the Exchange believes the proposal is pro-competitive. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to immediately effective filings recently submitted by CBOE, PHLX, Arca, MKT, and MIAX.[sic] ISE believes this proposed rule change is necessary to permit fair competition among the options exchanges with respect to STOS Programs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest in that it will allow ISE to offer additional STO products to traders and investors in the same manner as other exchanges.[12] In sum, the proposed rule change presents no novel issues, and waiver will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission designates the proposal operative upon filing.[13]

At any time within 60 days of the filing of the 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)[14] 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:

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–ISE–2013–47 on the subject line.

Paper comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2013–47. 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

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 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 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 requirement.

[12] *See supra,* note 5.

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

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 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–ISE–2013–47 and should be submitted on or before October 3, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–22163 Filed 9–11–13; 8:45 am]

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[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70342; File No. SR–NYSEArca-2013–71]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change to List and Trade Shares of the SPDR SSgA Ultra Short Term Bond ETF; SPDR SSgA Conservative Ultra Short Term Bond ETF; and SPDR SSgA Aggressive Ultra Short Term Bond ETF under NYSE Arca Equities Rule 8.600

September 6, 2013.

I. Introduction

On July 9, 2013, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the SPDR SSgA Ultra Short Term Bond ETF; SPDR SSgA Conservative Ultra Short Term Bond ETF; and SPDR SSgA Aggressive Ultra Short Term Bond ETF (each a ''Fund'' and collectively, ''Funds'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published for comment in the **Federal Register** on July 24, 2013.[3] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to list and trade Shares of the Funds under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by SSgA Active ETF Trust (''Trust''), which is organized as a Massachusetts business trust and is registered with the Commission as an open-end management investment company.[4] The investment adviser to the Funds will be SSgA Funds Management, Inc. (''Adviser''). State Street Global Markets, LLC (''Distributor'') will be the principal underwriter and distributor of the Funds' Shares. State Street Bank and Trust Company (''Administrator,'' ''Custodian,'' or ''Transfer Agent'') will serve as administrator, custodian, and transfer agent for the Funds.

The Exchange states that the Adviser is not a broker-dealer but is affiliated with a broker-dealer and has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition of and changes to the Funds' portfolio.[5]

SPDR SSgA Ultra Short Term Bond ETF

The SPDR SSgA Ultra Short Term Bond ETF will seek to provide current income consistent with preservation of capital and daily liquidity through short duration high quality investments. Under normal circumstances,[6] the Fund will invest all of its assets in the SSgA Ultra Short Term Bond Portfolio (''Bond Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Bond Portfolio.

The Adviser will invest, under normal circumstances, at least 80% of the Bond Portfolio's net assets (plus the amount of borrowings for investment purposes) in a diversified portfolio of U.S. dollar-denominated investment grade fixed income securities. The Bond Portfolio primarily will invest in investment grade fixed income securities that are rated a minimum of the lowest A rating by any Nationally Recognized Statistical Ratings Organization (''NRSRO''), or, if unrated, determined by the management team (who are employees of the Adviser) to be of equivalent quality.[7] The Bond Portfolio will invest in fixed and floating rate securities of varying maturities,[8] such as corporate obligations (including commercial paper of U.S. and foreign entities, master demand notes (subject to the 15% illiquid securities limit), and medium term notes); government bonds (including U.S. Treasury Bills, notes, and bonds); agency securities, including U.S. government agency securities, and non-U.S. sovereign and supranational debt; privately-issued securities (which,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 70005 (July 18, 2013), 78 FR 44609 (''Notice'').

[4] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On August 2, 2012, the Trust filed with the Commission an amendment to its registration statement on Form N–1A under the Securities Act of 1933 (''Securities Act'') and the 1940 Act relating to the Funds (File Nos. 333–173276 and 811–22542) (''Registration Statement''). The Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 29524 (December 13, 2010) (File No. 812–13487) (''Exemptive Order'').

[5] *See* NYSE Arca Equities Rule 8.600, Commentary .06. In the event (a) the Adviser or any sub-adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition of and changes to a portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[6] The term ''under normal circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[7] According to the Adviser, the Adviser may determine that unrated securities are of ''equivalent quality'' based on such credit quality factors that it deems appropriate, which may include, among other things, performing an analysis similar, to the extent possible, to that performed by an NRSRO when rating similar securities and issuers. In making such a determination, the Adviser may consider internal analyses and risk ratings, third party research and analysis, and other sources of information, as deemed appropriate by the Adviser.

[8] A floating rate security provides for the automatic adjustment of its interest rate whenever a specified interest rate changes. Interest rates on these securities are ordinarily tied to, and are a percentage of, a widely recognized interest rate, such as the yield on 90-day U.S. Treasury bills or the prime rate of a specified bank. These rates may change as often as twice daily.

for example, can be Rule 144A securities); asset-backed and mortgage-backed securities; and money market instruments (including U.S. and foreign bank time deposits, certificates of deposit, and banker's acceptances). Under normal circumstances, the effective duration of the Bond Portfolio is expected to be between three and nine months. [9] In addition, the Bond Portfolio expects to maintain a weighted average maturity between six and eighteen months.[10] For the purposes of determining the Bond Portfolio's weighted average maturity, a security's final maturity date or, for amortizing securities such as asset-backed and mortgage-backed securities, its weighted average life will be used for calculation purposes.

SPDR SSgA Conservative Ultra Short Term Bond ETF

The SPDR SSgA Conservative Ultra Short Term Bond ETF will seek to provide current income consistent with preservation of capital and daily liquidity through short duration high quality investments with the avoidance of excessive portfolio volatility.

Under normal circumstances, the Fund will invest all of its assets in the SSgA Conservative Ultra Short Term Bond Portfolio (''Conservative Portfolio''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Conservative Portfolio.

The Adviser will invest, under normal circumstances, at least 80% of the Conservative Portfolio's net assets (plus the amount of borrowings for investment purposes) in a diversified portfolio of U.S. dollar-denominated investment grade fixed income securities. The Conservative Portfolio primarily will invest in investment grade fixed income securities that are rated a minimum of the lowest A rating by any NRSRO, or, if unrated, determined by the portfolio management team (who are employees of the Adviser) to be of equivalent quality, determined as described above.[11] The Conservative Portfolio will invest in fixed and floating rate securities of varying maturities, such as corporate obligations (including commercial paper of U.S. and foreign entities, master demand notes (subject to the 15% illiquid securities limit), and medium term notes); government bonds (including U.S. Treasury Bills, notes, and bonds); agency securities; privately-issued securities (which, for example, can be Rule 144A securities); asset-backed and mortgage-backed securities; and money market instruments (including U.S. and foreign bank time deposits, certificates of deposit, and banker's acceptances).

Under normal circumstances, the effective duration of the Conservative Portfolio is expected to be four months or less. In addition, the Conservative Portfolio expects to maintain a weighted average maturity between six and eighteen months. For the purposes of determining the Conservative Portfolio's weighted average maturity, a security's final maturity date or, for amortizing securities such as asset-backed and mortgage-backed securities, its weighted average life will be used for calculation purposes.

SPDR SSgA Aggressive Ultra Short Term Bond ETF

The SPDR SSgA Aggressive Ultra Short Term Bond ETF will seek to maximize income consistent with preservation of capital through short duration high quality investments.

Under normal circumstances, the Fund will invest all of its assets in the SSgA Aggressive Ultra Short Term Bond Portfolio (''Aggressive Portfolio'' and, together with the Bond Portfolio and the Conservative Portfolio, collectively, ''Portfolios''), a separate series of the SSgA Master Trust with an identical investment objective as the Fund. As a result, the Fund will invest indirectly through the Aggressive Portfolio.

The Adviser will invest, under normal circumstances, at least 80% of the Aggressive Portfolio's net assets (plus the amount of borrowings for investment purposes) in a diversified portfolio of U.S. dollar-denominated investment grade fixed income securities. The Aggressive Portfolio primarily will invest in investment grade fixed income securities that are rated a minimum of the lowest BBB rating by any NRSRO or, if unrated, determined by the portfolio management team (who are employees of the Adviser) to be of equivalent quality, determined as described above.[12]

The Aggressive Portfolio will invest in fixed and floating rate securities of varying maturities, such as corporate obligations (including commercial paper of U.S. and foreign entities, master demand notes (subject to the 15% illiquid securities limit), and medium term notes); government bonds (including U.S. Treasury Bills, notes, and bonds); agency securities; privately-issued securities (which, for example, can be Rule 144A securities); asset-backed and mortgage-backed securities; and money market instruments (including U.S. and foreign bank time deposits, certificates of deposit, and banker's acceptances).

Under normal circumstances, the effective duration of the Aggressive Portfolio is expected to be between six and twelve months. In addition, the Aggressive Portfolio expects to maintain a weighted average maturity between 1.5 and 2.5 years. For the purposes of determining the Aggressive Portfolio's weighted average maturity, a security's final maturity date or, for amortizing securities such as asset-backed and mortgage-backed securities, its weighted average life will be used for calculation purposes.

Principal Investments

Each Portfolio will invest in bonds, including zero coupon bonds,[13] fixed rate bonds,[14] and ''floating-rate'' or ''variable-rate'' bonds.[15] In addition, each Portfolio may invest in U.S. and non-U.S. corporate bonds, which will be denominated in U.S. dollars.

Each Portfolio may invest in collateralized loan obligations (''CLOs'') to the extent they meet the minimum NRSRO rating requirement described

[9] Effective duration is a measure of the Bond Portfolio's price sensitivity to changes in yields or interest rates. Duration will be a distinguishing factor among the Funds, and each of the Funds' respective portfolios will have different effective durations, as described below.

[10] Weighted average maturity is a U.S. dollar-weighted average of the remaining term to maturity of the underlying securities in the Bond Portfolio.

[11] *See* note 7, *supra.*

[12] *See* note 7, *supra.*

[13] A zero coupon bond pays no interest to its holder during its life. The value of a zero coupon bond to a fund consists of the difference between such bond's face value at the time of maturity and the price for which it was acquired, which may be an amount significantly less than its face value (sometimes referred to as a ''deep discount'' price).

[14] The value of a fixed rate bond usually rises when market interest rates fall, and falls when market interest rates rise. Accordingly, a fixed rate bond's yield (income as a percent of the bond's current value) may differ from its coupon rate as its value rises or falls. Fixed rate bonds generally are also subject to inflation risk, which is the risk that the value of the bond or income from the bond will be worth less in the future as inflation decreases the value of money. This could mean that, as inflation increases, the ''real'' value of the assets of a fund holding fixed rate bonds can decline, as can the value of the fund's distributions.

[15] Variable rate securities are instruments issued or guaranteed by entities such as (1) the U.S. Government, or an agency or instrumentality thereof, (2) corporations, (3) financial institutions, (4) insurance companies or (5) trusts that have a rate of interest subject to adjustment at regular intervals but less frequently than annually. A variable rate security provides for the automatic establishment of a new interest rate on set dates. Variable rate obligations whose interest is readjusted no less frequently than annually will be deemed to have a maturity equal to the period remaining until the next readjustment of the interest rate.

above for each Portfolio. While the assets underlying CLOs are typically ''Senior Loans,''[16] the assets may also include (i) unsecured loans, (ii) other debt securities that are rated below investment grade, (iii) debt tranches of other CLOs,[17] and (iv) equity securities incidental to investments in Senior Loans.

Each Portfolio may invest in sovereign debt, which will be denominated in U.S. dollars, and in U.S. Government obligations. U.S. Government obligations include securities issued or guaranteed as to principal and interest by the U.S. Government or its agencies or instrumentalities.[18] The Portfolios may invest in asset-backed and commercial mortgaged-backed securities.[19] The percentage limitation of investments in asset backed and commercial mortgage-backed securities for the Bond Portfolio, the Conservative Portfolio, and the Aggressive Portfolio will be 50%, 35%, and 65%, respectively. The percentage limitation of an investment in each single structured collateral type of asset backed and commercial mortgage-backed securities for the Bond Portfolio, the Conservative Portfolio, and the Aggressive Portfolio will be 15%, 20%, and 25%, respectively. Non-agency residential mortgage-backed and commercial mortgage-backed investments each will be limited to 10% for each of the Portfolios.

Each Portfolio may invest a substantial portion of its assets in U.S. agency mortgage pass-through securities. Each Portfolio may invest in restricted securities.[20] Each Portfolio may invest in short-term instruments, including money market instruments, repurchase agreements, cash, and cash equivalents, on an ongoing basis to provide liquidity or for other reasons. Money market instruments are generally short-term investments that may include but are not limited to: (i) shares of money market funds (including those advised by the Adviser); (ii) obligations issued or guaranteed by the U.S. government or its agencies or instrumentalities (including government-sponsored enterprises); (iii) negotiable certificates of deposit, banker's acceptances, fixed time deposits and other obligations of U.S. and foreign banks (including foreign branches) and similar institutions; (iv) commercial paper rated at the date of purchase ''Prime-1'' by Moody's or ''A–1'' by S&P, or if unrated, of comparable quality as determined by the Adviser;[21] (v) non-convertible corporate debt securities (*e.g.,* bonds and debentures) that have remaining maturities at the date of purchase of not more than 397 days and that satisfy the rating requirements set forth in Rule 2a-7 under the 1940 Act; and (vi) short-term U.S. dollar-denominated obligations of foreign banks (including U.S. branches) that, in the opinion of the Adviser, are of comparable quality to obligations of U.S. banks that may be purchased by a Portfolio.

The Funds are actively-managed and are not tied to an index. The Exchange notes, however, that each Fund's Portfolio will meet certain criteria for index-based, fixed income exchange-traded funds contained in NYSEArca Equities Rule 5.2(j)(3), Commentary .02.[22]

Other Investments

The following are additional possible investments of each Portfolio that are not included under the 80% investment policies described above for each Fund.

Each Portfolio may invest in the securities of other investment companies, including money market funds and closed-end funds, exchange traded products (''ETPs''),[23] including

[16] A Senior Loan is an advance or commitment of funds made by one or more banks or similar financial institutions, including the Portfolios, to one or more corporations, partnerships or other business entities and typically pays interest at a floating or adjusting rate that is determined periodically at a designated premium above a base lending rate, most commonly the London-Interbank Offered Rate (''LIBOR''). A Senior Loan is considered senior to all other unsecured claims against the borrower, senior to or pari passu with all other secured claims, meaning that in the event of a bankruptcy the Senior Loan, together with other first lien claims, are entitled to be the first to be repaid out of proceeds of the assets securing the loans, before other existing claims or interests receive repayment. However, in bankruptcy proceedings, there may be other claims, such as taxes or additional advances, that take precedence. Senior Loans consist generally of obligations of companies and other entities (collectively, ''borrowers'') incurred for the purpose of reorganizing the assets and liabilities of a borrower; acquiring another company; taking over control of a company (leveraged buyout); temporary refinancing; or financing internal growth or other general business purposes. Senior Loans are often obligations of borrowers who have incurred a significant percentage of debt compared to equity issued and thus are highly leveraged.

[17] When investing in CLOs, each Portfolio will not invest in equity tranches, which are the lowest tranche. However, each Portfolio may invest in lower debt tranches of CLOs, which typically experience a lower recovery, greater risk of loss or deferral or non-payment of interest than more senior debt tranches of the CLO. In addition, each Portfolio intends to invest in CLOs consisting primarily of individual Senior Loans of borrowers and not repackaged CLO obligations from other high risk pools. The underlying Senior Loans purchased by CLOs are generally performing at the time of purchase but may become non-performing, distressed, or defaulted. CLOs with underlying assets of non-performing, distressed, or defaulted loans are not contemplated to constitute a significant portion of a Portfolio's investments in CLOs. The key feature of the CLO structure is the prioritization of the cash flows from a pool of debt securities among the several classes of the CLO. The SPV is a company founded solely for the purpose of securitizing payment claims arising out of this diversified asset pool. On this basis, marketable securities are issued by the SPV, which, due to the diversification of the underlying risk, generally represent a lower level of risk than the original assets. The redemption of the securities issued by the SPV typically takes place at maturity out of the cash flow generated by the collected claims.

[18] One type of U.S. Government obligation, U.S. Treasury obligations, are backed by the full faith and credit of the U.S. Treasury and differ only in their interest rates, maturities, and times of issuance. U.S. Treasury bills have initial maturities of one-year or less; U.S. Treasury notes have initial maturities of one to ten years; and U.S. Treasury bonds generally have initial maturities of greater than ten years.

Other U.S. Government obligations are issued or guaranteed by agencies or instrumentalities of the U.S. Government including, but not limited to, Federal National Mortgage Association (''Fannie Mae''), the Government National Mortgage Association (''Ginnie Mae''), the Small Business Administration, the Federal Farm Credit Administration, the Federal Home Loan Mortgage Corporation (''Freddie Mac''), the Federal Home Loan Banks (''FHLB''), Banks for Cooperatives (including the Central Bank for Cooperatives), the Federal Land Banks, the Federal Intermediate Credit Banks, the Tennessee Valley Authority, the Export-Import Bank of the United States, the Commodity Credit Corporation, the Federal Financing Bank, the Student Loan Marketing Association, the National Credit Union Administration, and the Federal Agricultural Mortgage Corporation (''Farmer Mac'').

[19] Asset-backed securities are securities backed by installment contracts, credit-card receivables, or other assets. Commercial mortgage-backed securities are securities backed by commercial real estate properties. Both asset-backed and commercial mortgage-backed securities represent interests in ''pools'' of assets in which payments of both interest and principal on the securities are made on a regular basis.

[20] Restricted securities are securities that are not registered under the Securities Act, but which can be offered and sold to ''qualified institutional buyers'' under Rule 144A under the Securities Act.

[21] Commercial paper consists of short-term promissory notes issued by banks, corporations, and other entities to finance short-term credit needs. These securities generally are discounted but sometimes may be interest bearing.

[22] *See* NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 governing fixed income based Investment Company Units. Each of the Funds' Portfolios will meet the following requirements of Rule 5.2(j)(3), Commentary .02(a): (i) Components that in the aggregate account for at least 75% of the weight of the index or portfolio must each have a minimum original principal amount outstanding of $100 million or more (Rule 5.2(j)(3), Commentary.02(a)(2)); (ii) no component fixed-income security (excluding Treasury Securities and government-sponsored entity securities) will represent more than 30% of the weight of the index or portfolio, and the five highest weighted component fixed-income securities will not in the aggregate account for more than 65% of the weight of the index or portfolio (Rule 5.2(j)(3), Commentary.02(a)(4)); and (iii) an underlying index or portfolio (excluding exempted securities) must include securities from a minimum of 13 non-affiliated issuers (Rule 5.2(j)(3), Commentary.02(a)(5)).

[23] For each of the Funds, ETPs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Index-Linked Securities (as described in NYSE Arca Equities Rule 5.2(j)(6)); Portfolio Depositary Receipts (as

exchange-traded funds registered under the 1940 Act that seek to track the performance of a market index (''Underlying ETFs'') and exchange traded notes (''ETNs'').[24]

Each Portfolio may invest in one or more ETPs that are qualified publicly traded partnerships (''QPTPs'') and whose principal activities are the buying and selling of commodities or options, futures, or forwards with respect to commodities.[25] Additionally, each Portfolio may invest in preferred securities, convertible securities, high yield debt securities, and Variable Rate Demand Obligations.

The Portfolios may invest in inflation-protected public obligations, commonly known as ''TIPS,'' of the U.S. Treasury, as well as TIPS of major governments and emerging market countries, excluding the United States. Each Portfolio may invest a portion of its assets in Build America Bonds. The Build America Bond program allows state and local governments to issue taxable bonds for capital projects and to receive a direct federal subsidy payment from the Treasury Department for a portion of their borrowing costs.[26]

Further, the Portfolios may seek to obtain exposure to U.S. agency mortgage pass-through securities through the use of ''to-be-announced'' or ''TBA transactions.'' ''TBA'' refers to a commonly used mechanism for the forward settlement of U.S. agency mortgage pass-through securities, and not to a separate type of mortgage-backed security. Most transactions in mortgage pass-through securities occur through the use of TBA transactions.

Each Portfolio may invest in repurchase agreements with commercial banks, brokers, or dealers to generate income from its excess cash balances. Additionally, each Portfolio may invest in sovereign debt, which may be denominated in local currencies. Each Portfolio may also invest in foreign currency transactions on a spot (cash) basis and currency forwards for hedging or trade settlement purposes.

Each Portfolio may enter into reverse repurchase agreements, which involve the sale of securities with an agreement to repurchase the securities at an agreed-upon price, date, and interest payment and which have the characteristics of borrowing.

Each Portfolio may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including Rule 144A securities deemed illiquid by the Adviser, master demand notes, privately-issued securities (which, for example, can be Rule 144A securities), loans, and loan participations. Each Portfolio will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of each Fund's (indirectly through its respective Portfolio) net assets are held in illiquid securities. Illiquid securities include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.[27]

Each Portfolio will be classified as a ''non-diversified'' investment company under the 1940 Act and will not concentrate its investments in any particular industry or sector. The Portfolios intend to qualify for and to elect treatment as a separate regulated investment company under Subchapter M of the Internal Revenue Code.

In extreme situations or market conditions,[28] a Fund may (either directly or through the corresponding Portfolio) temporarily depart from its normal investment policies and strategies provided that the alternative is consistent with the Fund's investment objective and is in the best interest of the Fund. For example, a Portfolio may hold a higher than normal proportion of its assets in cash in times of extreme market stress.

Except for ETPs that may hold non-U.S. equity issues, the Funds and the Portfolios will not otherwise invest in non-U.S equity issues. Neither the Funds nor the Portfolios will invest in options contracts, futures contracts, or swap agreements.

Master-Feeder Structure of the Funds

The Funds are intended to be managed in a ''master-feeder'' structure under which each Fund invests substantially all of its assets in a corresponding Portfolio (*i.e.,* ''master fund''), which is a separate mutual fund registered under the 1940 Act that has an identical investment objective. As a result, each Fund (*i.e.,* ''feeder fund'') has an indirect interest in all of the securities and other assets owned by the corresponding Portfolio. Because of this indirect interest, each Fund's investment returns should be the same as those of the corresponding Portfolio, adjusted for the expenses of the Fund. In extraordinary instances, each Fund reserves the right to make direct investments in securities.

The Adviser will manage the investments of each Portfolio. Under the master-feeder arrangement, and pursuant to an Investment Advisory Agreement between the Adviser and the Trust, investment advisory fees charged at the Portfolio level are deducted from the advisory fees charged at the Fund level. This arrangement avoids a ''layering'' of fees, *i.e.,* a Fund's total annual operating expenses would be no higher as a result of investing in a master-feeder arrangement than they would be if the Fund pursued its investment objectives directly. In addition, each Fund may discontinue investing through the master-feeder

described in NYSE Arca Equities Rule 8.100); Trust Issued Receipts (as described in NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (as described in NYSE Arca Equities Rule 8.201); Currency Trust Shares (as described in NYSE Arca Equities Rule 8.202); Commodity Index Trust Shares (as described in NYSE Arca Equities Rule 8.203); Trust Units (as described in NYSE Arca Equities Rule 8.500); Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600), and closed-end funds. The ETPs all will be listed and traded in the U.S. on registered exchanges. While a Fund may invest in inverse ETPs, a Fund will not invest in leveraged (*e.g.,* 2X or 3X) or leveraged inverse ETPs.

[24] ETNs are debt obligations of investment banks; they are traded on exchanges and their returns are linked to the performance of reference assets, including market indexes. In addition to trading ETNs on exchanges, investors may redeem ETNs directly with the issuer on a weekly basis, typically in a minimum amount of 50,000 units, or hold the ETNs until maturity.

[25] Examples of such entities are the PowerShares DB Energy Fund, PowerShares DB Oil Fund, PowerShares DB Precious Metals Fund, PowerShares DB Gold Fund, PowerShares DB Silver Fund, PowerShares DB Base Metals Fund, and PowerShares DB Agriculture Fund, which are listed and traded on the Exchange pursuant to NYSE Arca Equities Rule 8.200.

[26] Issuance of Build America Bonds ceased on December 31, 2010. The Build America Bonds outstanding continue to be eligible for the federal interest rate subsidy, which continues for the life of the Build America Bonds; however, no bonds issued following expiration of the Build America Bond program are eligible for the federal tax subsidy.

[27] The Exchange represents that the Trust's Board of Trustees (''Board'') has delegated the responsibility for determining the liquidity of Rule 144A restricted securities that a Portfolio may invest in to the Adviser. In reaching liquidity decisions, the Adviser may consider the following factors: the frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer).

[28] Such situations and conditions include, but are not limited to, trading halts in the fixed income markets or disruptions in the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

arrangement and pursue its investment objectives directly if the Trust's Board determines that doing so would be in the best interests of shareholders.

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [29] and the rules and regulations thereunder applicable to a national securities exchange.[30] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[31] which requires, among other things, that the Exchange's rules 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 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. The Commission notes that the Shares of the Funds must comply with the requirements of NYSE Arca Equities Rule 8.600 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[32] which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, an indicative optimized portfolio value, which is the Portfolio Indicative Value as defined in NYSE Arca Equities Rule 8.600(c)(3), relating to each Fund will be widely disseminated every 15 seconds during the Core Trading Session by one or more major market data vendors.[33] On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Adviser will disclose on its Web site the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), that will form the basis for the Funds' calculation of NAV at the end of the business day.[34] The NAV of a Fund will be determined once each business day, normally as of the closing of the regular trading session on the New York Stock Exchange (normally 4:00 p.m. Eastern Time). A basket composition file, which will include the security names and share quantities, if applicable, required to be delivered in exchange for a Fund's Shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the New York Stock Exchange via National Securities Clearing Corporation. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. The intra-day, closing, and settlement prices of the Portfolio securities and other assets will also be readily available from the national securities exchanges trading those securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. The Funds' Web site will include a form of the prospectus for the Funds and additional data relating to NAV and other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV for each Fund will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[35] In addition, trading in Shares of the Funds will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of the Funds may be halted. The Exchange may halt trading in the Shares if trading is not occurring in the securities or the financial instruments constituting the Disclosed Portfolio of the Funds, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[36] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.[37] The Commission also notes that the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange,[38] will communicate as needed regarding trading in the Shares with other markets that are members of the Intermarket Surveillance Group (''ISG'') or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. [39] The Exchange also states that the Adviser is affiliated with a broker-dealer, and the Adviser has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition of and changes to the portfolio.[40]

[29] 15 U.S.C. 78f.

[30] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 15 U.S.C. 78f(b)(5).

[32] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[33] According to the Exchange, several major market data vendors widely disseminate or make widely available Portfolio Indicative Values taken from CTA or other data feeds.

[34] On a daily basis, the Adviser will disclose for each portfolio security and other financial instrument of the Funds and of the Portfolios the following information on the Funds' Web site: Ticker symbol (if applicable); name of security and financial instrument; number of shares, if applicable, or dollar value of financial instruments and securities held in the portfolio; and percentage weighting of the security and financial instrument in the portfolio. The Web site information will be publicly available at no charge.

[35] *See* NYSE Arca Equities Rule 8.600(d)(1)(B).

[36] *See* NYSE Arca Equities Rule 8.600(d)(2)(C) (providing additional considerations for the suspension of trading in or removal from listing of Managed Fund Shares on the Exchange). With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[37] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[38] The Exchange states that, while FINRA surveils trading on the Exchange pursuant to a regulatory services agreement, the Exchange is responsible for FINRA's performance under this regulatory services agreement.

[39] The SSgA Master Trust's Pricing and Investment Committee has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Portfolios and the Funds.

[40] *See supra* note 4. An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication

The Exchange represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws and that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its Equity Trading Permit Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (d) how information regarding the Portfolio Indicative Value will be disseminated; (e) the requirement that Equity Trading Permit Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and continued listing, the Funds will be in compliance with Rule 10A–3 under the Exchange Act,[41] as provided by NYSE Arca Equities Rule 5.3.

(6) All equity securities held by the Funds or Portfolios, including shares of ETPs, will trade on U.S. national securities exchanges, all of which are members of ISG.

(7) For each of the Portfolios, the Adviser will invest, under normal circumstances, at least 80% of each Portfolio's net assets in a diversified portfolio of U.S. dollar-denominated investment grade fixed income securities. The Bond Portfolio and the Conservative Portfolio primarily will invest in investment grade fixed income securities that are rated a minimum of the lowest A rating by any NRSRO (and for the Aggressive Portfolio, a minimum of the lowest BBB rating by any NRSRO), or, if unrated, determined by the Adviser to be of equivalent quality.

(8) Each Fund's Portfolio will meet certain criteria for index-based fixed income exchange-traded funds contained in NYSEArca Equities Rule 5.2(j)(3), Commentary .02.[42]

(9) Except for ETPs that may hold non-U.S. equity issues, the Funds and the Portfolios will not otherwise invest in non-U.S. equity issues. Neither the Funds nor the Portfolios will invest in options contracts, futures contracts, or swap agreements. The Funds' investments will be consistent with its respective investment objective and will not be used to enhance leverage.

(10) Non-agency residential mortgage-backed and commercial mortgage-backed investments each will be limited to 10% for each of the Portfolios.

(11) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including Rule 144A securities deemed illiquid by the Adviser, master demand notes, other privately issued securities, loans, and loan participations.

(12) A minimum of 100,000 Shares for each Fund will be outstanding at the commencement of trading on the Exchange.

This approval order is based on all of the Exchange's representations and description of the Funds, including those set forth above and in the Notice.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[43] 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,[44] that the proposed rule change (SR–NYSEArca-2013–71) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–22166 Filed 9–11–13; 8:45 am]

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and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[41] 17 CFR 240.10A–3.

[42] *See* note 22, *supra.*

[43] 15 U.S.C. 78f(b)(5).

[44] 15 U.S.C. 78s(b)(2).

[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70336; File No. SR–CME–2013–13)

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Enhancements to CME's Price Quality Auction Process for CDS Index Products

September 6, 2013.

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 August 23, 2013, Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by CME. CME filed the proposal pursuant to Section 19(b)(3)(A)(iii)[3] of the Act, and Rule 19b–4(f)(4)(ii) thereunder,[4] so that the proposal was effective upon filing with the Commission. 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

CME is filing proposed rules changes that are limited to its business as a derivatives clearing organization. More specifically, the proposed rule changes would make amendments to its rules

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(4)(ii).

regarding CME's current Price Quality Auction settlement process for CDS index products.

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 self-regulatory organization included statements concerning the purpose 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 self-regulatory organization 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

CME is registered as a derivatives clearing organization with the Commodity Futures Trading Commission and currently offers clearing services for many different futures and swaps products. With this filing, CME proposes to make amendments that will affect its Price Quality Auction (''PQA'') settlement process for Credit Default Swaps (''CDS'') index products. Although these changes will be effective on filing, CME plans to operationalize the proposed changes on September 9, 2013.

The proposed change would be reflected in CME's Manual of Operations for CME Credit Default Swaps (''CDS Manual''). The change would allow CME to set the bid/ask spread for PQA submissions to a configurable level based on historical price analysis. The change is designed to make the configurable level more consistent with existing market conditions by reducing the acceptable range, which will in turn help ensure that settlement prices are not impacted by off market submissions. This change should help enhance the quality of the PQA process for determining settlement prices for CDS index products. The proposed parameter changes do not otherwise materially affect the PQA process.

The changes that are described in this filing will only impact CME's processes for clearing CDS index products. Thus, these changes are limited to CME's business as a derivatives clearing organization clearing products under the exclusive jurisdiction of the Commodity Futures Trading Commission (''CFTC'') and do not materially impact CME's security-based swap clearing business in any way. CME notes that it has already submitted the proposed rule changes that are the subject of this filing to its primary regulator, the CFTC, in CME Submission 13–295.

CME believes the proposed rule changes are consistent with the requirements of the Exchange Act including Section 17A of the Exchange Act.[5] The proposed rule changes are designed to enhance the quality of CME's PQA process for determining settlement prices for CDS index products and as such are designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivatives agreements, contracts, and transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, and, in general, to protect investors and the public interest consistent with Section 17A(b)(3)(F) of the Exchange Act.[6]

Furthermore, the proposed changes are limited in their effect to swaps products offered under CME's authority to act as a derivatives clearing organization. These products are under the exclusive jurisdiction of the CFTC. As such, the proposed CME changes are limited to CME's activities as a derivatives clearing organization clearing swaps that are not security-based swaps; CME notes that the policies of the CFTC with respect to administering the Commodity Exchange Act are comparable to a number of the policies underlying the Exchange Act, such as promoting market transparency for over-the-counter derivatives markets, promoting the prompt and accurate clearance of transactions and protecting investors and the public interest.

Because the proposed changes are limited in their effect to swaps products offered under CME's authority to act as a derivatives clearing organization, the proposed changes are properly classified as effecting a change in an existing service of CME that:

(a) Primarily affects the clearing operations of CME with respect to products that are not securities, including futures that are not security futures, and swaps that are not security-based swaps or mixed swaps; and

(b) does not significantly affect any securities clearing operations of CME or any rights or obligations of CME with respect to securities clearing or persons using such securities-clearing service.

As such, the changes are therefore consistent with the requirements of Section 17A of the Exchange Act[7] and are properly filed under Section 19(b)(3)(A)[8] and Rule 19b–4(f)(4)(ii)[9] thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

CME does not believe that the proposed rule change will have any impact, or impose any burden, on competition. The rule changes simply makes enhancements to CME's process for determining settlement prices for CDS index products.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

CME has not solicited, and does not intend to solicit, comments regarding this proposed rule change. CME has not received any unsolicited written comments from interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[10] of the Act and paragraph (f)(4)(ii) of Rule 19b–4[11] thereunder. At any time within 60 days of the filing of the 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.

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 No. SR–CME–2013–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary,

[5] 15 U.S.C. 78q–1.

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1.

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(4)(ii).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(4)(ii).

Securities and Exchange Commission, 100 F Street NE., Washington, DC, 20549–1090.

All submissions should refer to File Number SR–CME–2013–13. 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 or 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 CME and on CME's Web site at *http://www.cmegroup.com/market-regulation/rule-filings.html*.

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–CME–2013–13 and should be submitted on or before October 3, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–22164 Filed 9–11–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Exmocare, Inc. (n/k/a Second Solar, Inc.), First Transation Management, Inc., jetPADS, Inc., PepperBall Technologies, Inc., Pure Play Music, Ltd., Rim Semiconductor Co., Small Business Co., Inc., StarVox Communications, Inc., Steakhouse Partners, Inc., and Sutura, Inc., Order of Suspension of Trading

September 10, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Exmocare, Inc. (n/k/a Second Solar, Inc.) because it has not filed any periodic reports since the period ended February 29, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of First Transaction Management, Inc. because it has not filed any periodic reports since the period ended September 30, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of jetPADS, Inc. because it has not filed any periodic reports since the period ended December 31, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of PepperBall Technologies, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Pure Play Music, Ltd. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Rim Semiconductor Co. because it has not filed any periodic reports since the period ended April 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Small Business Co., Inc. because it has not filed any periodic reports since the period ended March 31, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of StarVox Communications, Inc. because it has not filed any periodic reports since the period ended May 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Steakhouse Partners, Inc. because it has not filed any periodic reports since the period ended December 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sutura, Inc. because it has not filed any periodic reports since the period ended December 31, 2008.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on September 10, 2013, through 11:59 p.m. EDT on September 23, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–22298 Filed 9–10–13; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

HydroGen Corp., QueryObject Systems Corp., Security Intelligence Technologies, Inc., Skins, Inc., SLM Holdings, Inc., Spring Creek Healthcare Systems, Inc., and Startech Environmental Corp.; Order of Suspension of Trading

September 10, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of HydroGen Corp. because it has not filed any periodic reports since the period ended June 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of QueryObject Systems Corp. because it has not filed any periodic reports since the period ended June 30, 2009.

It appears to the Securities and Exchange Commission that there is a

lack of current and accurate information concerning the securities of Security Intelligence Technologies, Inc. because it has not filed any periodic reports since the period ended March 31, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Skins, Inc. because it has not filed any periodic reports since the period ended March 31, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SLM Holdings, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Spring Creek Healthcare Systems, Inc. because it has not filed any periodic reports since the period ended September 30, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Startech Environmental Corp. because it has not filed any periodic reports since the period ended July 31, 2009.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on September 10, 2013, through 11:59 p.m. EDT on September 23, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–22301 Filed 9–10–13; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Big Bear Mining Corp., Four Rivers BioEnergy, Inc., Mainland Resources, Inc., QI Systems Inc., South Texas Oil Co., and Synova Healthcare Group, Inc.; Order of Suspension of Trading

September 10, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Big Bear Mining Corp. because it has not filed any periodic reports since the period ended December 31, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Four Rivers BioEnergy, Inc. because it has not filed any periodic reports since the period ended July 31, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Mainland Resources, Inc. because it has not filed any periodic reports since the period ended February 29, 2012.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of QI Systems, Inc. because it has not filed any periodic reports since the period ended March 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of South Texas Oil Co. because it has not filed any periodic reports since the period ended June 30, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Synova Healthcare Group, Inc. because it has not filed any periodic reports since the period ended September 30, 2007.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on September 10, 2013, through 11:59 p.m. EDT on September 23, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–22302 Filed 9–10–13; 4:15 pm]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a revision of an OMB-approved information collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.* (SSA), Social Security Administration, DCRDP, Attn: Reports Clearance Director, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than October 15, 2013. Individuals can obtain copies of the OMB clearance packages by writing to OR.Reports.Clearance@ssa.gov.

Social Security Benefits Application—20 CFR 404.310–404.311, 404.315–404.322, 404.330–404.333, 404.601–404.603, and 404.1501–404.1512—0960–0618. Title II of the Social Security Act (Act) provides retirement, survivors, and disability benefits to members of the public who meet the required eligibility criteria and file the appropriate application. This collection comprises the various application methods for each type of benefits. These methods include the following modalities: Paper forms (Forms SSA–1, SSA–2, and SSA–16); Modernized Claims System (MCS) screens for in-person interview applications; and Internet-based iClaim and iAppointment applications. SSA uses the information we collect through these modalities to determine: (1) the applicants' eligibility for the above-mentioned Social Security benefits and (2) the amount of the benefits. The respondents are applicants for retirement, survivors, and disability benefits under title II of the Act.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minute)	Estimated annual burden (hours)
Form SSA–1				
MCS/Signature Proxy	1,441,400	1	10	240,233
Paper	2,300	1	11	422
Medicare-only MCS	418,300	1	7	48,802
Medicare-only Paper	300	1	7	35
Totals	1,862,300			289,492
Form SSA–2				
MCS/Signature Proxy	364,000	1	14	84,933
Paper	1,200	1	15	300
Totals	341,200			85,233
Form SSA–16				
MCS/Signature Proxy	1,695,800	1	19	537,003
Paper	53,300	1	20	17,767
Totals	1,749,100			554,770
iClaim Screens				
iClaim 3rd Party	431,357	1	15	107,839
iClaim Applicant after 3rd Party Completion	431,357	1	5	35,946
First Party iClaim—Domestic Applicant	1,838,943	1	15	459,736
First Party iClaim—Foreign Applicant	8,291	1	3	415
Medicare-only iClaim	552,400	1	10	92,067
Totals	3,262,348			696,003
iAppointment Screens				
iAppointment	200,000	1	10	33,333
Grand Total				
Total	7,438,948			1,658,831

Dated: September 9, 2013.

Naomi Sipple,

Management Analyst,

Reports Clearance Team,

Social Security Administration.

[FR Doc. 2013–22169 Filed 9–11–13; 8:45 am]

BILLING CODE 4191–02–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*.

(SSA), Social Security Administration, DCRDP, Attn: Reports Clearance Director, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*.

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than November 12, 2013. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. *Agreement to Sell Property—20 CFR 416.1240—416.1245—0960–0127.* Individuals or couples who are otherwise eligible for Supplemental Security Income (SSI) payments but whose resources exceed the allowable limit may receive conditional payments if they agree to dispose of the excess non-liquid resources and make repayments. SSA uses Form SSA–8060–U3 to document this agreement, and to ensure the individuals understand their

obligations. Respondents are applicants for and recipients of SSI payments who will be disposing of excess non-liquid resources.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–8060–U3	20,000	1	10	3,000

2. *Epidemiological Research Report—20 CFR 401.165—0960–0701.* Section 311 of the Social Security Independence and Program Improvements Act of 1994 directs SSA to support health researchers involved in epidemiological research. Specifically, when we determine a study contributes to a national health interest, SSA furnishes information to determine if a study subject appears in SSA administrative records as alive or deceased (vital status). SSA charges a small fee per request for providing this information. Web-posted questions solicit the information SSA needs to provide the data and to collect the fees. The respondents are qualified health and scientific researchers who are applying to receive vital status information about individuals from Social Security administrative data records.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
State & Local Government	15	1	120	30
Private Entities	10	1	120	20
Totals	25			50

Cost Burden

Average annual cost per respondent (based on SSA data): $3,500.

Total estimated annual cost burden: $108,500.

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than October 15, 2013. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov*.

Disability Report—Child—20 CFR 416.912—0960–0577. Sections 223(d)(5)(A) and 1631(e)(1) of the Social Security Act (Act) require SSI claimants to furnish medical and other evidence to prove they are disabled. SSA uses Form SSA–3820 to collect various types of information about a child's condition from treating sources or other medical sources of evidence. State Disability Determination Services evaluators use the information from Form SSA–3820 to develop medical and school evidence, and to assess the alleged disability. The information, together with medical evidence, forms the evidentiary basis upon which SSA makes its initial disability evaluation. The respondents are claimants seeking SSI childhood disability payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3820	500	1	90	750
Electronic Disability Collect System	1,000	1	120	2,000
i3820	540,000	1	60	540,000
Totals	541,500			542,750

Dated: September 9, 2013.

Naomi Sipple,

Management Analyst, Reports Clearance Team, Social Security Administration.

[FR Doc. 2013–22168 Filed 9–11–13; 8:45 am]

BILLING CODE 4191–02–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2013–0034]

Consent Based Social Security Number Verification (CBSV) Service

AGENCY: Social Security Administration.

ACTION: Notice of Revised Transaction Fee for CBSV Service.

SUMMARY: We provide fee-based Social Security number (SSN) verification services to enrolled private businesses, State and local government agencies who obtain a valid, signed consent form from the SSN holder. We originally published a notice announcing the CBSV service in the **Federal Register** on August 10, 2007.

Based on the signed consent form, we verify the number holders' SSNs for the requesting party. The Privacy Act of 1974 (5 United States Code (U.S.C.) 552a(b)), section 1106 of the Social Security Act (42 U.S.C. 1306) and our regulation at 20 Code of Federal Regulation 401.100, establish the legal authority for us to provide SSN

verifications to third party requesters based on consent.

The CBSV process provides users with a consent-based SSN verification service in high volume. We developed CBSV as a user-friendly, internet-based application with safeguards that protect the public's information. In addition to the benefit of providing high volume, centralized SSN verification services to users in a secure manner, CBSV provides us with cost and workload management benefits.

New Information: To use CBSV, interested parties must pay a one-time non-refundable enrollment fee of $5,000. Currently, users also pay a fee of $1.05 per SSN verification transaction in advance of services. We agreed to periodically calculate our costs for providing CBSV services and adjust the fees as necessary. We also agreed to notify current CBSV users of any cost adjustment to allow them to cancel or continue using the service at the new SSN verification transaction fee.

Based on our most recent cost analysis, we will adjust the fiscal year 2014 fee to $1.10 per SSN verification transaction. New users must still pay the one-time $5,000 enrollment fee.

DATES: The changes described above are effective October 1, 2013.

FOR FURTHER INFORMATION CONTACT: Esset Tate, Office of Public Service and Operations Support, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, [410–966–8502], for more information about the CBSV service, visit our Internet site, Social Security Online, at: *http://www.socialsecurity.gov/cbsv.*

Dated: September 5, 2013.

Esset Tate,

Project Manager, Office of Public Service and Operations Support.

[FR Doc. 2013–22195 Filed 9–11–13; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 8465; No. 2013–5]

Determination Pursuant To the Foreign Missions Act

Pursuant to the authority vested in me under the Foreign Missions Act, 22 U.S.C. 4301 *et seq.* (''the Act''), and Department of State Delegation of Authority No. 198 of September 16, 1992, I hereby determine that the plans submitted by the Embassy of the Republic of South Africa to the Public Space Committee of the District of Columbia's Department of Consumer and Regulatory Affairs concerning the location of a flagpole in public space at its chancery located at 3051 Massachusetts Avenue NW, demonstrate substantial compliance with District of Columbia building and related codes in a manner determined by the Secretary not to be inconsistent with the international obligations of the United States, in accordance with section 206(g) of the Act.

Dated: August 20, 2013.

Patrick F. Kennedy,

Under Secretary for Management.

[FR Doc. 2013–22207 Filed 9–11–13; 8:45 am]

BILLING CODE 4710–43–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA – 2013–0353]

Article 19–A of the State of New York's Vehicle and Traffic Law

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of petition for determination of preemption; request for comments.

SUMMARY: FMCSA requests comments on petitions submitted by the American Bus Association (ABA) and Motor Coach Canada (MCC) seeking a determination that Article 19–A of the State of New York's Vehicle and Traffic Law governing drivers of passenger-carrying interstate motor vehicles is preempted by Federal law. FMCSA requests comments on whether Article 19–A has safety benefits, how it is being enforced against interstate passenger carriers and its effect, if any, on interstate commerce.

DATES: Comments are due on or before November 12, 2013.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Number in the heading of this document by any of the following methods. To allow effective public participation before the comment deadlines, however, the Agency encourages use of the Web site that is listed first. It will provide the most efficient and timely method of receiving and processing your comments. Do not submit the same comments by more than one method.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Ground floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number for this action. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Refer to the Privacy Act heading on *http://www.regulations.gov* for further information.

Public Participation: The *regulations.gov* system is generally available 24 hours each day, 365 days each year. You can find electronic submission and retrieval help and guidelines under the ''help'' section of the Web site. For notification that FMCSA received the comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments on line. Copies or abstracts of all documents referenced in this notice are in this docket. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. FMCSA will continue to file in the public docket relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

FOR FURTHER INFORMATION CONTACT: Genevieve D. Sapir, Office of the Chief Counsel, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–7056. If you have questions on viewing or submitting material to the docket, call U.S. DOT Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background

Provisions of Article 19–A of the State of New York's Vehicle and Traffic Law and its implementing regulations (15 CRR–NY ch. 6) establish a wide range of

requirements applicable to both interstate and intrastate passenger carriers operating in New York. Under this regulatory scheme, all interstate passenger carriers must file an annual compliance affidavit certifying that their drivers are not disqualified under State law and reporting the number of days and vehicle miles of bus service provided in New York during the previous year. An interstate carrier is generally exempt from the rest of Article 19–A, which includes requirements related to employment, driver medical qualifications, reporting, recordkeeping and other matters affecting both drivers and carriers, unless it operates certain types of school buses or operates in New York for more than 100 days or more than 10,000 vehicle miles annually. Interstate carriers that exceed the 100 day or 10,000 mile threshold can apply for a waiver for bus drivers who operate less than 30 days per year in New York (N.Y. Veh. & Traf. Law, § 509-n; 15 CRR–NY § 6.14). Otherwise, an interstate passenger carrier operating in New York is required to comply with Article 19–A. The New York Department of Motor Vehicles (NY DMV) makes information about compliance with Article 19–A available through the following web link: *http://www.dmv.ny.gov/art19.htm.*

By letter dated June 28, 2011, MCC requested that FMCSA preempt Article 19–A, alleging that it creates a burden on interstate commerce by imposing requirements that are more stringent than Federal regulations. MCC stated that 49 CFR part 391 of the Federal Motor Carrier Safety Regulations (FMCSRs) contains comprehensive driver qualification and licensing requirements and that the requirements of Article 19–A impermissibly regulate interstate passenger carrier operations. MCC specifically identified New York's request for bus driver information (a two-page form for each driver), an Affidavit of Compliance and an annually-updated roster as unlawful burdens. On July 18, 2011, the ABA wrote a similar letter, objecting to New York's enforcement of Article 19–A, but, at that time, specifically stated that it was not requesting preemption.

In response, on March 29, 2012, FMCSA sent a letter giving the NY DMV an opportunity to respond to MCC's and the ABA's letters. The letter also asked whether the NY DMV applies Article 19–A to interstate carriers and how it uses the information it collects. By letter dated July 31, 2012, the DMV responded, stating that Article 19–A applies to interstate carriers and that it keeps the information it collects in its files, notifies carriers when a driver's CDL is revoked or suspended, and notifies school bus operators of the results of the mandatory criminal history checks.

On September 7, 2012, the ABA sent another letter, this time requesting that FMCSA determine that Article 19–A is preempted because it has no demonstrated safety benefit, is not compatible with federal requirements and places an undue burden on interstate commerce. ABA stated that the requirements of Article 19–A exceed Federal driver qualification requirements, burdening interstate carriers. ABA specifically objected to those provisions of Article 19–A that require carriers to report information to the NY DMV about a driver's employment status, disqualification, pending criminal charges, out-of-State driving record, miles driven and number of convictions and accidents. ABA also objected to the requirements that carriers participate in New York's Conviction and Accident Notification program, establish an escrow account in New York, administer tests and assessments of driving skills in excess of that required by the FMCSRs, and submit affidavits attesting to compliance with Article 19–A.

The letters referenced above are available in the docket for this proceeding.

Applicable law

Section 31141 of title 49, United States Code, prohibits States from enforcing a law or regulation on CMV safety that the Secretary of Transportation (Secretary) has determined to be preempted. To determine whether a State law or regulation is preempted, the Secretary must decide whether a State law or regulation: (1) Has the same effect as a regulation prescribed under 49 U.S.C. 31136, which is the authority for much of the Federal Motor Carrier Safety Regulations (FMCSRs); (2) is less stringent than such a regulation; or (3) is additional to or more stringent than such a regulation (49 U.S.C. 31141(c)(1)). If the Secretary determines that a State law or regulation has the same effect as a regulation based on § 31136, it may be enforced (49 U.S.C. 31141(c)(2)). A State law or regulation that is less stringent may not be enforced (49 U.S.C. 31141(c)(3)). And a State law or regulation the Secretary determines to be additional to or more stringent than a regulation based on § 31136 may be enforced unless the Secretary decides that the State law or regulation (1) Has no safety benefit; (2) is incompatible with the regulation prescribed by the Secretary; or (3) would cause an unreasonable burden on interstate commerce (49 U.S.C. 31141(c)(4)). To determine whether a State law or regulation will cause an unreasonable burden on interstate commerce, the Secretary may consider the cumulative effect that the State's law or regulation and all similar laws and regulations of other States will have on interstate commerce (49 U.S.C. 31141(c)(5)). The Secretary's authority under § 31141 is delegated to the FMCSA Administrator by 49 CFR 1.87(f).

Request for Comments

Although preemption under § 31141 is a legal determination reserved to the judgment of the Agency, FMCSA seeks comment on what effect, if any, Article 19–A and its accompanying regulations have on interstate motor carrier operations. Commenters are encouraged to provide information about the regulatory scheme's safety benefits, if any, and whether it constitutes a burden on interstate commerce or is incompatible with the FMCSRs. FMCSA is particularly interested in specific information on how New York enforces Article 19–A against interstate passenger carriers. In requesting comments, FMCSA does not seek legal conclusions, but requests commenters to submit data supporting their positions.

Issued under the authority of delegation in 49 CFR 1.87.

Dated: September 3, 2013.

Anne S. Ferro,

Administrator.

[FR Doc. 2013–22162 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2013–0119]

Pipeline Safety: Public Workshop on Integrity Verification Process, Comment Extension

AGENCY: Pipeline and Hazardous Materials Safety Administration, DOT.

ACTION: Notice of extension of comment period.

SUMMARY: On May 28, 2013, PHMSA published in the **Federal Register** a notice announcing a public workshop on ''Integrity Verification Process'' which took place on August 7, 2013. The notice also sought comments on the proposed ''Integrity Verification Process.'' In response to the comments received, PHMSA has made some revisions to the proposed ''Integrity

Verification Process'' flowchart. PHMSA is using this notice to announce the revised ''Integrity Verification Process'' flowchart and extend the comment period from September 9, 2013, to October 7, 2013.

DATES: The closing date for filing comments is extended from September 9, 2013, to October 7, 2013.

COMMENTS: Comments should reference Docket No. PHMSA–2013–0119. Comments may be submitted in the following ways:

- *E-Gov Web site: http://www.regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590.

Hand Delivery: DOT Docket Management System, Room W12–140, on the ground floor 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.

Instructions: Identify the docket number at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA has received your comments, include a self-addressed stamped postcard. Internet users may submit comments at *http://www.regulations.gov.*

Note: Comments will be posted without changes or edits to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act Statement heading below for additional information.

Privacy Act Statement: Anyone may search the electronic form of all comments received for any of our dockets. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: Cameron Satterthwaite, Office of Pipeline Safety, at 202–366–1319 or by email at *cameron.satterthwaite@dot.gov,* regarding the subject matter of this notice.

SUPPLEMENTARY INFORMATION: On May 28, 2013, PHMSA published in the **Federal Register** a notice (78 FR 32010) to solicit comments and announce a public workshop regarding an ''Integrity Verification Process.'' The public workshop was held on August 7, 2013. At the workshop, PHMSA, the National Association of State Pipeline Safety Representatives and various other stakeholders presented information regarding the ''Integrity Verification Process'' that will help address several mandates set forth in Section 23, Maximum Allowable Operating Pressure, of the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011. Presentations, archived webcast, charts, and other pertinent information have been made available online at *http://www.phmsa.dot.gov/pipeline.*

In response to stakeholder feedback, PHMSA has made some revisions to the proposed ''Integrity Verification Process.'' The revised ''Integrity Verification Process'' is available in the docket at *www.regulations.gov,* Docket Number ''PHMSA–2013–0119''. In an effort to provide the public with adequate time to comment on the proposed revision, PHMSA is extending the comment period from September 9, 2013, to October 7, 2013.

Issued in Washington, DC, on September 6, 2013, under delegated authority in 49 CFR 1.97.

Jeffrey D. Wiese,

Associate Administrator for Pipeline Safety.

[FR Doc. 2013–22161 Filed 9–11–13; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, October 15, 2013.

FOR FURTHER INFORMATION CONTACT: Linda Rivera at 1–888–912–1227 or (202) 622–8390.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Tuesday, October 15, 2013 at 11:00 a.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Linda Rivera. For more information please contact: Ms. Rivera at 1–888–912–1227 or (202) 622–8390, or write TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing Toll-free issues and public input is welcomed.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22154 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, October 23, 2013.

FOR FURTHER INFORMATION CONTACT: Susan Gilbert at 1–888–912–1227 or (515) 564–6638.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, October 23, 2013 at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Susan Gilbert. For more information please contact Ms. Gilbert at 1–888–912–1227 or (515) 564–6638 or write: TAP Office, 210 Walnut Street, Stop 5115, Des Moines, IA 50309 or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the

IRS and other TAP related topics. Public input is welcomed.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22158 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, October 17, 2013.

FOR FURTHER INFORMATION CONTACT: Ellen Smiley or Patti Robb at 1–888–912–1227 or 414–231–2360.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, October 17, 2013, at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Ms. Ellen Smiley or Ms. Patti Robb. For more information please contact Ms. Smiley or Ms. Robb at 1–888–912–1227 or 414–231–2360, or write TAP Office Stop 1006MIL, 211 West Wisconsin Avenue, Milwaukee, WI 53203–2221, or post comments to the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Taxpayer Communications and public input is welcome.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22159 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, October 9, 2013.

FOR FURTHER INFORMATION CONTACT: Marisa Knispel at 1–888–912–1227 or 718–834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be held Wednesday, October 9, 2013 at 11:00 a.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Ms. Knispel. For more information please contact Ms. Knispel at 1–888–912–1227 or 718–834–2203, or write TAP Office, 2 Metro Tech Center, 100 Myrtle Avenue, 7th Floor, Brooklyn, NY 11201, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Tax Forms and Publications and public input is welcomed.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22157 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, October 9, 2013.

FOR FURTHER INFORMATION CONTACT: Timothy Shepard at 1–888–912–1227 or 206–220–6095.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Wednesday, October 9, 2013, at 12 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Timothy Shepard. For more information please contact Mr. Shepard at 1–888–912–1227 or 206–220–6095, or write TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include a discussion on various letters, and other issues related to written communications from the IRS.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22155 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, October 8, 2013.

FOR FURTHER INFORMATION CONTACT: Donna Powers at 1–888–912–1227 or (954) 423–7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Tuesday, October 8, 2013, at 2:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Donna Powers. For more information please contact Ms. Donna Powers at 1–888–912–1227 or (954) 423–7977, or write TAP Office, 1000 S. Pine Island Road, Plantation, FL 33324 or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to the Taxpayer Assistance Centers and public input is welcomed.

Dated: September 6, 2013.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2013–22156 Filed 9–11–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

FY 2014–2020 Draft VA Strategic Plan

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Availability and Request for Comments.

SUMMARY: The Department of Veterans Affairs (VA) is announcing the availability of the FY 2014–2020 Draft VA Strategic Plan (Strategic Plan) for public review and comment, as required by the Government Performance and Results Act Modernization Act of 2010 (GPRAMA) (Pub. L. 111–352).

The Strategic Plan provides the Department's long-term direction and places a stronger emphasis on defining success by Veterans' outcomes; enhancing the quality of and access to benefits and services through integration within VA and with our partners; and developing our workforce with the skills, tools, and leadership to meet our clients' needs and expectations.

DATES: Comments must be received by VA on or before October 15, 2013.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to the ''FY 2014–2020 Draft VA Strategic Plan.'' Please view and download the draft Strategic Plan for public comment at *http://www.va.gov/performance/docs/VA2014 StrategicPlanDraft20130808.pdf.* Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. This is not a toll-free number. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Sullivan, Acting Deputy Assistant Secretary, Office of Policy, Office of Policy and Planning at (202) 461- 5831. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The GPRAMA creates a more defined performance framework by defining a governance structure and by better connecting plans, programs, and performance information. Specifically, GPRAMA requires agencies require more frequent reporting and reviews (quarterly instead of annually) that are intended to increase the use of performance information in program decision-making.

The FY 2014–2020 Draft VA Strategic Plan builds on the prior (fiscal year (FY) 2011–2015) VA strategic plan. It outlines how the Department is transforming itself and how it will continue to increase access, eliminate the claims backlog, and end Veteran homelessness. In addition, this plan places a stronger emphasis on defining success by Veteran outcomes; enhancing the quality of and access to benefits and services through integration within VA and with our partners; and developing our workforce with the skills, tools, and leadership to meet our clients' needs and expectations.

VA's FY 2014–2020 strategic goals are to: (1) Empower Veterans to Improve Their Well-being; (2) Enhance and Develop Trusted Partnerships; and (3) Manage and Improve VA Operations to Deliver Seamless and Integrated Support. The strategic goals are statements of what VA wants to achieve to advance our mission and address changes and opportunities. VA's FY 2014–2020 goals and objectives shift the focus from improvements within a service or benefit delivery program to coordination and integration across programs and organizations, measuring performance by the ultimate outcome for Veterans and putting Veterans in control of how, when, and where they wish to be served.

As appropriate, public input received will be included in the updated Strategic Plan; however, VA will not be able to provide individual responses to the public comments that are received.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the

Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on September 5, 2013, for publication.

Dated: September 6, 2013.

William F. Russo,

Deputy Director, Office of Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2013–22150 Filed 9–11–13; 8:45 am]

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Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

Occupational Exposure to Respirable Crystalline Silica; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–2010–0034]

RIN 1218–AB70

Occupational Exposure to Respirable Crystalline Silica

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes to amend its existing standards for occupational exposure to respirable crystalline silica. The basis for issuance of this proposal is a preliminary determination by the Assistant Secretary of Labor for Occupational Safety and Health that employees exposed to respirable crystalline silica face a significant risk to their health at the current permissible exposure limits and that promulgating these proposed standards will substantially reduce that risk.

This document proposes a new permissible exposure limit, calculated as an 8-hour time-weighted average, of 50 micrograms of respirable crystalline silica per cubic meter of air (50 μg/m^3). OSHA also proposes other ancillary provisions for employee protection such as preferred methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. OSHA is proposing two separate regulatory texts—one for general industry and maritime, and the other for construction—in order to tailor requirements to the circumstances found in these sectors.

DATES: *Written comments.* Written comments, including comments on the information collection determination described in Section IX of the preamble (OMB Review under the Paperwork Reduction Act of 1995), must be submitted (postmarked, sent, or received) by December 11, 2013.

Informal public hearings. The Agency plans to hold informal public hearings beginning on March 4, 2014, in Washington, DC. OSHA expects the hearings to last from 9:30 a.m. to 5:30 p.m., local time; a schedule will be released prior to the start of the hearings. The exact daily schedule may be amended at the discretion of the presiding administrative law judge (ALJ). If necessary, the hearings will continue at the same time on subsequent days. Peer reviewers of OSHA's Health Effects Literature Review and Preliminary Quantitative Risk Assessment will be present in Washington, DC to hear testimony on the second day of the hearing, March 5, 2014; *see* Section XV for more information on the peer review process.

Notice of intention to appear at the hearings. Interested persons who intend to present testimony or question witnesses at the hearings must submit (transmit, send, postmark, deliver) a notice of their intention to do so by November 12, 2013. The notice of intent must indicate if the submitter requests to present testimony in the presence of the peer reviewers.

Hearing testimony and documentary evidence. Interested persons who request more than 10 minutes to present testimony, or who intend to submit documentary evidence, at the hearings must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence by December 11, 2013. *See* Section XV below for details on the format and how to file a notice of intention to appear, submit documentary evidence at the hearing, and request an appropriate amount of time to present testimony.

ADDRESSES: *Written comments.* You may submit comments, identified by Docket No. OSHA–2010–0034, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions on-line for making electronic submissions.

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: You must submit your comments to the OSHA Docket Office, Docket No. OSHA–2010–0034, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger, or courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., E.T.

Instructions: All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA–2010–0034). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.,* consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific and technical analyses, OSHA requests that you disclose: (1) The nature of any financial relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party prior to its submission. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

Informal public hearings. The Washington, DC hearing will be held in the auditorium of the U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Notice of intention to appear, hearing testimony and documentary evidence. You may submit (transmit, send, postmark, deliver) your notice of intention to appear, hearing testimony, and documentary evidence, identified by docket number (OSHA–2010–0034), by any of the following methods:

Electronically: http://www.regulations.gov. Follow the instructions online for electronic submission of materials, including attachments.

Fax: If your written submission does not exceed 10 pages, including attachments, you may fax it to the OSHA Docket Office at (202) 693–1648.

Regular mail, express delivery, hand delivery, and messenger and courier service: Submit your materials to the OSHA Docket Office, Docket No. OSHA–2010–0034, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (TTY number (877) 889–5627). Deliveries (express mail, hand delivery, and messenger and courier service) are accepted during the Department of Labor's and OSHA Docket Office's normal hours of operation, 8:15 a.m. to 4:45 p.m., ET.

Instructions: All submissions must include the Agency name and docket number for this rulemaking (Docket No. OSHA–2010–0034). All submissions, including any personal information, are placed in the public docket without change and may be available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting certain personal information, such as social security numbers and birthdates. Because of security-related procedures, the use of regular mail may cause a significant delay in the receipt of your submissions. For information about security-related procedures for submitting materials by express delivery, hand delivery, messenger, or courier service, please contact the OSHA Docket Office. For additional information on submitting notices of intention to appear, hearing testimony or documentary evidence, *see* Section XV of this preamble, Public Participation.

Docket: To read or download comments, notices of intention to appear, and materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA–2010–0034 at *http://www.regulations.gov* or to the OSHA Docket Office at the address above. All comments and submissions are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All comments and submissions are available for inspection and, where permissible, copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://regulations.gov.* Copies also are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1888. This document, as well as news releases and other relevant information, is also available at OSHA's Web site at *http://www.osha.gov.*

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. For technical inquiries, contact William Perry or David O'Connor, 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 or fax (202) 693–1678. For hearing 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.*

SUPPLEMENTARY INFORMATION:

The preamble to the proposed standard on occupational exposure to respirable crystalline silica follows this outline:

I. Issues
II. Pertinent Legal Authority
III. Events Leading to the Proposed Standards
IV. Chemical Properties and Industrial Uses
V. Health Effects Summary
VI. Summary of the Preliminary Quantitative Risk Assessment
VII. Significance of Risk
VIII. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis
IX. OMB Review Under the Paperwork Reduction Act of 1995
X. Federalism
XI. State Plans
XII. Unfunded Mandates
XIII. Protecting Children From Environmental Health and Safety Risks
XIV. Environmental Impacts
XV. Public Participation
XVI. Summary and Explanation of the Standards
(a) Scope and Application
(b) Definitions
(c) Permissible Exposure Limit (PEL)
(d) Exposure Assessment
(e) Regulated Areas and Access Control
(f) Methods of Compliance
(g) Respiratory Protection
(h) Medical Surveillance
(i) Communication of Respirable Crystalline Silica Hazards to Employees
(j) Recordkeeping
(k) Dates
XVII. References
XVIII. Authority and Signature

OSHA currently enforces permissible exposure limits (PELs) for respirable crystalline silica in general industry, construction, and shipyards. These PELs were adopted in 1971, shortly after the Agency was created, and have not been updated since then. The PEL for quartz (the most common form of crystalline silica) in general industry is a formula that is approximately equivalent to 100 micrograms per cubic meter of air (μg/m^3) as an 8-hour time-weighted average. The PEL for quartz in construction and shipyards is a formula based on a now-obsolete particle count sampling method that is approximately equivalent to 250 μg/m^3. The current PELs for two other forms of crystalline silica (cristobalite and tridymite) are one-half of the values for quartz in general industry. OSHA is proposing a new PEL for respirable crystalline silica (quartz, cristobalite, and tridymite) of 50 μg/m^3 in all industry sectors covered by the rule. OSHA is also proposing other elements of a comprehensive health standard, including requirements for exposure assessment, preferred methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping.

OSHA's proposal 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 of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases, including chronic obstructive pulmonary disease (COPD).

As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in Section VIII of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed 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 revised standard and an evaluation of the potential 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 has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA directed Inforum—a not-for-profit corporation (based at the University of Maryland) well recognized for its macroeconomic modeling—to run its LIFT (Long-term Interindustry Forecasting Tool) model of the U.S. economy to estimate the industry and aggregate employment effects of the proposed silica rule. Inforum developed estimates of the employment impacts over the ten-year period from 2014–2023 by feeding OSHA's year-by-year and industry-by-industry estimates of the compliance costs of the proposed rule into its LIFT model. Based on the resulting Inforum estimates of employment impacts, OSHA has preliminarily concluded that the proposed rule would have a negligible—albeit slightly positive—net impact on aggregate U.S. employment.

OSHA believes that a new PEL, expressed as a gravimetric measurement of respirable crystalline silica, will improve compliance because the PEL is simple and relatively easy to understand. In comparison, the existing PELs require application of a formula to account for the crystalline silica content of the dust sampled and, in the case of the construction and shipyard PELs, a conversion from particle count to mg/m³ as well. OSHA also expects that the approach to methods of compliance for construction operations included in this proposal will improve compliance with the standard. This approach, which specifies exposure control methods for selected construction operations, gives employers a simple option to identify the control measures that are appropriate for these operations. Alternately, employers could conduct exposure assessments to determine if worker exposures are in compliance with the PEL. In either case, the proposed rule would provide a basis for ensuring that appropriate measures are in place to limit worker exposures.

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires that OSHA either certify that a rule would not have a significant economic impact on a substantial number of small firms or prepare a regulatory flexibility analysis and hold a Small Business Advocacy Review (SBAR) Panel prior to proposing the rule. OSHA has determined that a regulatory flexibility analysis is needed and has provided this analysis in Section VIII.G of this preamble. OSHA also previously held a SBAR Panel for this rule. The recommendations of the Panel and OSHA's response to them are summarized in Section VIII.G of this preamble.

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget, and the remainder of this section summarizes the key findings of the analysis with respect to costs and benefits of the rule and then presents several possible alternatives to the rule.

Table SI–1—which, like all the tables in this section, 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 proposed rule using a discount rate of 3 percent. As shown, the proposed rule is estimated to prevent 688 fatalities and 1,585 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $637 million annually. Also as shown in Table SI–1, the discounted monetized benefits of the proposed rule are estimated to be $5.3 billion annually, and the proposed rule is estimated to generate net benefits of $4.6 billion annually. These estimates are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed silica rule. The courts have ruled that OSHA may not use benefit-cost analysis or a criterion of maximizing net benefits as a basis for setting OSHA health standards.[1]

[1] *Am. Textile Mfrs. Inst., Inc.* v. *Nat'l Cotton Council of Am.,* 452 U.S. 490, 513 (1981); *Pub. Citizen Health Research Group* v. *U.S. Dep't of Labor,* 557 F.3d 165, 177 (3d Cir. 2009); *Friends of the Boundary Waters Wilderness* v. *Robertson,* 978 F.2d 1484, 1487 (8th Cir. 1992).

Table SI-1: Annualized Benefits, Costs and Net Benefits of OSHA's Proposed Silica Standard of 50 μg/m³

Discount Rate		**3%**
Annualized Costs		
Engineering Controls (includes Abrasive Blasting)		$329,994,068
Respirators		$90,573,449
Exposure Assessment		$72,504,999
Medical Surveillance		$76,233,932
Training		$48,779,433
Regulated Area or Access Control		$19,243,500
Total Annualized Costs (point estimate)		**$637,329,380**
Annual Benefits: Number of Cases Prevented		
Fatal Lung Cancers (midpoint estimate)	162	
Fatal Silicosis & other Non-Malignant Respiratory Diseases	375	
Fatal Renal Disease	151	
Silica-Related Mortality	688	$3,268,102,481
Silicosis Morbidity	1,585	$1,986,214,921
Monetized Annual Benefits (midpoint estimate)		**$5,254,317,401**
Net Benefits		**$4,616,988,022**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Both the costs and benefits of Table SI–1 reflect the incremental costs and benefits associated with achieving full compliance with the proposed rule. They do not include (a) costs and benefits associated with current compliance that have already been achieved with regard to the new requirements, or (b) costs and benefits associated with achieving compliance with existing requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements. They also do not include costs or benefits associated with relatively rare, extremely high exposures that can lead to acute silicosis.

Subsequent to completion of the PEA, OSHA identified an industry, hydraulic fracturing, that would be impacted by the proposed standard. Hydraulic fracturing, sometimes called ''fracking,'' is a process used to extract natural gas and oil deposits from shale and other tight geologic formations. A recent cooperative study by the National Institute for Occupational Safety and Health (NIOSH) and industry partners identified overexposures to silica among workers conducting hydraulic fracturing operations. An industry focus group has been working with OSHA and NIOSH to disseminate information about this hazard, share best practices, and develop engineering controls to limit worker exposures to silica. OSHA finds that there are now sufficient data to provide the main elements of the economic analysis for this rapidly growing industry and has done so in Appendix A to the PEA.

Based on recent data from the U.S. Census Bureau and industry sources, OSHA estimates that roughly 25,000 workers in 444 establishments (operated by 200 business entities) in hydraulic fracturing would be affected by the proposed standard. Annual benefits of the proposed 50 μg/m³ PEL include approximately 12 avoided fatalities—2.9 avoided lung cancers (mid-point estimate), 6.3 prevented non-cancer respiratory illnesses, and 2.3 prevented cases of renal failure—and 40.8 avoided cases of silicosis morbidity. Monetized benefits are expected to range from $75.1 million at a seven percent discount rate to $105.4 million at a three percent discount rate to undiscounted benefits of $140.3 million. OSHA estimates that under the proposed standard, annualized compliance costs for the hydraulic fracturing industry will total $28.6 million at a discount rate of 7 percent or $26.4 million at a discount rate of 3 percent.

In addition to the proposed rule itself, this preamble discusses several regulatory alternatives to the proposed OSHA silica standard. These are presented below as well as in Section VIII of this preamble. OSHA believes that this presentation of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to respirable crystalline silica. The second is tied to the Agency's statutory requirement, which underlies the proposed rule, to reduce significant risk to the extent feasible. If, based on evidence presented during notice and comment, OSHA is unable to justify its preliminary findings of significant risk and feasibility as presented in this preamble to the proposed rule, the Agency must then consider regulatory alternatives that do satisfy its statutory obligations.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m³; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

In addition, OSHA would like to draw attention to one possible modification to the proposed rule, involving methods of compliance, that the Agency would not consider to be a legitimate regulatory alternative: To permit the use of respiratory protection as an alternative to engineering and work practice controls as a primary means to achieve the PEL.

As described in Section XVI of the preamble, Summary and Explanation of the Proposed Standards, OSHA is proposing to require primary reliance on engineering controls and work practices because reliance on these methods is consistent with long-established good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with the Agency's traditional adherence to a hierarchy of preferred controls. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see AFL–CIO* v. *Marshall,* 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers* v. *Marshall,* 647 F.2d 1189 (D.C. Cir. 1980), *cert. denied,* 453 U.S. 913 (1981) (lead standard); *ASARCO* v. *OSHA,* 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel* v. *OSHA,* 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen* v. *U.S. Dep't of Labor,* 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

Engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored, allow for predictable performance levels, and can efficiently remove a toxic substance from the workplace. Once removed, the toxic substance no longer poses a threat to employees. The effectiveness of engineering controls does not generally depend on human behavior to the same extent as personal protective equipment does, and the operation of equipment is not as vulnerable to human error as is personal protective equipment.

Respirators are another important means of protecting workers. 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 of these conditions can reduce or eliminate the protection that respirators provide to some or all of the employees who wear them.

In addition, use of respirators in the workplace presents other safety and health concerns. Respirators impose substantial physiological burdens on some 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. Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees. These concerns about the burdens placed on workers by the use of respirators are the basis for the requirement 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. Although experience in industry shows that most healthy workers do not have physiological problems wearing properly chosen and fitted respirators, common health problems can sometime preclude an employee from wearing a respirator. Safety problems created by respirators that limit vision and communication must also be considered. In some difficult or dangerous jobs, effective vision or communication is vital. Voice transmission through a respirator can be difficult and fatiguing.

Because respirators are less reliable than engineering and work practice controls and may create additional problems, OSHA believes that primary reliance on respirators to protect workers is generally inappropriate when feasible engineering and work practice controls are available. 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. OSHA's PELs, including the current PELs for respirable crystalline silica, also incorporate this hierarchy of controls. In addition, the industry consensus standards for crystalline silica (ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities) incorporate the hierarchy of controls.

It is important to note that the very concept of technological feasibility for OSHA standards is grounded in the hierarchy of controls. As indicated in Section II of this preamble, Pertinent Legal Authority, the courts have clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . 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. [*See United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980)]

Allowing use of respirators instead of engineering and work practice controls would be at odds with this framework for evaluating the technological feasibility of a PEL.

Alternative PELs

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industry sectors covered by the rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³).

Tables SI–2 and SI–3 present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m³ and for the regulatory alternatives of a PEL of 100 μg/m³ and a PEL of 25 μg/m³ (Regulatory Alternatives #1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m³ to the proposed PEL of 50 μg/m³ and then of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Table

SI–2 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table SI–3 breaks out costs and benefits by major industry sector.

Table SI-2: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

As Tables SI–2 and SI–3 show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its preliminary findings that the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically

Table SI-3: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables SI–2 and SI–3 also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA preliminarily determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables SI–2 and SI–3, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other than the PEL), including requirements for exposure assessment, medical surveillance, training, and regulated areas or access control. As shown in Table SI–2, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in this preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) Help ensure that the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table SI–4. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Under Regulatory Alternative #3, the action level would be raised from 25 μg/m³ to 50 μg/m³ while keeping the PEL at 50 μg/m³. As a result, exposure monitoring requirements would be triggered only if workers were exposed

Table SI-4: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	—	—	—
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	—	—	—
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

above the proposed PEL of 50 μg/m³. As shown in Table SI–4, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table SI–4, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table SI–4, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table SI–4, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, 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 employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed construction standard, employers would

be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under that regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

OSHA will strongly consider alternatives that would reduce the economic impact of the rule and provide additional flexibility for firms coming into compliance with the requirements of the rule. The Agency solicits comment and suggestions from stakeholders, particularly small business representatives, on options for phasing in requirements for engineering controls, medical surveillance, and other provisions of the rule (*e.g.,* over 1, 2, 3, or more years). These options will be considered for specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

Although OSHA did not explicitly develop or quantitatively analyze the multitude of potential regulatory alternatives involving longer-term or more complex phase-ins of the standard, the Agency is soliciting comments on this issue. Such a particularized, multi-year phase-in could have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. Second, a differential phase-in for smaller firms would aid very small firms by allowing them to gain from the control experience of larger firms. Finally, a phase-in would be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard.

OSHA analyzed one regulatory alternative (Regulatory Alternative #9) involving the timing of the standard which would arise if, contrary to OSHA's preliminary findings, a PEL of 50 μg/m^3 with an action level of 25 μg/m^3 were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 μg/m^3 and an action level of 25 μg/m^3 to take effect in five years, but at the same time issue an interim PEL of 100 μg/m^3 and an action level of 50 μg/m^3 to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 μg/m^3 with an action level of 50 μg/m^3 and those estimated for a PEL of 50 μg/m^3 with an action level of 25 μg/m^3, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

I. Issues

OSHA requests comment on all relevant issues, including health effects, risk assessment, significance of risk, technological and economic feasibility, and the provisions of the proposed regulatory text. In addition, OSHA requests comments on all of the issues raised by the Small Business Regulatory Fairness Enforcement Act (SBREFA) Panel, as summarized in Table VIII–H–4 in Section VIII.H of this preamble.

OSHA is including Section I on issues at the beginning of the document to assist readers as they review the proposal and consider any comments they may want to submit. However, to fully understand the questions in this section and provide substantive input in response to them, the parts of the preamble that address these issues in detail should be read and reviewed. These include: Section V, Health Effects Summary; Section VI, Summary of the Preliminary Quantitative Risk Assessment; Section VII, Significance of Risk; Section VIII, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis; and Section XVI, Summary and Explanation of the Standards. In addition, OSHA invites comment on additional technical questions and discussions of economic issues presented in the Preliminary Economic Analysis (PEA) of the proposed standards. Section XIX is the text of the standards and is the final authority on what is required in them.

OSHA requests that comments be organized, to the extent possible, around the following issues and numbered questions. Comment on particular provisions should contain a heading setting forth the section and the paragraph in the standard that the comment is addressing. Comments addressing more than one section or paragraph will have correspondingly more headings.

Submitting comments in an organized manner and with clear reference to the issue raised will enable all participants

to easily see what issues the commenter addressed and how they were addressed. This is particularly important in a rulemaking such as silica, which has multiple adverse health effects and affects many diverse processes and industries. Many commenters, especially small businesses, are likely to confine their interest (and comments) to the issues that affect them, and they will benefit from being able to quickly identify comments on these issues in others' submissions. Of course, the Agency welcomes comments concerning this proposal that fall outside the issues raised in this section. However, OSHA is especially interested in responses, supported by evidence and reasons, to the following questions:

Health Effects

1. OSHA has described a variety of studies addressing the major adverse health effects that have been associated with exposure to respirable crystalline silica. Has OSHA adequately identified and documented all critical health impairments associated with occupational exposure to respirable crystalline silica? If not, what adverse health effects should be added? Are there any additional studies, other data, or information that would affect the information discussed or significantly change the determination of material health impairment? Submit any relevant information, data, or additional studies (or the citations), and explain your reasoning for recommending the inclusion of any studies you suggest.

2. Using currently available epidemiologic and experimental studies, OSHA has made a preliminary determination that respirable crystalline silica presents risks of lung cancer, silicosis, and non-malignant respiratory disease (NMRD) as well as autoimmune and renal disease risks to exposed workers. Is this determination correct? Are there additional studies or other data OSHA should consider in evaluating any of these adverse health risks? If so, submit the studies (or citations) and other data and include your reasons for finding them germane to determining adverse health effects of exposure to crystalline silica.

Risk Assessment

3. OSHA has relied upon risk models using cumulative respirable crystalline silica exposure to estimate the lifetime risk of death from occupational lung cancer, silicosis, and NMRD among exposed workers. Additionally, OSHA has estimated the lifetime risk of silicosis morbidity among exposed workers. Is cumulative exposure the correct metric for exposure for each of these models? If not, what exposure measure should be used?

4. Some of the literature OSHA reviewed indicated that the risk of contracting accelerated silicosis and lung cancer may be non-linear at very high exposures and may be described by an exposure dose rate health effect model. OSHA used the more conservative model of cumulative exposure that is more protective to the worker. Are there additional data to support or rebut any of these models used by OSHA? Are there other models that OSHA should consider for estimating lung cancer, silicosis, or NMRD risk? If so, describe the models and the rationale for their use.

5. Are there additional studies or sources of data that OSHA should have included in its qualitative and quantitative risk assessments? What are these studies and have they been peer-reviewed, or are they soon to be peer-reviewed? What is the rationale for recommending the studies or data?

6. Steenland et al. (2001a) pooled data from 10 cohort studies to conduct an analysis of lung cancer mortality among silica-exposed workers. Can you provide quantitative lung cancer risk estimates from other data sources? Have or will the data you submit be peer-reviewed? OSHA is particularly interested in quantitative risk analyses that can be conducted using the industrial sand worker studies by McDonald, Hughes, and Rando (2001) and the pooled center-based case-control study conducted by Cassidy et al. (2007).

7. OSHA has made a preliminary determination that the available data are not sufficient or suitable for quantitative analysis of the risk of autoimmune disease, stomach cancer, and other cancer and non-cancer health effects. Do you have, or are you aware of, studies, data, and rationale that would be suitable for a quantitative risk assessment for these adverse health effects? Submit the studies (or citations), data, and rationale.

Profile of Affected Industries

8. In its PEA of the proposed rule, summarized in Section VIII of this preamble, OSHA presents a profile of the affected worker population. The profile includes estimates of the number of affected workers by industry sector or operation and job category, and the distribution of exposures by job category. If your company has potential worker exposures to respirable crystalline silica, is your industry among those listed by North American Industry Classification System (NAICS) code as affected industries? Are there additional data that will enable the Agency to refine its profile of the worker population exposed to respirable crystalline silica? If so, provide or reference such data and explain how OSHA should use these data to revise the profile.

Technological and Economic Feasibility of the Proposed PEL

9. What are the job categories in which employees are potentially exposed to respirable crystalline silica in your company or industry? For each job category, provide a brief description of the operation and describe the job activities that may lead to respirable crystalline silica exposure. How many employees are exposed, or have the potential for exposure, to respirable crystalline silica in each job category in your company or industry? What are the frequency, duration, and levels of exposures to respirable crystalline silica in each job category in your company or industry? Where responders are able to provide exposure data, OSHA requests that, where available, exposure data be personal samples with clear descriptions of the length of the sample, analytical method, and controls in place. Exposure data that provide information concerning the controls in place are more valuable than exposure data without such information.

10. Please describe work environments or processes that may expose workers to cristobalite. Please provide supporting evidence, or explain the basis of your knowledge.

11. Have there been technological changes within your industry that have influenced the magnitude, frequency, or duration of exposure to respirable crystalline silica or the means by which employers attempt to control such exposures? Describe in detail these technological changes and their effects on respirable crystalline silica exposures and methods of control.

12. Has there been a trend within your industry or an effort in your firm to reduce or eliminate respirable crystalline silica from production processes, products, and services? If so, please describe the methods used and provide an estimate of the percentage reduction in respirable crystalline silica, and the extent to which respirable crystalline silica is still necessary in specific processes within product lines or production activities. If you have substituted another substance(s) for crystalline silica, identify the substance(s) and any adverse health effects associated with exposure to the substitute substances, and the cost impact of substitution (cost of materials, productivity impact). OSHA also

requests that responders describe any health hazards or technical, economic, or other deterrents to substitution.

13. Has your industry or firm used outsourcing or subcontracting, or concentrated high exposure tasks in-house, in order to expose fewer workers to respirable crystalline silica? An example would be subcontracting for the removal of hardened concrete from concrete mixing trucks, a task done typically 2–4 times a year, to a specialty subcontractor. What methods have you used to reduce the number of workers exposed to respirable crystalline silica and how were they implemented? Describe any trends related to concentration of high exposure tasks and provide any supporting information.

14. Does any job category or employee in your workplace have exposures to respirable crystalline silica that air monitoring data do not adequately portray due to the short duration, intermittent or non-routine nature, or other unique characteristics of the exposure? Explain your response and indicate peak levels, duration, and frequency of exposures for employees in these job categories.

15. OSHA requests the following information regarding engineering and work practice controls to control exposure to crystalline silica in your workplace or industry:

a. Describe the operations and tasks in which the proposed PEL is being achieved most of the time by means of engineering and work practice controls.

b. What engineering and work practice controls have been implemented in these operations and tasks?

c. For all operations and tasks in facilities where respirable crystalline silica is used, what engineering and work practice controls have been implemented to control respirable crystalline silica? If you have installed engineering controls or adopted work practices to reduce exposure to respirable crystalline silica, describe the exposure reduction achieved and the cost of these controls.

d. Where current work practices include the use of regulated areas and hygiene facilities, provide data on the implementation of these controls, including data on the costs of installation, operation, and maintenance associated with these controls.

e. Describe additional engineering and work practice controls that could be implemented in each operation where exposure levels are currently above the proposed PEL to further reduce exposure levels.

f. When these additional controls are implemented, to what levels can exposure be expected to be reduced, or what percent reduction is expected to be achieved?

g. What amount of time is needed to develop, install, and implement these additional controls? Will the added controls affect productivity? If so, how?

h. Are there any processes or operations for which it is not reasonably possible to implement engineering and work practice controls within one year to achieve the proposed PEL? If so, how much additional time would be necessary?

16. OSHA requests information on whether there are any specific conditions or job tasks involving exposure to respirable crystalline silica where engineering and work practice controls are not available or are not capable of reducing exposure levels to or below the proposed PEL most of the time. Provide data and evidence to support your response.

17. OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. OSHA has further made a preliminary determination that the proposed rule is technologically feasible. OSHA solicits comments on the reasonableness of these preliminary determinations.

Compliance Costs

18. In its PEA (summarized in Section VIII.3 of this preamble), OSHA developed its estimate of the costs of the proposed rule. The Agency requests comment on the methodological and analytical assumptions applied in the cost analysis. Of particular importance are the unit cost estimates provided in tables and text in Chapter V of the PEA for all major provisions of the proposed rule. OSHA requests the following information regarding unit and total compliance costs:

a. If you have installed engineering controls or adopted work practices to reduce exposure to respirable crystalline silica, describe these controls and their costs. If you have substituted another substance(s) for crystalline silica, what has been the cost impact of substitution (cost of materials, productivity impact)?

b. OSHA has proposed to limit the prohibition on dry sweeping to situations where this activity could contribute to exposure that exceeds the PEL and estimated the costs for the use of wet methods to control dust. OSHA requests comment on the use of wet methods as a substitute for dry sweeping and whether the prohibition on dry sweeping is feasible and cost-effective.

c. In its PEA, OSHA presents estimated baseline levels of use of personal protective equipment (PPE) and the incremental PPE costs associated with the proposed rule. Are OSHA's estimated PPE compliance rates reasonable? Are OSHA's estimates of PPE costs, and the assumptions underlying these estimates, consistent with current industry practice? If not, provide data and evidence describing current industry PPE practices.

d. Do you currently conduct exposure monitoring for respirable crystalline silica? Are OSHA's estimates of exposure assessment costs reasonable? Would your company require outside consultants to perform exposure monitoring?

e. Are OSHA's estimates for medical surveillance costs—including direct medical costs, the opportunity cost of worker time for offsite travel and for the health screening, and recordkeeping costs—reasonable?

f. In its PEA, OSHA presents estimated baseline levels of training and information concerning respirable crystalline silica-related hazards and the incremental costs associated with the additional requirements for training and information in the proposed rule. OSHA requests information on information and training programs addressing respirable crystalline silica that are currently being implemented by employers and any necessary additions to those programs that are anticipated in response to the proposed rule. Are OSHA's baseline estimates and unit costs for training reasonable and consistent with current industry practice?

g. Are OSHA's estimated costs for regulated areas and written access control plans reasonable?

h. The cost estimates in the PEA take the much higher labor turnover rates in construction into account when calculating costs. For the proposed rule, OSHA used the most recent BLS turnover rate of 64 percent for construction (versus a turnover rate of 27.2 percent for general industry). OSHA believes that the estimates in the PEA capture the effect of high turnover rates in construction and solicits comments on this issue.

i. Has OSHA omitted any costs that would be incurred to comply with the proposed rule?

Effects on Small Entities

19. OSHA has considered the effects on small entities raised during its SBREFA process and addressed these concerns in Chapter VIII of the PEA. Are there additional difficulties small

entities may encounter when attempting to comply with requirements of the proposed rule? Can any of the proposal's requirements be deleted or simplified for small entities, while still providing equivalent protection of the health of employees? Would allowing additional time for small entities to comply make a difference in their ability to comply? How much additional time would be necessary?

Economic Impacts

20. OSHA, in its PEA, has estimated compliance costs per affected entity and the likely impacts on revenues and profits. OSHA requests that affected employers provide comment on OSHA's estimate of revenue, profit, and the impacts of costs for their industry or application group. The Agency also requests that employers provide data on their revenues, profits, and the impacts of cost, if available. Are there special circumstances—such as unique cost factors, foreign competition, or pricing constraints—that OSHA needs to consider when evaluating economic impacts for particular applications and industry groups?

21. OSHA seeks comment as to whether establishments will be able to finance first-year compliance costs from cash flow, and under what circumstances a phase-in approach will assist firms in complying with the proposed rule.

22. The Agency invites comment on potential employment impacts of the proposed silica rule, and on Inforum's estimates of the employment impacts of the proposed silica rule on the U.S. economy.

Outreach and Compliance Assistance

23. If the proposed rule is promulgated, OSHA will provide outreach materials on the provisions of the standards in order to encourage and assist employers in complying. Are there particular materials that would make compliance easier for your company or industry? What materials would be especially useful for small entities? Submit recommendations or samples.

Benefits and Net Benefits

24. OSHA requests comments on any aspect of its estimation of benefits and net benefits from the proposed rule, including the following:

a. The use of willingness-to-pay measures and estimates based on compensating wage differentials.

b. The data and methods used in the benefits calculations.

c. The choice of discount rate for annualizing the monetized benefits of the proposed rule.

d. Increasing the monetary value of a statistical life over time resulting from an increase in real per capita income and the estimated income elasticity of the value of life.

e. Extending the benefits analysis beyond the 60-year period used in the PEA.

f. The magnitude of non-quantified health benefits arising from the proposed rule and methods for better measuring these effects. An example would be diagnosing latent tuberculosis (TB) in the silica-exposed population and thereby reducing the risk of TB being spread to the population at large.

Overlapping and Duplicative Regulations

25. Do any federal regulations duplicate, overlap, or conflict with the proposed respirable crystalline silica rule? If so, provide or cite to these regulations.

Alternatives/Ways to Simplify a New Standard

26. Comment on the alternative to new comprehensive standards (which have ancillary provisions in addition to a permissible exposure limit) that would be simply improved outreach and enforcement of the existing standards (which is only a permissible exposure limit with no ancillary provisions). Do you believe that improved outreach and enforcement of the existing permissible exposure limits would be sufficient to reduce significant risks of material health impairment in workers exposed to respirable crystalline silica? Provide information to support your position.

27. OSHA solicits comments on ways to simplify the proposed rule without compromising worker protection from exposure to respirable crystalline silica. In particular, provide detailed recommendations on ways to simplify the proposed standard for construction. Provide evidence that your recommended simplifications would result in a standard that was effective, to the extent feasible, in reducing significant risks of material health impairment in workers exposed to respirable crystalline silica.

Environmental Impacts

28. Submit data, information, or comments pertaining to possible environmental impacts of adopting this proposal, including any positive or negative environmental effects and any irreversible commitments of natural resources that would be involved. In particular, consideration should be given to the potential direct or indirect impacts of the proposal on water and air pollution, energy use, solid waste disposal, or land use. Would compliance with the silica rule require additional actions to comply with federal, state, or local environmental requirements?

29. Some small entity representatives advised OSHA that the use of water as a control measure is limited at their work sites due to potential water and soil contamination. OSHA believes these limits may only apply in situations where crystalline silica is found with other toxic substances such as during abrasive blasting of metal or painted metal structures, or in locations where state and local requirements are more restrictive than EPA requirements. OSHA seeks comments on this issue, including cites to applicable requirements.

a. Are there limits on the use of water controls in your operations due to environmental regulations? If so, are the limits due to the non-silica components of the waste stream? What are these non-silica components?

b. What metals or other toxic chemicals are in your silica waste streams and what are the procedures and costs to filter out these metals or other toxic chemicals from your waste streams? Provide documentation to support your cost estimates.

Provisions of the Standards

Scope

30. OSHA's Advisory Committee on Construction Safety and Health (ACCSH) has historically advised the Agency to take into consideration the unique nature of construction work environments by either setting separate standards or making accommodations for the differences in work environments in construction as compared to general industry. ASTM, for example, has separate silica standards of practice for general industry and construction, E 1132–06 and E 2625–09, respectively. To account for differences in the workplace environments for these different sectors, OSHA has proposed separate standards for general industry/maritime and construction. Is this approach necessary and appropriate? What other approaches, if any, should the Agency consider? Provide a rationale for your response.

31. OSHA has proposed that the scope of the construction standard include all occupational exposures to respirable crystalline silica in construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926, rather

than restricting the application of the rule to specific construction operations. Should OSHA modify the scope to limit what is covered? What should be included and what should be excluded? Provide a rationale for your position. Submit your proposed language for the scope and application provision.

32. OSHA has not proposed to cover agriculture because the Agency does not have data sufficient to determine the feasibility of the proposed PEL in agricultural operations. Should OSHA cover respirable crystalline silica exposure in agriculture? Provide evidence to support your position. OSHA seeks information on agricultural operations that involve respirable crystalline silica exposures, including information that identifies particular activities or crops (*e.g.,* hand picking fruit and vegetables, shaking branches and trees, harvesting with combines, loading storage silos, planting) associated with exposure, information indicating levels of exposure, and information relating to available control measures and their effectiveness. OSHA also seeks information related to the development of respirable crystalline silica-related adverse health effects and diseases among workers in the agricultural sector.

33. Should OSHA limit coverage of the rule to materials that contain a threshold concentration (*e.g.,* 1%) of crystalline silica? For example, OSHA's Asbestos standard defines ''asbestos-containing material'' as any material containing more than 1% asbestos, for consistency with EPA regulations. OSHA has not proposed a comparable limitation to the definition of respirable crystalline silica. Is this approach appropriate? Provide the rationale for your position.

34. OSHA has proposed to cover shipyards under the general industry standard. Are there any unique circumstances in shipyard employment that would justify development of different provisions or a separate standard for the shipyard industry? What are the circumstances and how would they not be adequately covered by the general industry standard?

Definitions

35. Competent person. OSHA has proposed limited duties for a competent person relating to establishment of an access control plan. The Agency did not propose specific requirements for training of a competent person. Is this approach appropriate? Should OSHA include a competent person provision? If so, should the Agency add to, modify, or delete any of the duties of a competent person as described in the proposed standard? Provide the basis for your recommendations.

36. Has OSHA defined ''respirable crystalline silica'' appropriately? If not, provide the definition that you believe is appropriate. Explain the basis for your response, and provide any data that you believe are relevant.

37. The proposed rule defines ''respirable crystalline silica'' in part as ''airborne particles that contain quartz, cristobalite, and/or tridymite.'' OSHA believes that tridymite is rarely found in nature or in the workplace. Please describe any instances of occupational exposure to tridymite of which you are aware. Please provide supporting evidence, or explain the basis of your knowledge. Should tridymite be included in the scope of this proposed rule? Please provide any evidence to support your position.

PEL and Action Level

38. OSHA has proposed a TWA PEL for respirable crystalline silica of 50 μg/m^3 for general industry, maritime, and construction. The Agency has made a preliminary determination that this is the lowest level that is technologically feasible. The Agency has also determined that a PEL of 50 μg/m^3 will substantially reduce, but not eliminate, significant risk of material health impairment. Is this PEL appropriate, given the Agency's obligation to reduce significant risk of material health impairment to the extent feasible? If not, what PEL would be more appropriate? The Agency also solicits comment on maintaining the existing PELs for respirable crystalline silica. Provide evidence to support your response.

39. OSHA has proposed a single PEL for respirable crystalline silica (quartz, cristobalite, and tridymite). Is a single PEL appropriate, or should the Agency maintain separate PELs for the different forms of respirable crystalline silica? Provide the rationale for your position.

40. OSHA has proposed an action level for respirable crystalline silica exposure of 25 μg/m^3 in general industry, maritime, and construction. Is this an appropriate approach and level, and if not, what approach or level would be more appropriate and why? Should an action level be included in the final rule? Provide the rationale for your position.

41. If an action level is included in the final rule, which provisions, if any, should be triggered by exposure above or below the action level? Provide the basis for your position and include supporting information.

42. If no action level is included in the final rule, which provisions should apply to all workers exposed to respirable crystalline silica? Which provisions should be triggered by the PEL? Are there any other appropriate triggers for the requirements of the rule?

Exposure Assessment

43. OSHA is proposing to allow employers to initially assess employee exposures using air monitoring or objective data. Has OSHA defined ''objective data'' sufficiently for an employer to know what data may be used? If not, submit an alternative definition. Is it appropriate to allow employers to use objective data to perform exposure assessments? Explain why or why not.

44. The proposed rule provides two options for periodic exposure assessment: (1) A fixed schedule option, and (2) a performance option. The performance option provides employers flexibility in the methods used to determine employee exposures, but requires employers to accurately characterize employee exposures. The proposed approach is explained in the Summary and Explanation for paragraph (d) Exposure Assessment. OSHA solicits comments on this proposed exposure assessment provision. Is the wording of the performance option in the regulatory text understandable and does it clearly indicate what would constitute compliance with the provision? If not, suggest alternative language that would clarify the provision, enabling employers to more easily understand what would constitute compliance.

45. Do you conduct initial air monitoring or do you rely on objective data to determine respirable crystalline silica exposures? If objective data, what data do you use? Have you conducted historical exposure monitoring of your workforce that is representative of current process technology and equipment use? Describe any other approaches you have implemented for assessing an employee's initial exposure to respirable crystalline silica.

46. OSHA is proposing specific requirements for laboratories that perform analyses of respirable crystalline silica samples. The rationale is to improve the precision in individual laboratories and reduce the variability of results between laboratories, so that sampling results will be more reliable. Are these proposed requirements appropriate? Will the laboratory requirements add necessary reliability and reduce inter-lab variability, or might they be overly proscriptive? Provide the basis for your response.

47. Has OSHA correctly described the accuracy and precision of existing methods of sampling and analysis for

respirable crystalline silica at the proposed action level and PEL? Can worker exposures be accurately measured at the proposed action level and PEL? Explain the basis for your response, and provide any data that you believe are relevant.

48. OSHA has not addressed the performance of the analytical method with respect to tridymite since we have found little available data. Please comment on the performance of the analytical method with respect to tridymite and provide any data to support your position.

Regulated Areas and Access Control

49. Where exposures exceed the PEL, OSHA has proposed to provide employers with the option of either establishing a regulated area or establishing a written access control plan. For which types of work operations would employers be likely to establish a written access control plan? Will employees be protected by these options? Provide the basis for your position and include supporting information.

50. The Summary and Explanation for paragraph (e) Regulated Areas and Access Control clarifies how the regulated area requirements would apply to multi-employer worksites in the proposed standard. OSHA solicits comments on this issue.

51. OSHA is proposing limited requirements for protective clothing in the silica rule. Is this appropriate? Are you aware of any situations where more or different protective clothing would be needed for silica exposures? If so, what type of protective clothing and equipment should be required? Are there additional provisions related to protective clothing that should be incorporated into this rule that will enhance worker protection? Provide the rationale and data that support your conclusions.

Methods of Compliance

52. In OSHA's cadmium standard (29 CFR 1910.1027(f)(1)(ii),(iii), and (iv)), the Agency established separate engineering control air limits (SECALs) for certain processes in selected industries. SECALs were established where compliance with the PEL by means of engineering and work practice controls was infeasible. For these industries, a SECAL was established at the lowest feasible level that could be achieved by engineering and work practice controls. The PEL was set at a lower level, and could be achieved by any allowable combination of controls, including respiratory protection. In OSHA's chromium (VI) standard (29 CFR 1910.1026), an exception similar to SECALs was made for painting airplanes and airplane parts. Should OSHA follow this approach for respirable crystalline silica in any industries or processes? If so, in what industries or processes, and at what exposure levels, should the SECALs be established? Provide the basis for your position and include supporting information.

53. The proposed standards do not contain a requirement for a written exposure control program. The two ASTM standards for general industry and construction (E 1132–06, section 4.2.6, and E 2626–09, section 4.2.5) state that, where overexposures are persistent (such as in regulated areas or abrasive blasting operations), a written exposure control plan shall establish engineering and administrative controls to bring the area into compliance, if feasible. In addition, the proposed regulatory language developed by the Building and Construction Trades Department, AFL–CIO contains provisions for a written program. The ASTM standards recommend that, where there are regulated areas with persistent exposures or tasks, tools, or operations that tend to cause respirable crystalline silica exposure, the employer will conduct a formal analysis and implement a written control plan (an abatement plan) on how to bring the process into compliance. If that is not feasible, the employer is to indicate the respiratory protection and other protective procedures that will be used to protect employee(s) permanently or until compliance will be achieved. Should OSHA require employers to develop and implement a written exposure control plan and, if so, what should be required to be in the plans?

54. Table 1 in the proposed construction standard specifies engineering and work practice controls and respiratory protection for selected construction operations, and exempts employers who implement these controls from exposure assessment requirements. Is this approach appropriate? Are there other operations that should be included, or listed operations that should not be included? Are the specified control measures effective? Should any other changes be made in Table 1? How should OSHA update Table 1 in the future to account for development of new technologies? Provide data and information to support your position.

55. OSHA requests comments on the degree of specificity used for the engineering and work practice controls for tasks identified in Table 1, including maintenance requirements. Should OSHA require an evaluation or inspection checklist for controls? If so, how frequently should evaluations or inspections be conducted? Provide any examples of such checklists, along with information regarding their frequency of use and effectiveness.

56. In the proposed construction standard, when employees perform an operation listed in Table 1 and the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1 for that operation, the employer is not required to assess the exposure of the employees performing such operations. However, the employer must still ensure compliance with the proposed PEL for that operation. OSHA seeks comment on whether employers fully complying with Table 1 for an operation should still need to comply with the proposed PEL for that operation. Instead, should OSHA treat compliance with Table 1 as automatically meeting the requirements of the proposed PEL?

57. Are the descriptions of the operations (specific task or tool descriptions) and control technologies in Table 1 clear and precise enough so that employers and workers will know what controls they should be using for the listed operations? Identify the specific operation you are addressing and whether your assessment is based on your anecdotal experience or research. For each operation, are the data and other supporting information sufficient to predict the range of expected exposures under the controlled conditions? Identify operations, if any, where you believe the data are not sufficient. Provide the reasoning and data that support your position.

58. In one specific example from Table 1, OSHA has proposed the option of using a wet method for hand-operated grinders, with respirators required only for operations lasting four hours or more. Please comment and provide OSHA with additional information regarding wet grinding and the adequacy of this control strategy. OSHA is also seeking additional information on the second option (commercially available shrouds and dust collection systems) to confirm that this control strategy (including the use of half-mask respirators) will reduce workers' exposure to or below the PEL.

59. For impact drilling operations lasting four hours or less, OSHA is proposing in Table 1 to allow workers to use water delivery systems without the use of respiratory protection, as the Agency believes that this dust suppression method alone will provide

consistent, sufficient protection. Is this control strategy appropriate? Please provide the basis for your position and any supporting evidence or additional information that addresses the appropriateness of this control strategy.

60. In the case of rock drilling, in order to ensure that workers are adequately protected from the higher exposures that they would experience working under shrouds, OSHA is proposing in Table 1 that employers ensure that workers use half-mask respirators when working under shrouds at the point of operation. Is this specification appropriate? Please provide the basis for your position and any supporting evidence or additional information that addresses the appropriateness of this specification.

61. OSHA has specified a control strategy for concrete drilling in Table 1 that includes use of a dust collection system as well as a low-flow water spray. Please provide to OSHA any data that you have that describes the efficacy of these controls. Is the control strategy in Table 1 adequate? Please provide the basis for your position and any supporting evidence or additional information regarding the adequacy of this control strategy.

62. One of the control options in Table 1 in the proposed construction standard for rock-crushing operations is local exhaust ventilation. However, OSHA is aware of difficulties in applying this control to this operation. Is this control strategy appropriate and practical for rock-crushing operations? Please provide any information that you have addressing this issue.

63. OSHA has not proposed to prohibit the use of crystalline silica as an abrasive blasting agent. Abrasive blasting, similar to other operations that involve respirable crystalline silica exposures, must follow the hierarchy of controls, which means, if feasible, that substitution, engineering, or administrative controls or a combination of these controls must be used to minimize or eliminate the exposure hazard. Is this approach appropriate? Provide the basis for your position and any supporting evidence.

64. The technological feasibility study (PEA, Chapter 4) indicates that employers use substitutes for crystalline silica in a variety of operations. If you are aware of substitutes for crystalline silica that are currently being used in any operation not considered in the feasibility study, please provide to OSHA relevant information that contains data supporting the effectiveness, in reducing exposure to crystalline silica, of those substitutes. Provide any information you may have on the health hazards associated with exposure to these substitutes.

65. Information regarding the effectiveness of dust control kits that incorporate local exhaust ventilation in the railroad transportation industry in reducing worker exposure to crystalline silica is not available from the manufacturer. If you have any relevant information on the effectiveness of such kits, please provide it to OSHA.

66. The proposed rule prohibits the use of compressed air and dry brushing and sweeping for cleaning of surfaces and clothing in general industry, maritime, and construction and promotes the use of wet methods and HEPA-filter vacuuming as alternatives. Are there any circumstances in general industry, maritime, or construction work where dry sweeping is the only kind of sweeping that can be done? Have you done dry sweeping and, if so, what has been your experience with it? What methods have you used to minimize dust when dry sweeping? Can exposure levels be kept below the proposed PEL when dry sweeping is conducted? How? Provide exposure data for periods when you conducted dry sweeping. If silica respirable dust samples are not available, provide real time respirable dust or gravimetric respirable dust data. Is water available at most sites to wet down dust prior to sweeping? How effective is the use of water? Does the use of water cause other problems for the worksite? Are there other substitutes that are effective?

67. A 30-day exemption from the requirement to implement engineering and work practice controls was not included in the proposed standard for construction, and has been removed from the proposed standard for general industry and maritime. OSHA requests comment on this issue.

68. The proposed prohibition on employee rotation is explained in the Summary and Explanation for paragraph (f) Methods of Compliance. OSHA solicits comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL.

Medical Surveillance

69. Is medical surveillance being provided for respirable crystalline silica-exposed employees at your worksite? If so:

a. How do you determine which employees receive medical surveillance (*e.g.,* by exposure level or other factors)?

b. Who administers and implements the medical surveillance (*e.g.,* company doctor or nurse, outside doctor or nurse)?

c. What examinations, tests, or evaluations are included in the medical surveillance program? Does your medical surveillance program include testing for latent TB? Do you include pulmonary function testing in your medical surveillance program?

d. What benefits (*e.g.,* health, reduction in absenteeism, or financial) have been achieved from the medical surveillance program?

e. What are the costs of your medical surveillance program? How do your costs compare with OSHA's estimated unit costs for the physical examination and employee time involved in the medical surveillance program? Are OSHA's baseline assumptions and cost estimates for medical surveillance consistent with your experiences providing medical surveillance to your employees?

f. How many employees are included in your medical surveillance program?

g. What NAICS code describes your workplace?

70. Is the content and frequency of proposed examinations appropriate? If not, how should content and frequency be modified?

71. Is the specified content of the physician or other licensed health care professional's (PLHCP) written medical opinion sufficiently detailed to enable the employer to address the employee's needs and potential workplace improvements, and yet appropriately limited so as to protect the employee's medical privacy? If not, how could the medical opinion be improved?

72. Is the requirement for latent TB testing appropriate? Does the proposed rule implement this requirement in a cost-effective manner? Provide the data or cite references that support your position.

73. Is the requirement for pulmonary function testing initially and at three-year intervals appropriate? Is there an alternate strategy or schedule for conducting follow-up testing that is better? Provide data or cite references to support your position.

74. Is the requirement for chest X-rays initially and at three-year intervals appropriate? Is there an alternate strategy or schedule for conducting follow-up chest X-rays that you believe would be better? Provide data or cite references to support your position.

75. Are there other tests that should be included in medical surveillance?

76. Do you provide medical surveillance to employees under another OSHA standard or as a matter of company policy? If so, describe your program in terms of what standards the program addresses and such factors as content and frequency of examinations

and referrals, and reports to the employer.

77. Is exposure for 30 days at or above the PEL the appropriate number of days to trigger medical surveillance? Should the appropriate reference for medical monitoring be the PEL or the action level? Is 30 days from initial assignment a reasonable amount of time to provide a medical exam? Indicate the basis for your position.

78. Are PLHCPs available in your geographic area to provide medical surveillance to workers who are covered by the proposed rule? For example, do you have access to qualified X-ray technicians, NIOSH-certified B-readers, and pulmonary specialists? Describe any difficulties you may have with regard to access to PLHCPs to provide surveillance for the rule. Note what you consider your ''geographic area'' in responding to this question.

79. OSHA is proposing to allow an ''equivalent diagnostic study'' in place of requirements to use a chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration; interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader). Two other radiological test methods, computed tomography (CT) and high resolution computed tomography (HRCT), could be considered ''equivalent diagnostic studies'' under paragraph (h)(2)(iii) of the proposal. However, the benefits of CT or HRCT should be balanced with risks, including higher radiation doses. Also, standardized methods for interpreting and reporting results of CT or HRCT are not currently available. The Agency requests comment on whether CT and HRCT should be considered ''equivalent diagnostic studies'' under the rule. Provide a rationale and evidence to support your position.

80. OSHA has not included requirements for medical removal protection (MRP) in the proposed rule, because OSHA has made a preliminary determination that there are few instances where temporary worker removal and MRP will be useful. The Agency requests comment as to whether the respirable crystalline silica rule should include provisions for the temporary removal and extension of MRP benefits to employees with certain respirable crystalline silica-related health conditions. In particular, what medical conditions or findings should trigger temporary removal and for what maximum amount of time should MRP benefits be extended? OSHA also seeks information on whether or not MRP is currently being used by employers with respirable crystalline silica-exposed workers, and the costs of such programs.

Hazard Communication and Training

81. OSHA has proposed that employers provide hazard information to employees in accordance with the Agency's Hazard Communication standard (29 CFR 1910.1200). Compliance with the Hazard Communication standard would mean that there would be a requirement for a warning label for substances that contain more than 0.1 percent crystalline silica. Should this requirement be changed so that warning labels would only be required of substances more than 1 percent by weight of silica? Provide the rationale for your position. The Agency also has proposed additional training specific to work with respirable crystalline silica. Should OSHA include these additional requirements in the final rule, or are the requirements of the Hazard Communication standard sufficient?

82. OSHA is providing an abbreviated training section in this proposal as compared to ASTM consensus standards (*see* ASTM E 1132–06, sections 4.8.1–5). The Hazard Communication standard is comprehensive and covers most of the training requirements traditionally included in an OSHA health standard. Do you concur with OSHA that performance-based training specified in the Hazard Communication standard, supplemented by the few training requirements of this section, is sufficient in its scope and depth? Are there any other training provisions you would add?

83. The proposed rule does not alter the requirements for substances to have warning labels, specify wording for labels, or otherwise modify the provisions of the OSHA's Hazard Communication standard. OSHA invites comment on these issues.

Recordkeeping

84. OSHA is proposing to require recordkeeping for air monitoring data, objective data, and medical surveillance records. The proposed rule's recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) Recordkeeping. The Agency seeks comment on the utility of these recordkeeping requirements as well as the costs of making and maintaining these records. Provide evidence to support your position.

Dates

85. OSHA requests comment on the time allowed for compliance with the provisions of the proposed rule. Is the time proposed appropriate, or should there be a longer or shorter phase-in of requirements? In particular, should requirements for engineering controls and/or medical surveillance be phased in over a longer period of time (*e.g.,* over 1, 2, 3, or more years)? Should an extended phase-in period be provided for specific industries (*e.g.,* industries where first-year or annualized cost impacts are highest), specific size-classes of employers (*e.g.,* employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule? Identify any industries, processes, or operations that have special needs for additional time, the additional time required, and the reasons for the request.

86. OSHA is proposing a two-year start-up period to allow laboratories time to achieve compliance with the proposed requirements, particularly with regard to requirements for accreditation and round robin testing. OSHA also recognizes that requirements for monitoring in the proposed rule will increase the required capacity for analysis of respirable crystalline silica samples. Do you think that this start-up period is enough time for laboratories to achieve compliance with the proposed requirements and to develop sufficient analytic capacity? If you think that additional time is needed, please tell OSHA how much additional time is required and give your reasons for this request.

Appendices

87. Some OSHA health standards include appendices that address topics such as the hazards associated with the regulated substance, health screening considerations, occupational disease questionnaires, and PLHCP obligations. In this proposed rule, OSHA has included a non-mandatory appendix to clarify the medical surveillance provisions of the rule. What would be the advantages and disadvantages of including such an appendix in the final rule? If you believe it should be included, comment on the appropriateness of the information included. What additional information, if any, should be included in the appendix?

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 et seq. (''the 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 promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b) (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 Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as this proposed standard regulating occupational exposure to respirable crystalline silica, 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).

The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, she must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 641–42 (1980) (''*The Benzene case''*). Thus, section 6(b)(5) of the Act requires health standards to reduce significant risk to the extent feasible. *Id.*

The Court further observed that what constitutes ''significant risk'' is ''not a mathematical straitjacket'' and must be ''based largely on policy considerations.'' *The Benzene case,* 448 U.S. at 655. The Court gave the example that if,

> . . . the odds are one in a billion that a person will die from cancer . . . the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. [*Id.*]

OSHA standards must be both technologically and economically feasible. *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1980) (''The Lead I case''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–510 (1981) (''*The Cotton Dust case''*). The courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility,

> . . . within the limits of the best available evidence . . . 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. [*See The Lead I case,* 647 F.2d at 1272]

With respect to economic feasibility, the courts have held that a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry. *Id.* at 1265. A court must 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 . . . [T]he practical question is whether the standard threatens the competitive stability of an industry, . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration. [*Id.* (citing *Indus. Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467 (D.C. Cir. 1974))]

The courts have further observed that granting companies reasonable time to comply with new PELs may enhance economic feasibility. *The Lead I case* at 1265. While a standard must be economically feasible, the Supreme Court has held that a cost-benefit analysis of health standards is not required by the Act because a feasibility analysis is required. *The Cotton Dust case,* 453 U.S. at 509.

Finally, sections 6(b)(7) and 8(c) of the Act authorize OSHA to include among a standard's requirements labeling, monitoring, medical testing, and other information-gathering and -transmittal provisions. 29 U.S.C. 655(b)(7), 657(c).

III. Events Leading to the Proposed Standards

OSHA's current standards for workplace exposure to respirable crystalline silica were adopted in 1971, pursuant to section 6(a) of the OSH Act (36 FR 10466, May 29, 1971). Section 6(a) provided that in the first two years after the effective date of the Act, OSHA had 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, OSHA in 1971 promulgated approximately 425 permissible exposure limits (PELs) for air contaminants, including silica, 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 recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH).

For general industry (*see* 29 CFR 1910.1000, Table Z–3), the PEL for crystalline silica in the form of respirable quartz is based on two alternative formulas: (1) A particle-count formula, $PEL_{mppcf} = 250/(\%\ quartz + 5)$; and (2) a mass formula proposed by ACGIH in 1968, PEL = (10 mg/m^3)/(% quartz + 2). The general industry PELs for cristobalite and tridymite are one-half of the value calculated from either of the above two formulas. For construction (29 CFR 1926.55, Appendix A) and shipyards (29 CFR 1915.1000, Table Z), the formula for the PEL for crystalline silica in the form of quartz ($PEL_{mppcf} = 250/(\%\ quartz + 5)$), which requires particle counting, is derived from the 1970 ACGIH threshold limit value (TLV).[2] The formula based on particle-counting technology used in the general industry, construction, and shipyard PELs is now considered obsolete.

In 1974, the National Institute for Occupational Safety and Health (NIOSH) evaluated crystalline silica as a workplace hazard and issued criteria for a recommended standard on occupational exposure to crystalline silica (NIOSH, 1974). NIOSH recommended that occupational exposure to crystalline silica be controlled so that no worker is exposed to a time-weighted average (TWA) of free (respirable crystalline) silica greater than 50 μg/m^3 as determined by a full-shift sample for up to a 10-hour workday, 40-hour workweek. The document also recommended a number of ancillary provisions for a standard, such as exposure monitoring and medical surveillance.

In December 1974, OSHA published an Advanced Notice of Proposed Rulemaking (ANPRM) based on the recommendations in the NIOSH criteria document (39 FR 44771, Dec. 27, 1974). In the ANPRM, OSHA solicited ''public participation on the issues of whether a new standard for crystalline silica

[2] The Mineral Dusts tables that contain the silica PELs for construction and shipyards do not clearly express PELs for cristobalite and tridymite. 29 CFR 1926.55; 29 CFR 1915.1000. This lack of textual clarity likely results from a transcription error in the Code of Federal Regulations. OSHA's current proposal provides the same PEL for quartz, cristobalite, and tridymite, in general industry, construction, and shipyards.

should be issued on the basis of the [NIOSH] criteria or any other information, and, if so, what should be the contents of a proposed standard for crystalline silica.'' OSHA also set forth the particular issues of concern on which comments were requested. The Agency did not pursue a final rule for crystalline silica at that time.

As information developed during the 1980s and 1990s, national and international classification organizations came to recognize crystalline silica as a human carcinogen. In June 1986, the International Agency for Research on Cancer (IARC) evaluated the available evidence regarding crystalline silica carcinogenicity and concluded that it was ''probably carcinogenic to humans'' (IARC, 1987). An IARC working group met again in October 1996 to evaluate the complete body of research, including research that had been conducted since the initial 1986 evaluation. IARC concluded that ''crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans'' (IARC, 1997).

In 1991, in the Sixth Annual Report on Carcinogens, the U.S. National Toxicology Program (NTP) concluded that respirable crystalline silica was ''reasonably anticipated to be a human carcinogen'' (NTP, 1991). NTP reevaluated the available evidence and concluded, in the Ninth Report on Carcinogens (NTP, 2000), that ''respirable crystalline silica (RCS), primarily quartz dust occurring in industrial and occupational settings, is known to be a human carcinogen, based on sufficient evidence of carcinogenicity from studies in humans indicating a causal relationship between exposure to RCS and increased lung cancer rates in workers exposed to crystalline silica dust'' (NTP, 2000). ACGIH listed respirable crystalline silica (in the form of quartz) as a suspected human carcinogen in 2000, while lowering the TLV to 0.05 mg/m^3 (ACGIH, 2001). ACGIH subsequently lowered the TLV for crystalline silica to 0.025 mg/m^3 in 2006, which is the current value (ACGIH, 2010).

In 1989, OSHA established 8-hour TWA PELs of 0.1 for quartz and 0.05 mg/m^3 for cristobalite and tridymite, as part of the Air Contaminants final rule for general industry (54 FR 2332, Jan. 19, 1989). OSHA stated that these limits presented no substantial change from the Agency's former formula limits, but would simplify sampling procedures. In providing comments on the proposed rule, NIOSH recommended that crystalline silica be considered a potential carcinogen.

In 1992, OSHA, as part of the Air Contaminants proposed rule for maritime, construction, and agriculture, proposed the same PELs as for general industry, to make the PELs consistent across all the OSHA-regulated sectors (57 FR 26002, June 12, 1992). However, on July 7 of the same year, the U.S. Court of Appeals for the Eleventh Circuit vacated the 1989 Air Contaminants final rule for general industry (*Am. Fed'n of Labor and Cong. of Indus. Orgs.* v. *OSHA,* 965 F.2d 962 (1992)), which also mooted the proposed rule for maritime, construction, and agriculture. The Court's decision to vacate the rule forced the Agency to return to the PELs adopted in the 1970s.

In 1994, OSHA launched a process to determine which safety and health hazards in the U.S. needed most attention. A priority planning committee included safety and health experts from OSHA, NIOSH, and the Mine Safety and Health Administration (MSHA). The committee reviewed available information on occupational deaths, injuries, and illnesses and held an extensive dialogue with representatives of labor, industry, professional and academic organizations, the States, voluntary standards organizations, and the public. The National Advisory Committee on Occupational Safety and Health and the Advisory Committee on Construction Safety and Health also made recommendations. Rulemaking for crystalline silica exposure was one of the priorities designated by this process. OSHA indicated that crystalline silica would be added to the Agency's regulatory agenda as other standards were completed and resources became available.

In August 1996, the Agency initiated enforcement efforts under a Special Emphasis Program (SEP) on crystalline silica. The SEP was intended to reduce worker silica dust exposures that can cause silicosis. It included extensive outreach as well as inspections. Among the outreach materials available were slides presenting information on hazard recognition and crystalline silica control technology, a video on crystalline silica and silicosis, and informational cards for workers explaining crystalline silica, health effects related to exposure, and methods of control. The SEP provided guidance for targeting inspections of worksites with employees at risk of developing silicosis.

As a follow-up to the SEP, OSHA undertook numerous non-regulatory actions to address silica exposures. For example, in October of 1996, OSHA launched a joint silicosis prevention effort with MSHA, NIOSH, and the American Lung Association (DOL, 1996). This public education campaign involved distribution of materials on how to prevent silicosis, including a guide for working safely with silica and stickers for hard hats to remind workers of crystalline silica hazards. Spanish language versions of these materials were also made available. OSHA and MSHA inspectors distributed materials at mines, construction sites, and other affected workplaces. The joint silicosis prevention effort included a National Conference to Eliminate Silicosis in Washington, DC, in March of 1997, which brought together approximately 650 participants from labor, business, government, and the health and safety professions to exchange ideas and share solutions to reach the goal of eliminating silicosis. The conference highlighted the best methods of eliminating silicosis and included problem-solving workshops on how to prevent the disease in specific industries and job operations; plenary sessions with senior government, labor, and corporate officials; and opportunities to meet with safety and health professionals who had implemented successful silicosis prevention programs.

In 2003, OSHA examined enforcement data for the years between 1997 and 2002 and identified high rates of noncompliance with the OSHA respirable crystalline silica PEL, particularly in construction. This period covers the first five years of the SEP. These enforcement data, presented in Table 1, indicate that 24 percent of silica samples from the construction industry and 13 percent from general industry were at least three times the OSHA PEL. The data indicate that 66 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, while only 58 percent of the samples collected in construction were in compliance.

TABLE III–1—RESULTS OF TIME-WEIGHTED AVERAGE (TWA) EXPOSURE RESPIRABLE CRYSTALLINE SILICA SAMPLES FOR CONSTRUCTION AND GENERAL INDUSTRY

[January 1, 1997–December 31, 2002]

Exposure (severity relative to the PEL)	Construction		Other than construction	
	Number of samples	Percent	Number of samples	Percent
< 1 PEL	424	58	2226	66
1 × PEL to < 2 × PEL	86	12	469	14
2 × PEL to < 3 × PEL	48	6	215	6
≥ 3 × PEL and higher (3+)	180	24	453	13
Total # of samples	738		3363	

Source: OSHA Integrated Management Information System.

In an effort to expand the 1996 SEP, on January 24, 2008, OSHA implemented a National Emphasis Program (NEP) to identify and reduce or eliminate the health hazards associated with occupational exposure to crystalline silica (OSHA, 2008). The NEP targeted worksites with elevated exposures to crystalline silica and included new program evaluation procedures designed to ensure that the goals of the NEP were measured as accurately as possible, detailed procedures for conducting inspections, updated information for selecting sites for inspection, development of outreach programs by each Regional and Area Office emphasizing the formation of voluntary partnerships to share information, and guidance on calculating PELs in construction and shipyards. In each OSHA Region, at least two percent of inspections every year are silica-related inspections. Additionally, the silica-related inspections are conducted at a range of facilities reasonably representing the distribution of general industry and construction work sites in that region.

A recent analysis of OSHA enforcement data from January 2003 to December 2009 (covering the period of continued implementation of the SEP and the first two years of the NEP) shows that considerable noncompliance with the PEL continues to occur. These enforcement data, presented in Table 2, indicate that 14 percent of silica samples from the construction industry and 19 percent for general industry were at least three times the OSHA PEL during this period. The data indicate that 70 percent of the silica samples obtained during inspections in general industry were in compliance with the PEL, and 75 percent of the samples collected in construction were in compliance.

TABLE III–2—RESULTS OF TIME-WEIGHTED AVERAGE (TWA) EXPOSURE RESPIRABLE CRYSTALLINE SILICA SAMPLES FOR CONSTRUCTION AND GENERAL INDUSTRY

[January 1, 2003–December 31, 2009]

Exposure (severity relative to the PEL)	Construction		Other than construction	
	Number of samples	Percent	Number of samples	Percent
< 1 PEL	548	75	948	70
1 × PEL to < 2 × PEL	49	7	107	8
2 × PEL to < 3 × PEL	32	4	46	3
≥ 3 × PEL and higher (3+)	103	14	254	19
Total # of samples	732		1355	

Source: OSHA Integrated Management Information System.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, ASTM (originally known as the American Society for Testing and Materials) has published recommended standards for addressing the hazards of crystalline silica, and the Building and Construction Trades Department, AFL–CIO also has recommended a comprehensive program standard. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance. The National Industrial Sand Association has also developed exposure assessment, medical surveillance, and training guidance products.

In 1997, OSHA announced in its Unified Agenda under Long-Term Actions that it planned to publish a proposed rule on crystalline silica ''because the agency has concluded that there will be no significant progress in the prevention of silica-related diseases without the adoption of a full and comprehensive silica standard, including provisions for product substitution, engineering controls, training and education, respiratory protection and medical screening and surveillance. A full standard will improve worker protection, ensure adequate prevention programs, and further reduce silica-related diseases.'' (62 FR 57755, 57758, Oct. 29, 1997). In November 1998, OSHA moved ''Occupational Exposure to Crystalline Silica'' to the pre-rule stage in the Regulatory Plan (63 FR 61284, 61303–304, Nov. 9, 1998). OSHA held a series of stakeholder meetings in 1999 and 2000 to get input on the rulemaking. Stakeholder meetings for all industry sectors were held in Washington, Chicago, and San Francisco. A separate stakeholder meeting for the construction sector was held in Atlanta.

OSHA initiated Small Business Regulatory Enforcement Fairness Act (SBREFA) proceedings in 2003, seeking the advice of small business representatives on the proposed rule (68 FR 30583, 30584, May 27, 2003). The SBREFA panel, including representatives from OSHA, the Small Business Administration (SBA), and the Office of Management and Budget (OMB), was convened on October 20, 2003. The panel conferred with small entity representatives (SERs) from general industry, maritime, and construction on November 10 and 12, 2003, and delivered its final report, which included comments from the SERs and recommendations to OSHA for the proposed rule, to OSHA's Assistant Secretary on December 19, 2003 (OSHA, 2003).

Throughout the crystalline silica rulemaking process, OSHA has presented information to, and has consulted with, the Advisory Committee on Construction Safety and Health (ACCSH) and the Maritime Advisory Committee on Occupational Safety and Health (MACOSH). In December of 2009, OSHA representatives met with ACCSH to discuss the rulemaking and receive their comments and recommendations. On December 11, ACCSH passed motions supporting the concept of Table 1 in the draft proposed construction rule and recognizing that the controls listed in Table 1 are effective. (As discussed with regard to paragraph (f) of the proposed rule, Table 1 presents specified control measures for selected construction operations.) ACCSH also recommended that OSHA maintain the protective clothing provision found in the SBREFA panel draft regulatory text and restore the ''competent person'' requirement and responsibilities to the proposed rule. Additionally, the group recommended that OSHA move forward expeditiously with the rulemaking process.

In January 2010, OSHA completed a peer review of the draft Health Effects analysis and Preliminary Quantitative Risk Assessment following procedures set forth by OMB in the Final Information Quality Bulletin for Peer Review, published on the OMB Web site on December 16, 2004 (*see* 70 FR 2664, Jan. 14, 2005). Each peer reviewer submitted a written report to OSHA. The Agency revised its draft documents as appropriate and made the revised documents available to the public as part of this Notice of Proposed Rulemaking. OSHA also made the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports, and the Agency's response to the peer reviewers' reports publicly available with publication of this proposed rule. OSHA will schedule time during the informal rulemaking hearing for participants to testify on the Health Effects analysis and Preliminary Quantitative Risk Assessment in the presence of peer reviewers and will request the peer reviewers to submit any amended final comments they may wish to add to the record. The Agency will consider amended final comments received from the peer reviewers during development of a final rule and will make them publicly available as part of the silica rulemaking record.

IV. Chemical Properties and Industrial Uses

Silica is a compound composed of the elements silicon and oxygen (chemical formula SiO_2). Silica has a molecular weight of 60.08, and exists in crystalline and amorphous states, both in the natural environment and as produced during manufacturing or other processes. These substances are odorless solids, have no vapor pressure, and create non-explosive dusts when particles are suspended in air (IARC, 1997).

Silica is classified as part of the ''silicate'' class of minerals, which includes compounds that are composed of silicon and oxygen and which may also be bonded to metal ions or their oxides (Hurlbut, 1966). The basic structural units of silicates are silicon tetrahedrons (SiO_4), pyramidal structures with four triangular sides where a silicon atom is located in the center of the structure and an oxygen atom is located at each of the four corners. When silica tetrahedrons bond exclusively with other silica tetrahedrons, each oxygen atom is bonded to the silicon atom of its original ion, as well as to the silicon atom from another silica ion. This results in a ratio of one atom of silicon to two atoms of oxygen, expressed as SiO_2. The silicon-oxygen bonds within the tetrahedrons use only one-half of each oxygen's total bonding energy. This leaves negatively charged oxygen ions available to bond with available positively charged ions. When they bond with metal and metal oxides, commonly of iron, magnesium, aluminum, sodium, potassium, and calcium, they form the silicate minerals commonly found in nature (Bureau of Mines, 1992).

In crystalline silica, the silicon and oxygen atoms are arranged in a three-dimensional repeating pattern. Silica is said to be polymorphic, as different forms are created when the silica tetrahedrons combine in different crystalline structures. The primary forms of crystalline silica are quartz, cristobalite, and tridymite. In an amorphous state, silicon and oxygen atoms are present in the same proportions but are not organized in a repeating pattern. Amorphous silica includes natural and manufactured glasses (vitreous and fused silica, quartz glass), biogenic silica, and opals which are amorphous silica hydrates (IARC, 1997).

Quartz is the most common form of crystalline silica and accounts for almost 12% by volume of the earth's crust. Alpha quartz, the quartz form that is stable below 573 °C, is the most prevalent form of crystalline silica found in the workplace. It accounts for the overwhelming majority of naturally found silica and is present in varying amounts in almost every type of mineral. Alpha quartz is found in igneous, sedimentary, and metamorphic rock, and all soils contain at least a trace amount of quartz (Bureau of Mines, 1992). Alpha quartz is used in many products throughout various industries and is a common component of building materials (Madsen et al., 1995). Common trade names for commercially available quartz include: CSQZ, DQ 12, Min-U-Sil, Sil-Co-Sil, Snowit, Sykron F300, and Sykron F600 (IARC, 1997).

Cristobalite is a form of crystalline silica that is formed at high temperatures (>1470 °C). Although naturally occurring cristobalite is relatively rare, volcanic eruptions, such as Mount St. Helens, can release cristobalite dust into the air. Cristobalite can also be created during some processes conducted in the workplace. For example, flux-calcined diatomaceous earth is a material used as a filtering aid and as a filler in other products (IARC, 1997). It is produced when diatomaceous earth (diatomite), a geological product of decayed unicellular organisms called diatoms, is heated with flux. The finished product can contain between 40 and 60 percent cristobalite. Also, high temperature furnaces are often lined with bricks that contain quartz. When subjected to prolonged high temperatures, this quartz can convert to cristobalite.

Tridymite is another material formed at high temperatures (>870 °C) that is associated with volcanic activity. The creation of tridymite requires the presence of a flux such as sodium oxide. Tridymite is rarely found in nature and rarely reported in the workplace (Smith, 1998).

When heated or cooled sufficiently, crystalline silica can transition between the polymorphic forms, with specific transitions occurring at different temperatures. At higher temperatures the linkages between the silica

tetrahedrons break and reform, resulting in new crystalline structures. Quartz converts to cristobalite at 1470 °C, and at 1723 °C cristobalite loses its crystalline structure and becomes amorphous fused silica. These high temperature transitions reverse themselves at extremely slow rates, with different forms co-existing for a long time after the crystal cools.

Other types of transitions occur at lower temperatures when the silica-oxygen bonds in the silica tetrahedron rotate or stretch, resulting in a new crystalline structure. These low-temperature, or alpha to beta, transitions are readily and rapidly reversed as the crystal cools. At temperatures encountered by workers, only the alpha form of crystalline silica exists (IARC, 1997).

Crystalline silica minerals produce distinct X-ray diffraction patterns, specific to their crystalline structure. The patterns can be used to distinguish the crystalline polymorphs from each other and from amorphous silica (IARC, 1997).

The specific gravity and melting point of silica vary between polymorphs. Silica is insoluble in water at 20 °C and in most acids, but its solubility increases with higher temperatures and pH, and it dissolves readily in hydrofluoric acid. Solubility is also affected by the presence of trace metals and by particle size. Under humid conditions water vapor in the air reacts with the surface of silica particles to form an external layer of silinols (SiOH). When these silinols are present the crystalline silica becomes more hydrophilic. Heating or acid washing reduces the amount of silinols on the surface area of crystalline silica particles. There is an external amorphous layer found in aged quartz, called the Beilby layer, which is not found on freshly cut quartz. This amorphous layer is more water soluble than the underlying crystalline core. Etching with hydrofluoric acid removes the Beilby layer as well as the principal metal impurities on quartz.

Crystalline silica has limited chemical reactivity. It reacts with alkaline aqueous solutions, but does not readily react with most acids, with the exception of hydrofluoric acid. In contrast, amorphous silica and most silicates react with most mineral acids and alkaline solutions. Analytical chemists relied on this difference in acid reactivity to develop the silica point count analytical method that was widely used prior to the current X-ray diffraction and infrared methods (Madsen et al., 1995).

Crystalline silica is used in industry in a wide variety of applications. Sand and gravel are used in road building and concrete construction. Sand with greater than 98% silica is used in the manufacture of glass and ceramics. Silica sand is used to form molds for metal castings in foundries, and in abrasive blasting operations. Silica is also used as a filler in plastics, rubber, and paint, and as an abrasive in soaps and scouring cleansers. Silica sand is used to filter impurities from municipal water and sewage treatment plants, and in hydraulic fracturing for oil and gas recovery. Silica is also used to manufacture artificial stone products used as bathroom and kitchen countertops, and the silica content in those products can exceed 93 percent (Kramer et al., 2012).

There are over thirty major industries and operations where exposures to crystalline silica can occur. They include such diverse workplaces as foundries, dental laboratories, concrete products and paint and coating manufacture, as well as construction activities including masonry cutting, grinding and tuckpointing, operating heavy equipment, and road work. A more detailed discussion of the industries affected by the proposed standard is presented in Section VIII of this preamble. Crystalline silica exposures can also occur in mining, and in agriculture during plowing and harvesting.

V. Health Effects Summary

This section presents a summary of OSHA's review of the health effects literature for respirable crystalline silica. OSHA's full analysis is contained in Section I of the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment,'' which has been placed in rulemaking docket OSHA–2010–0034. OSHA's review of the literature on the adverse effects associated with exposure to crystalline silica covers the following topics:

(1) Silicosis (including relevant data from U.S. disease surveillance efforts);

(2) Lung cancer and cancer at other sites;

(3) Non-malignant respiratory disease (other than silicosis);

(4) Renal and autoimmune effects; and

(5) Physical factors affecting the toxicity of crystalline silica.

The purpose of the Agency's scientific review is to present OSHA's preliminary findings on the nature of the hazards presented by exposure to respirable crystalline silica, and to present an adequate basis for the quantitative risk assessment section to follow. OSHA's review reflects the relevant literature identified by the Agency through previously published reviews, literature searches, and contact with outside experts. Most of the evidence that describes the health risks associated with exposure to silica consists of epidemiological studies of worker populations; in addition, animal and *in vitro* studies on mode of action and molecular toxicology are also described. OSHA's review of the silicosis literature focused on a few particular issues, such as the factors that affect progression of the disease and the relationship between the appearance of radiological abnormalities indicative of silicosis and pulmonary function decline. Exposure to respirable crystalline silica is the only known cause of silicosis and there are literally thousands of research papers and case studies describing silicosis among working populations. OSHA did not review every one of these studies, because many of them do not relate to the issues that are of interest to OSHA.

OSHA's health effects literature review addresses exposure only to airborne respirable crystalline silica since there is no evidence that dermal or oral exposure presents a hazard to workers. This review is also confined to issues related to inhalation of respirable dust, which is generally defined as particles that are capable of reaching the gas-exchange region of the lung (*i.e.,* particles less than 10 μm in aerodynamic diameter). The available studies include populations exposed to quartz or cristobalite, the two forms of crystalline silica most often encountered in the workplace. OSHA was unable to identify any relevant epidemiological literature concerning a third polymorph, tridymite, which is also currently regulated by OSHA and included in the scope of OSHA's proposed crystalline silica standard.

OSHA's approach in this review is based on a weight-of-evidence approach, in which studies (both positive and negative) are evaluated for their overall quality, and causal inferences are drawn based on a determination of whether there is substantial evidence that exposure increases the risk of a particular effect. Factors considered in assessing the quality of studies include size of the cohort studied and power of the study to detect a sufficiently low level of disease risk; duration of follow-up of the study population; potential for study bias (such as selection bias in case-control studies or survivor effects in cross-sectional studies); and adequacy of underlying exposure information for

examining exposure-response relationships. Studies were deemed suitable for inclusion in OSHA's Preliminary Quantitative Risk Assessment where there was adequate quantitative information on exposure and disease risks and the study was judged to be sufficiently high quality according to the criteria described above. The Preliminary Quantitative Risk Assessment is included in Section II of the background document and is summarized in Section VI of this preamble.

A draft health effects review document was submitted for external scientific peer review in accordance with the Office of Management and Budget's ''Final Information Quality Bulletin for Peer Review'' (OMB, 2004). A summary of OSHA's responses to the peer reviewers' comments appears in Section III of the background document. Since the draft health effects review document was submitted for external scientific peer review, new studies or reviews examining possible associations between occupational exposure to respirable crystalline silica and lung cancer have been published. OSHA's analysis of that new information is presented in a supplemental literature review and is available in the docket (OSHA, 2013).

A. Silicosis and Disease Progression

1. Pathology and Diagnosis

Silicosis is a progressive disease in which accumulation of respirable crystalline silica particles causes an inflammatory reaction in the lung, leading to lung damage and scarring, and, in some cases, progresses to complications resulting in disability and death. Three types of silicosis have been described: an *acute* form following intense exposure to respirable dust of high crystalline silica content for a relatively short period (*i.e.,* a few months or years); an *accelerated* form, resulting from about 5 to 15 years of heavy exposure to respirable dusts of high crystalline silica content; and, most commonly, a *chronic* form that typically follows less intense exposure of usually more than 20 years (Becklake, 1994; Balaan and Banks, 1992). In both the accelerated and chronic form of the disease, lung inflammation leads to the formation of excess connective tissue, or fibrosis, in the lung. The hallmark of the chronic form of silicosis is the silicotic islet or nodule, one of the few agent-specific lesions in pathology (Balaan and Banks, 1992). As the disease progresses, these nodules, or fibrotic lesions, increase in density and can develop into large fibrotic masses, resulting in progressive massive fibrosis (PMF). Once established, the fibrotic process of chronic silicosis is thought to be irreversible (Becklake, 1994), and there is no specific treatment for silicosis (Davis, 1996; Banks, 2005). Unlike chronic silicosis, the acute form of the disease almost certainly arises from exposures well in excess of current OSHA standards and presents a different pathological picture, one of pulmonary alveolar proteinosis.

Chronic silicosis is the most frequently observed type of silicosis in the U.S. today. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction and/or obstruction caused by the development of fibrotic scarring in the alveolar sacs and lower region of the lung. The scarring can be detected by chest x-ray or computerized tomography (CT) when the lesions become large enough to appear as visible opacities. The result is restriction of lung volumes and decreased pulmonary compliance with concomitant reduced gas transfer (Balaan and Banks, 1992). Early stages of chronic silicosis can be referred to as either *simple* or nodular silicosis; later stages are referred to as either *pulmonary massive fibrosis* (PMF), *complicated,* or *advanced* silicosis.

The clinical diagnosis of silicosis has three requisites (Balaan and Banks, 1992; Banks, 2005). The first is the recognition by the physician that exposure to crystalline silica adequate to cause this disease has occurred. The second is the presence of chest radiographic abnormalities consistent with silicosis. The third is the absence of other illnesses that could resemble silicosis on chest radiograph, *e.g.,* pulmonary fungal infection or miliary tuberculosis. To describe the presence and severity of silicosis from chest x-ray films or digital radiographic images, a standardized system exists to classify the opacities seen on chest radiographs (the International Labor Organization (ILO) International Classification of Radiographs of the Pneumoconioses (ILO, 1980, 2002, 2011; Merchant and Schwartz, 1998; NIOSH, 2011). This system standardizes the description of chest x-ray films or digital radiographic images with respect to the size, shape, and density of opacities, which together indicate the severity and extent of lung involvement. The density of opacities seen on chest x-ray films or digital radiographic images is classified on a 4-point major category scale (0, 1, 2, or 3), with each major category divided into three subcategories, giving a 12-point scale between 0/0 and 3/+. (For each subcategory, the top number indicates the major category that the profusion most closely resembles, and the bottom number indicates the major category that was given secondary consideration.) Major category 0 indicates the absence of visible opacities and categories 1 to 3 reflect increasing profusion of opacities and a concomitant increase in severity of disease. Biopsy is not necessary to make a diagnosis and a diagnosis does not require that chest x-ray films or digital radiographic images be rated using the ILO system (NIOSH, 2002). In addition, an assessment of pulmonary function, though not itself necessary to confirm a diagnosis of silicosis, is important to evaluate whether the individual has impaired lung function.

Although chest x-ray is typically used to examine workers exposed to respirable crystalline silica for the presence of silicosis, it is a fairly insensitive tool for detecting lung fibrosis (Hnizdo et al., 1993; Craighead and Vallyathan, 1980; Rosenman et al., 1997). To address the low sensitivity of chest x-rays for detecting silicosis, Hnizdo et al. (1993) recommended that radiographs consistent with an ILO category of 0/1 or greater be considered indicative of silicosis among workers exposed to a high concentration of silica-containing dust. In like manner, to maintain high specificity, chest x-rays classified as category 1/0 or 1/1 should be considered as a positive diagnosis of silicosis.

Newer imaging technologies with both research and clinical applications include computed tomography, and high resolution tomography. High-resolution computed tomography (HRCT) uses thinner image slices and a different reconstruction algorithm to improve spatial resolution over CT. Recent studies of high-resolution computerized tomography (HRCT) have found HRCT to be superior to chest x-ray imaging for detecting small opacities and for identifying PMF (Sun et al., 2008; Lopes et al., 2008; Blum et al., 2008).

The causal relationship between exposure to crystalline silica and silicosis has long been accepted in the scientific and medical communities. Of greater interest to OSHA is the quantitative relationship between exposure to crystalline silica and development of silicosis. A large number of cross-sectional and retrospective studies have been conducted to evaluate this relationship (Kreiss and Zhen, 1996; Love et al., 1999; Ng and Chan, 1994; Rosenman et al., 1996; Hughes et al., 1998; Muir et al., 1989a, 1989b; Park et al., 2002; Chen

et al., 2001; Hnizdo and Sluis-Cremer, 1993; Miller et al., 1998; Buchanan et al., 2003; Steenland and Brown, 1995b). In general, these studies, particularly those that included retirees, have found a risk of radiological silicosis (usually defined as x-ray films classified ILO major category 1 or greater) among workers exposed near the range of cumulative exposure permitted by current exposure limits. These studies are presented in detail in OSHA's Preliminary Quantitative Risk Assessment (Section II of the background document and summarized in Section VI of this preamble).

2. Silicosis in the United States

Unlike most occupational diseases, surveillance statistics are available that provide information on the prevalence of silicosis mortality and morbidity in the U.S. The most comprehensive and current source of surveillance data in the U.S. related to occupational lung diseases, including silicosis, is the National Institute for Occupational Safety and Health (NIOSH) Work-Related Lung Disease (WoRLD) Surveillance System; the WoRLD Surveillance Report is compiled from the most recent data from the WoRLD System (NIOSH, 2008c). National statistics on mortality associated with occupational lung diseases are also compiled in the National Occupational Respiratory Mortality System (NORMS, available on the Internet at *http://webappa.cdc.gov/ords/norms.html*), a searchable database administered by NIOSH. In addition, NIOSH published a recent review of mortality statistics in its MMWR Report Silicosis Mortality, Prevention, and Control—United States, 1968–2002 (CDC, 2005). For each of these sources, data are compiled from death certificates reported to state vital statistics offices, which are collected by the National Center for Health Statistics (NCHS). Data on silicosis morbidity are available from only a few states that administer occupational disease surveillance systems, and from data on hospital discharges. OSHA believes that the mortality and morbidity statistics compiled in these sources and summarized below indicate that silicosis remains a significant occupational health problem in the U.S. today.

From 1968 to 2002, silicosis was recorded as an underlying or contributing cause of death on 16,305 death certificates; of these, a total of 15,944 (98 percent) deaths occurred in males (CDC, 2005). From 1968 to 2002, the number of silicosis deaths decreased from 1,157 (8.91 per million persons aged ≥15 years) to 148 (0.66 per million), corresponding to a 93-percent decline in the overall mortality rate. In its most recent WoRLD Report (NIOSH, 2008c), NIOSH reported that the number of silicosis deaths in 2003, 2004, and 2005 were 179, 166, and 161, respectively, slightly higher than that reported in 2002. The number of silicosis deaths identified each year has remained fairly constant since the late 1990's.

NIOSH cited two main factors that were likely responsible for the declining trend in silicosis mortality since 1968. First, many of the deaths in the early part of the study period occurred among persons whose main exposure to crystalline silica dust probably occurred before introduction of national standards for silica dust exposure established by OSHA and the Mine Safety and Health Administration (MSHA) (*i.e.,* permissible exposure limits (PELs)) that likely led to reduced silica dust exposure. Second, there has been declining employment in heavy industries (*e.g.,* foundries) where silica exposure was prevalent (CDC, 2005). Although the factors described by NIOSH are reasonable explanations for the steep reduction in silicosis-related mortality, it should be emphasized that the surveillance data are insufficient for the analysis of residual risk associated with current occupational exposure limits for crystalline silica. Analyses designed to explore this question must make use of appropriate exposure-response data, as is presented in OSHA's Preliminary Quantitative Risk Assessment (summarized in Section VI of this preamble).

Although the number of deaths from silicosis overall has declined since 1968, the number of silicosis-associated deaths reported among persons aged 15 to 44 had not declined substantially prior to 1995 (CDC 1998). Unfortunately, it is not known to what extent these deaths among younger workers were caused by acute or accelerated forms of silicosis.

Silicosis deaths among workers of all ages result in significant premature mortality; between 1996 and 2005, a total of 1,746 deaths resulted in a total of 20,234 years of life lost from life expectancy, with an average of 11.6 years of life lost. For the same period, among 307 decedents who died before age 65, or the end of a working life, there were 3,045 years of life lost to age 65, with an average of 9.9 years of life lost from a working life (NIOSH, 2008c).

Data on the prevalence of silicosis morbidity are available from only three states (Michigan, Ohio, and New Jersey) that have administered disease surveillance programs over the past several years. These programs rely primarily on hospital discharge records, reporting of cases from the medical community, workers' compensation programs, and death certificate data. For the reporting period 1993–2002, the last year for which data are available, three states (Michigan, New Jersey and Ohio) recorded 879 cases of silicosis (NIOSH 2008c). Hospital discharge records represent the primary ascertainment source for all three states. It should be noted that hospital discharge records most likely include cases of acute silicosis or very advance chronic silicosis since it is unlikely that there would be a need for hospitalization in cases with early radiographic signs of silicosis, such as for an ILO category 1/0 x-ray. Nationwide hospital discharge data compiled by NIOSH (2008c) and the Council of State and Territorial Epidemiologists (CSTE, 2005) indicates that there are at least 1,000 hospitalizations each year due to silicosis.

Data on silicosis mortality and morbidity are likely to understate the true impact of exposure of U.S. workers to crystalline silica. This is in part due to underreporting that is characteristic of passive case-based disease surveillance systems that rely on the health care community to generate records (Froines et al., 1989). Health care professionals play the main role in such surveillance by virtue of their unique role in recognizing and diagnosing diseases, but most health care professionals do not take occupational histories (Goldman and Peters, 1981; Rutstein et al., 1983). In addition to the lack of information about exposure histories, difficulty in recognizing occupational illnesses that have long latency periods, like silicosis, contributes to under-recognition and underreporting by health care providers. Based on an analysis of data from Michigan's silicosis surveillance activities, Rosenman et al. (2003) estimated that the true incidence of silicosis mortality and morbidity were understated by a factor of between 2.5 and 5, and that there were estimated to be from 3,600 to 7,300 new cases of silicosis occurring in the U.S. annually between 1987 and 1996. Taken with the surveillance data presented above, OSHA believes that exposure to crystalline silica remains a cause of significant mortality and morbidity in the U.S.

3. Progression of Silicosis and Its Associated Impairment

As described above, silicosis is a progressive lung disease that is usually first detected by the appearance of a

diffuse nodular fibrosis on chest x-ray films. To evaluate the clinical significance of radiographic signs of silicosis, OSHA reviewed several studies that have examined how exposure affects progression of the disease (as seen by chest radiography) as well as the relationship between radiologic findings and pulmonary function. The following summarizes OSHA's preliminary findings from this review.

Of the several studies reviewed by OSHA that documented silicosis progression in populations of workers, four studies (Hughes et al., 1982; Hessel et al., 1988; Miller et al., 1998; Ng et al., 1987a) included quantitative exposure data that were based on either current or historical measurements of respirable quartz. The exposure variable most strongly associated in these studies with progression of silicosis was cumulative respirable quartz (or silica) exposure (Hessel et al., 1988; Hughes et al., 1982; Miller et al., 1998; Ng et al., 1987a), though both average concentration of respirable silica (Hughes et al., 1982; Ng et al., 1987a) and duration of employment in dusty jobs have also been found to be associated with the progression of silicosis (Hughes et al., 1982; Ogawa et al., 2003).

The study reflecting average exposures most similar to current exposure conditions is that of Miller et al. (1998), which followed a group of 547 British coal miners in 1990–1991 to evaluate chest x-ray changes that had occurred after the mines closed in 1981. This study had data available from chest x-rays taken during health surveys conducted between 1954 and 1978, as well as data from extensive exposure monitoring conducted between 1964 and 1978. The mean and maximum cumulative exposure reported in the study correspond to average concentrations of 0.12 and 0.55 mg/m^3, respectively, over the 15-year sampling period. However, between 1971 and 1976, workers experienced unusually high concentrations of respirable quartz in one of the two coal seams in which the miners worked. For some occupations, quarterly mean quartz concentrations ranged from 1 to 3 mg/m^3, and for a brief period, concentrations exceeded 10 mg/m^3 for one job. Some of these high exposures likely contributed to the extent of disease progression seen in these workers; in its Preliminary Quantitative Risk Assessment, OSHA reviewed a study by Buchanan et al. (2003), who found that short-term exposures to high (>2 mg/m^3) concentrations of silica can increase the silicosis risk by 3-fold over what would be predicted by cumulative exposure alone (*see* Section VI).

Among the 504 workers whose last chest x-ray was classified as ILO 0/0 or 0/1, 20 percent had experienced onset of silicosis (*i.e.,* chest x-ray was classified as ILO 1/0 by the time of follow up in 1990–1991), and 4.8 percent progressed to at least category 2. However, there are no data available to continue following the progression of this group because there have been no follow-up surveys of this cohort since 1991.

In three other studies examining the progression of silicosis, (Hessel et al., 1988; Hughes et al., 1982; Ng et al., 1987a) cohorts were comprised of silicotics (individuals already diagnosed with silicosis) that were followed further to evaluate disease progression. These studies reflect exposures of workers to generally higher average concentrations of respirable quartz than are permitted by OSHA's current exposure limit. Some general findings from this body of literature follow. First, size of opacities on initial radiograph is a determinant for further progression. Individuals with large opacities on initial chest radiograph have a higher probability of further disease progression than those with small opacities (Hughes et al., 1982; Lee, et al., 2001; Ogawa et al., 2003). Second, although silicotics who continue to be exposed are more likely to progress than silicotics who are not exposed (Hessel et al., 1988), once silicosis has been detected there remains a likelihood of progression in the absence of additional exposure to silica (Hessel et al., 1988; Miller et al., 1998; Ogawa, et al., 2003; Yang et al., 2006). There is some evidence in the literature that the probability of progression is likely to decline over time following the end of the exposure, although this observation may also reflect a survivor effect (Hughes et al., 1982; Lee et al., 2001). In addition, of borderline statistical significance was the association of tuberculosis with increased likelihood of silicosis progression (Lee et al., 2001).

Of the four studies reviewed by OSHA that provided quantitative exposure information, two studies (Miller et al., 1998; Ng et al., 1987a) provide the information most relevant to current exposure conditions. The range of average concentration of respirable crystalline silica to which workers were exposed in these studies (0.12 to 0.48 mg/m^3, respectively) is relatively narrow and is of particular interest to OSHA because current enforcement data indicate that exposures in this range or not much lower are common today, especially in construction and foundries, and sandblasting operations. These studies reported the percentage of workers whose chest x-rays show signs of progression at the time of follow-up; the annual rate at which workers showed disease progression were similar, 2 percent and 6 percent, respectively.

Several cross-sectional and longitudinal studies have examined the relationship between progressive changes observed on radiographs and corresponding declines in lung-function parameters. In general, the results are mixed: some studies have found that pulmonary function losses correlate with the extent of fibrosis seen on chest x-ray films, and others have not found such correlations. The lack of a correlation in some studies between degree of fibrotic profusion seen on chest x-rays and pulmonary function have led some to suggest that pulmonary function loss is an independent effect of exposure to respirable crystalline silica, or may be a consequence of emphysematous changes that have been seen in conjunction with radiographic silicosis.

Among studies that have reported finding a relationship between pulmonary function and x-ray abnormalities, Ng and Chan (1992) found that forced expiratory volume (FEV_1) and forced vital capacity (FVC) were statistically significantly lower for workers whose x-ray films were classified as ILO profusion categories 2 and 3, but not among workers with ILO category 1 profusion compared to those with a profusion score of 0/0. As expected, highly significant reductions in FEV_1, FVC, and FEV_1/FVC were noted in subjects with large opacities. The authors concluded that chronic simple silicosis, except that classified as profusion category 1, is associated with significant lung function impairment attributable to fibrotic disease.

Similarly, Moore et al. (1988) also found chronic silicosis to be associated with significant lung function loss, especially among workers with chest x-rays classified as ILO profusion categories 2 and 3. For those classified as category 1, lung function was not diminished. Bégin et al. (1988) also found a correlation between decreased lung function (FVC and the ratio of FEV_1/FVC) and increased profusion and coalescence of opacities as determined by CT scan. This study demonstrated increased impairment among workers with higher imaging categories (3 and 4), as expected, but also impairment (significantly reduced expiratory flow rates) among persons with more moderate pulmonary fibrosis (group 2).

In a population of gold miners, Cowie (1998) found that lung function

declined more rapidly in men with silicosis than those without. In addition to the 24 ml./yr. decrements expected due to aging, this study found an additional loss of 8 ml. of FEV_1 per year would be expected from continued exposure to dust in the mines. An earlier cross-sectional study by these authors (Cowie and Mabena, 1991), which examined 1,197 black underground gold miners who had silicosis, found that silicosis (analyzed as a continuous variable based on chest x-ray film classification) was associated with reductions in FVC, FEV_1, FEV_1/FVC, and carbon monoxide diffusing capacity (DL_{co}), and these relationships persisted after controlling for duration and intensity of exposure and smoking.

In contrast to these studies, other investigators have reported finding pulmonary function decrements in exposed workers independent of radiological evidence of silicosis. Hughes et al. (1982) studied a representative sample of 83 silicotic sandblasters, 61 of whom were followed for one to seven years. A multiple regression analysis showed that the annual reductions in FVC, FEV_1 and DL_{co} were related to average silica concentrations but not duration of exposure, smoking, stage of silicosis, or time from initial exposure. Ng et al. (1987b) found that, among male gemstone workers in Hong Kong with x-rays classified as either Category 0 or 1, declines in FEV_1 and FVC were not associated with radiographic category of silicosis after adjustment for years of employment. The authors concluded that there was an independent effect of respirable dust exposure on pulmonary function. In a population of 61 gold miners, Wiles et al. (1992) also found that radiographic silicosis was not associated with lung function decrements. In a re-analysis and follow-up of an earlier study, Hnizdo (1992) found that silicosis was not a significant predictor of lung function, except for FEV_1 for non-smokers.

Wang et al. (1997) observed that silica-exposed workers (both nonsmokers and smokers), even those without radiographic evidence of silicosis, had decreased spirometric parameters and diffusing capacity (DL_{co}). Pulmonary function was further decreased in the presence of silicosis, even those with mild to moderate disease (ILO categories 1 and 2). The authors concluded that functional abnormalities precede radiographic changes of silicosis.

A number of studies were conducted to examine the role of emphysematous changes in the presence of silicosis in reducing lung function; these have been reviewed by Gamble et al. (2004), who concluded that there is little evidence that silicosis is related to development of emphysema in the absence of PMF. In addition, Gamble et al. (2004) found that, in general, studies found that the lung function of those with radiographic silicosis in ILO category 1 was indistinguishable from those in category 0, and that those in category 2 had small reductions in lung function relative to those with category 0 and little difference in the prevalence of emphysema. There were slightly greater decrements in lung function with category 3 and more significant reductions with progressive massive fibrosis. In studies for which information was available on both silicosis and emphysema, reduced lung function was more strongly related to emphysema than to silicosis.

In conclusion, many studies reported finding an association between pulmonary function decrements and ILO category 2 or 3 background profusion of small opacities; this appears to be consistent with the histopathological view, in which individual fibrotic nodules conglomerate to form a massive fibrosis (Ng and Chan, 1992). Emphysema may also play a role in reducing lung function in workers with higher grades of silicosis. Pulmonary function decrements have not been reported in some studies among workers with silicosis scored as ILO category 1. However, a number of other studies have documented declines in pulmonary function in persons exposed to silica and whose radiograph readings are in the major ILO category 1 (*i.e.* 1/0, 1/1, 1/2), or even before changes were seen on chest x-ray (Bégin et al., 1988; Cowie, 1998; Cowie and Mabena, 1991; Ng et al., 1987a; Wang et al., 1997). It may also be that studies designed to relate x-ray findings with pulmonary function declines are further confounded by pulmonary function declines caused by chronic obstructive pulmonary disease (COPD) seen among silica-exposed workers absent radiological silicosis, as has been seen in many investigations of COPD. OSHA's review of the literature on crystalline silica exposure and development of COPD appears in section II.D of the background document and is summarized in section V.D below.

OSHA believes that the literature reviewed above demonstrates decreased lung function among workers with radiological evidence of silicosis consistent with an ILO classification of major category 2 or higher. Also, given the evidence of functional impairment in some workers prior to radiological evidence of silicosis, and given the low sensitivity of radiography, particularly in detecting early silicosis, OSHA believes that exposure to silica impairs lung function in at least some individuals before silicosis can be detected on chest radiograph.

4. Pulmonary Tuberculosis

As silicosis progresses, it may be complicated by severe mycobacterial infections, the most common of which is pulmonary tuberculosis (TB). Active tuberculosis infection is a well-recognized complication of chronic silicosis, and such infections are known as silicotuberculosis (IARC, 1997; NIOSH, 2002). The risk of developing TB infection is higher in silicotics than non-silicotics (Balmes, 1990; Cowie, 1994; Hnizdo and Murray, 1998; Kleinschmidt and Churchyard, 1997; and Murray et al., 1996). There also is evidence that exposure to silica increases the risk for pulmonary tuberculosis independent of the presence of silicosis (Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude et al., 2006). In a summary of the literature on silica-related disease mechanisms, Ding et al. (2002) noted that it is well documented that exposure to silica can lead to impaired cell-mediated immunity, increasing susceptibility to mycobacterial infection. Reduced numbers of T-cells, increased numbers of B-cells, and alterations of serum immunoglobulin levels have been observed in workers with silicosis. In addition, according to Ng and Chan (1991), silicosis and TB act synergistically to increase fibrotic scar tissue (leading to massive fibrosis) or to enhance susceptibility to active mycobacterial infection. Lung fibrosis is common to both diseases and both diseases decrease the ability of alveolar macrophages to aid in the clearance of dust or infectious particles.

B. Carcinogenic Effects of Silica (Cancer of the Lung and Other Sites)

OSHA conducted an independent review of the epidemiological literature on exposure to respirable crystalline silica and lung cancer, covering more than 30 occupational groups in over a dozen industrial sectors. In addition, OSHA reviewed a pooled case-control study, a large national death certificate study, two national cancer registry studies, and six meta-analyses. In all, OSHA's review included approximately 60 primary epidemiological studies.

Based on its review, OSHA preliminarily concludes that the human data summarized in this section

provides ample evidence that exposure to respirable crystalline silica increases the risk of lung cancer among workers. The strongest evidence comes from the worldwide cohort and case-control studies reporting excess lung cancer mortality among workers exposed to respirable crystalline silica dust as quartz in various industrial sectors, including the granite/stone quarrying and processing, industrial sand, mining, and pottery and ceramic industries, as well as to cristobalite in diatomaceous earth and refractory brick industries. The 10-cohort pooled case-control analysis by Steenland et al. (2001a) confirms these findings. A more recent clinic-based pooled case-control analysis of seven European countries by Cassidy et al. (2007) as well as two national death certificate registry studies (Pukkala et al., 2005 in Finland; Calvert et al., 2003 in the United States) support the findings from the cohort and case-control analysis.

1. Overall and Industry Sector-Specific Findings

Associations between exposure to respirable crystalline silica and lung cancer have been reported in worker populations from many different industrial sectors. IARC (1997) concluded that crystalline silica is a confirmed human carcinogen based largely on nine studies of cohorts in four industry sectors that IARC considered to be the least influenced by confounding factors (sectors included quarries and granite works, gold mining, ceramic/pottery/refractory brick industries, and the diatomaceous earth industry). IARC (2012) recently reaffirmed that crystalline silica is a confirmed human carcinogen. NIOSH (2002) also determined that crystalline silica is a human carcinogen after evaluating updated literature.

OSHA believes that the strongest evidence for carcinogenicity comes from studies in five industry sectors. These are:

- Diatomaceous Earth Workers (Checkoway et al., 1993, 1996, 1997, and 1999; Seixas et al., 1997);
- British Pottery Workers (Cherry et al., 1998; McDonald et al., 1995);
- Vermont Granite Workers (Attfield and Costello, 2004; Graham et al., 2004; Costello and Graham, 1988; Davis et al., 1983);
- North American Industrial Sand Workers (Hughes et al., 2001; McDonald et al., 2001, 2005; Rando et al., 2001; Sanderson et al., 2000; Steenland and Sanderson, 2001); and
- British Coal Mining (Miller et al., 2007; Miller and MacCalman, 2009).

The studies above were all retrospective cohort or case-control studies that demonstrated positive, statistically significant exposure-response relationships between exposure to crystalline silica and lung cancer mortality. Except for the British pottery studies, where exposure-response trends were noted for average exposure only, lung cancer risk was found to be related to cumulative exposure. OSHA credits these studies because in general, they are of sufficient size and have adequate years of follow up, and have sufficient quantitative exposure data to reliably estimate exposures of cohort members. As part of their analyses, the authors of these studies also found positive exposure-response relationships for silicosis, indicating that underlying estimates of worker exposures were not likely to be substantially misclassified. Furthermore, the authors of these studies addressed potential confounding due to other carcinogenic exposures through study design or data analysis.

A series of studies of the diatomaceous earth industry (Checkoway et al., 1993, 1996, 1997, 1999) demonstrated positive exposure-response trends between cristobalite exposures and lung cancer as well as non-malignant respiratory disease mortality (NMRD). Checkoway et al. (1993) developed a ''semi-quantitative'' cumulative exposure estimate that demonstrated a statistically significant positive exposure-response trend ($p = 0.026$) between duration of employment or cumulative exposure and lung cancer mortality. The quartile analysis showed a monotonic increase in lung cancer mortality, with the highest exposure quartile having a RR of 2.74 for lung cancer mortality. Checkoway et al. (1996) conducted a re-analysis to address criticisms of potential confounding due to asbestos and again demonstrated a positive exposure response risk gradient when controlling for asbestos exposure and other variables. Rice et al. (2001) conducted a re-analysis and quantitative risk assessment of the Checkoway et al. (1997) study, which OSHA has included as part of its assessment of lung cancer mortality risk (*See* Section II, Preliminary Quantitative Risk Assessment).

In the British pottery industry, excess lung cancer risk was found to be associated with crystalline silica exposure among workers in a PMR study (McDonald et al., 1995) and in a cohort and nested case-control study (Cherry et al., 1998). In the PMR study, elevated PMRs for lung cancer were found after adjusting for potential confounding by asbestos exposure. In the study by Cherry et al., odds ratios for lung cancer mortality were statistically significantly elevated after adjusting for smoking. Odds ratios were related to average, but not cumulative, exposure to crystalline silica. The findings of the British pottery studies are supported by other studies within their industrial sector. Studies by Winter et al. (1990) of British pottery workers and by McLaughlin et al. (1992) both reported finding suggestive trends of increased lung cancer mortality with increasing exposure to respirable crystalline silica.

Costello and Graham (1988) and Graham et al. (2004) in a follow-up study found that Vermont granite workers employed prior to 1930 had an excess risk of lung cancer, but lung cancer mortality among granite workers hired after 1940 (post-implementation of controls) was not elevated in the Costello and Graham (1988) study and was only somewhat elevated (not statistically significant) in the Graham et al. (2004) study. Graham et al. (2004) concluded that their results did not support a causal relationship between granite dust exposure and lung cancer mortality. Looking at the same population, Attfield and Costello (2004) developed a quantitative estimate of cumulative exposure (8 exposure categories) adapted from a job exposure matrix developed by Davis et al. (1983). They found a statistically significant trend with log-transformed cumulative exposure. Lung cancer mortality rose reasonably consistently through the first seven increasing exposure groups, but fell in the highest cumulative exposure group. With the highest exposure group omitted, a strong positive dose-response trend was found for both untransformed and log-transformed cumulative exposures. Attfield and Costello (2004) concluded that exposure to crystalline silica in the range of cumulative exposures typically experienced by contemporarily exposed workers causes an increased risk of lung cancer mortality. The authors explained that the highest exposure group would have included the most unreliable exposure estimates being reconstructed from exposures 20 years prior to study initiation when exposure estimation was less precise. Also, even though the highest exposure group consisted of only 15 percent of the study population, it had a disproportionate effect on dampening the exposure-response relationship.

OSHA believes that the study by Attfield and Costello (2004) is of superior design in that it was a categorical analysis that used

quantitative estimates of exposure and evaluated lung cancer mortality rates by exposure group. In contrast, the findings by Graham et al. (2004) are based on a dichotomous comparison of risk among high- versus low-exposure groups, where date-of-hire before and after implementation of ventilation controls is used as a surrogate for exposure. Consequently, OSHA believes that the study by Attfield and Costello is the more convincing study, and is one of the studies used by OSHA for quantitative risk assessment of lung cancer mortality due to crystalline silica exposure.

The conclusions of the Vermont granite worker study (Attfield and Costello, 2004) are supported by the findings in studies of workers in the U.S. crushed stone industry (Costello et al., 1995) and Danish stone industry (Guénel et al., 1989a, 1989b). Costello et al. (1995) found a non-statistically significant increase in lung cancer mortality among limestone quarry workers and a statistically significant increased lung cancer mortality in granite quarry workers who worked 20 years or more since first exposure. Guénel et al. (1989b), in a Danish cohort study, found statistically significant increases in lung cancer incidence among skilled stone workers and skilled granite stone cutters. A study of Finnish granite workers that initially showed increasing risk of lung cancer with increasing silica exposure, upon extended follow-up, did not show an association and is therefore considered a negative study (Toxichemica, Inc., 2004).

Studies of two overlapping cohorts in the industrial sand industry (Hughes et al., 2001; McDonald et al., 2001, 2005; Rando et al., 2001; Sanderson et al., 2000; Steenland and Sanderson, 2001) reported comparable results. These studies found a statistically significantly increased risk of lung cancer mortality with increased cumulative exposure in both categorical and continuous analyses. McDonald et al. (2001) examined a cohort that entered the workforce, on average, a decade earlier than the cohorts that Steenland and Sanderson (2001) examined. The McDonald cohort, drawn from eight plants, had more years of exposure in the industry (19 versus 8.8 years). The Steenland and Sanderson (2001) cohort worked in 16 plants, 7 of which overlapped with the McDonald, et al. (2001) cohort. McDonald et al. (2001), Hughes et al. (2001), and Rando et al. (2001) had access to smoking histories, plant records, and exposure measurements that allowed for historical reconstruction and the development of a job exposure matrix. Steenland and Sanderson (2001) had limited access to plant facilities, less detailed historic exposure data, and used MSHA enforcement records for estimates of recent exposure. These studies (Hughes et al., 2001; McDonald et al., 2005; Steenland and Sanderson, 2001) show very similar exposure response patterns of increased lung cancer mortality with increased exposure. OSHA included the quantitative exposure-response analysis from the Hughes et al. (2001) study in its Preliminary Quantitative Risk Assessment (Section II).

Brown and Rushton (2005a, 2005b) found no association between risk of lung cancer mortality and exposure to respirable crystalline silica among British industrial sand workers. However, the small sample size and number of years of follow-up limited the statistical power of the analysis. Additionally, as Steenland noted in a letter review (2005a), the cumulative exposures of workers in the Brown and Ruston (2005b) study were over 10 times lower than the cumulative exposures experienced by the cohorts in the pooled analysis that Steenland et al. (2001b) performed. The low exposures experienced by this cohort would have made detecting a positive association with lung cancer mortality even more difficult.

Excess lung cancer mortality was reported in a large cohort study of British coal miners (Miller et al., 2007; Miller and MacCalman, 2009). These studies examined the mortality experience of 17,800 miners through the end of 2005. By that time, the cohort had accumulated 516,431 person years of observation (an average of 29 years per miner), with 10,698 deaths from all causes. Overall lung cancer mortality was elevated (SMR=115.7, 95% C.I. 104.8–127.7), and a positive exposure-response relationship with crystalline silica exposure was determined from Cox regression after adjusting for smoking history. Three of the strengths of this study are the detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. For lung cancer, analyses based on the Cox regression provide strong evidence that, for these coal miners, quartz exposures were associated with increased lung cancer risk but that simultaneous exposures to coal dust did not cause increased lung cancer risk. Because of these strengths, OSHA included the quantitative analysis from this study in its Preliminary Quantitative Risk Assessment (Section II).

Studies of lung cancer mortality in metal ore mining populations reflect mixed results. Many of these mining studies were subject to confounding due to exposure to other potential carcinogens such as radon and arsenic. IARC (1997) noted that in only a few ore mining studies was confounding from other occupational carcinogens taken into account. IARC (1997) also noted that, where confounding was absent or accounted for in the analysis (gold miners in the U.S., tungsten miners in China, and zinc and lead miners in Sardinia, Italy), an association between silica exposure and lung cancer was absent. Many of the studies conducted since IARC's (1997) review more strongly implicate crystalline silica as a human carcinogen. Pelucchi et al. (2006), in a meta-analysis of studies conducted since IARC's (1997) review, reported statistically significantly elevated relative risks of lung cancer mortality in underground and surface miners in three cohort and four case-control studies (*See* Table I–15). Cassidy et al. (2007), in a pooled case-control analysis, showed a statistically significant increased risk of lung cancer mortality among miners (OR = 1.48). Cassidy et al. (2007) also demonstrated a clear linear trend of increasing odds ratios for lung cancer with increasing exposures.

Among workers in Chinese tungsten and iron mines, mortality from lung cancer was not found to be statistically significantly increased (Chen et al., 1992; McLaughlin et al., 1992). In contrast, studies of Chinese tin miners found increased lung cancer mortality rates and positive exposure-response associations with increased silica exposure (Chen et al., 1992). Unfortunately, in many of these Chinese tin mines, there was potential confounding from arsenic exposure, which was highly correlated with exposure to crystalline silica (Chen and Chen, 2002; Chen et al., 2006). Two other studies (Carta et al. (2001) of Sardinian miners and stone quarrymen; Finkelstein (1998) primarily of Canadian miners) were limited to silicotics. The Sardinian study found a non-statistically significant association between crystalline silica exposure and lung cancer mortality but no apparent exposure-response trend with silica exposure. The authors attributed the increased lung cancer to increased radon exposure and smoking among cases as compared to controls. Finkelstein (1998) found a positive association between silica exposure and lung cancer.

Gold mining has been extensively studied in the United States, South

Africa, and Australia in four cohort and associated nested case-control studies, and in two separate case-control studies conducted in South Africa. As with metal ore mining, gold mining involves exposure to radon and other carcinogenic agents, which may confound the relationship between silica exposure and lung cancer. The U.S. gold miner study (Steenland and Brown, 1995a) did not find an increased risk of lung cancer, while the western Australian gold miner study (de Klerk and Musk, 1998) showed a SMR of 149 (95% CI 1.26–1.76) for lung cancer. Logistic regression analysis of the western Australian case control data showed that lung cancer mortality was statistically significantly associated with log cumulative silica exposure after adjusting for smoking and bronchitis. After additionally adjusting for silicosis, the relative risk remained elevated but was no longer statistically significant. The authors concluded that their findings showed statistically significantly increased lung cancer mortality in this cohort but that the increase in lung cancer mortality was restricted to silicotic members of the cohort.

Four studies of gold miners were conducted in South Africa. Two case control studies (Hessel et al., 1986, 1990) reported no significant association between silica exposure and lung cancer, but these two studies may have underestimated risk, according to Hnizdo and Sluis-Cremer (1991). Two cohort studies (Reid and Sluis-Cremer, 1996; Hnizdo and Sluis-Cremer, 1991) and their associated nested case-control studies found elevated SMRs and odds ratios, respectively, for lung cancer. Reid and Sluis-Cremer (1996) attributed the increased mortality due to lung cancer and other non-malignant respiratory diseases to cohort members' lifestyle choices (particularly smoking and alcohol consumption). However, OSHA notes that the study reported finding a positive, though not statistically significant, association between cumulative crystalline silica exposure and lung cancer, as well as statistically significant association with renal failure, COPD, and other respiratory diseases that have been implicated with silica exposure.

In contrast, Hnizdo and Sluis-Cremer (1991) found a positive exposure-response relationship between cumulative exposure and lung cancer mortality among South African gold miners after accounting for smoking. In a nested case-control study from the same cohort, Hnizdo et al. (1997) found a statistically significant increase in lung cancer mortality that was associated with increased cumulative dust exposure and time spent underground. Of the studies examining silica and lung cancer among South African gold miners, these two studies were the least likely to have been affected by exposure misclassification, given their rigorous methodologies and exposure measurements. Although not conclusive in isolation, OSHA considers the mining study results, particularly the gold mining and the newer mining studies, as supporting evidence of a causal relationship between exposure to silica and lung cancer risk.

OSHA has preliminarily determined that the results of the studies conducted in three industry sectors (foundry, silicon carbide, and construction sectors) were confounded by the presence of exposures to other carcinogens. Exposure data from these studies were not sufficient to distinguish between exposure to silica dust and exposure to other occupational carcinogens. Thus, elevated rates of lung cancer found in these industries could not be attributed to silica. IARC previously made a similar determination in reference to the foundry industry. However, with respect to the construction industry, Cassidy et al. (2007), in a large, European community-based case-control study, reported finding a clear linear trend of increasing odds ratio with increasing cumulative exposure to crystalline silica (estimated semi-quantitatively) after adjusting for smoking and exposure to insulation and wood dusts. Similar trends were found for workers in the manufacturing and mining industries as well. This study was a very large multi-national study that utilized information on smoking histories and exposure to silica and other occupational carcinogens. OSHA believes that this study provides further evidence that exposure to crystalline silica increases the risk of lung cancer mortality and, in particular, in the construction industry.

In addition, a recent analysis of 4.8 million death certificates from 27 states within the U.S. for the years 1982 to 1995 showed statistically significant excesses in lung cancer mortality, silicosis mortality, tuberculosis, and NMRD among persons with occupations involving medium and high exposure to respirable crystalline silica (Calvert et al., 2003). A national records and death certificate study was also conducted in Finland by Pukkala et al. (2005), who found a statistically significant excess of lung cancer incidence among men and women with estimated medium and heavy exposures. OSHA believes that these large national death certificate studies and the pooled European community-based case-control study are strongly supportive of the previously reviewed epidemiologic data and supports the conclusion that occupational exposure to crystalline silica is a risk factor for lung cancer mortality.

One of the more compelling studies evaluated by OSHA is the pooled analysis of 10 occupational cohorts (5 mines and 5 industrial facilities) conducted by Steenland et al. (2001a), which demonstrated an overall positive exposure-response relationship between cumulative exposure to silica and lung cancer mortality. These ten cohorts included 65,980 workers and 1,072 lung cancer deaths, and were selected because of the availability of raw data on exposure to crystalline silica and health outcomes. The investigators used a nested case control design and found lung cancer risk increased with increasing cumulative exposure, log cumulative exposure, and average exposure. Exposure-response trends were similar between mining and non-mining cohorts. From their analysis, the authors concluded that ''[d]espite this relatively shallow exposure–response trend, overall our results tend to support the recent conclusion by IARC (1997) that inhaled crystalline silica in occupational settings is a human carcinogen, and suggest that existing permissible exposure limits for silica need to be lowered (Steenland et al., 2001a). To evaluate the potential effect of random and systematic errors in the underlying exposure data from these 10 cohort studies, Steenland and Bartell (Toxichemica, Inc., 2004) conducted a series of sensitivity analyses at OSHA's request. OSHA's Preliminary Quantitative Risk Assessment (Section II) presents additional information on the Steenland et al. (2001a) pooled cohort study and the sensitivity analysis performed by Steenland and Bartell (Toxichemica, Inc., 2004).

2. Smoking, Silica Exposure, and Lung Cancer

Smoking is known to be a major risk factor for lung cancer. However, OSHA believes it is unlikely that smoking explains the observed exposure-response trends in the studies described above, particularly the retrospective cohort or nested case-control studies of diatomaceous earth, British pottery, Vermont granite, British coal, South African gold, and industrial sand workers. Also, the positive associations between silica exposure and lung cancer in multiple studies in multiple sectors indicates that exposure to crystalline

silica independently increases the risk of lung cancer.

Studies by Hnizdo et al. (1997), McLaughlin et al. (1992), Hughes et al. (2001), McDonald et al. (2001, 2005), Miller and MacCalman (2009), and Cassidy et al. (2007) had detailed smoking histories with sufficiently large populations and a sufficient number of years of follow-up time to quantify the interaction between crystalline silica exposure and cigarette smoking. In a cohort of white South African gold miners (Hnizdo and Sluis-Cremer, 1991) and in the follow-up nested case-control study (Hnizdo et al., 1997) found that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive, suggesting a multiplicative effect. This synergy appeared to be greatest for miners with greater than 35 pack-years of smoking and higher cumulative exposure to silica. In the Chinese nested case-control studies reported by McLaughlin et al. (1992), cigarette smoking was associated with lung cancer, but control for smoking did not influence the association between silica and lung cancer in the mining and pottery cohorts studied. The studies of industrial sand workers by Hughes et al. (2001) and British coal workers by Miller and MacCalman (2009) found positive exposure-response trends after adjusting for smoking histories, as did Cassidy et al. (2007) in their community-based case-control study of exposed European workers.

In reference to control of potential confounding by cigarette smoking in crystalline silica studies, Stayner (2007), in an invited journal commentary, stated:

> Of particular concern in occupational cohort studies is the difficulty in adequately controlling for confounding by cigarette smoking. Several of the cohort studies that adjusted for smoking have demonstrated an excess of lung cancer, although the control for smoking in many of these studies was less than optimal. The results of the article by Cassidy et al. presented in this journal appear to have been well controlled for smoking and other workplace exposures. It is quite implausible that residual confounding by smoking or other risk factors for lung cancer in this or other studies could explain the observed excess of lung cancer in the wide variety of populations and study designs that have been used. Also, it is generally considered very unlikely that confounding by smoking could explain the positive exposure-response relationships observed in these studies, which largely rely on comparisons between workers with similar socioeconomic backgrounds.

Given the findings of investigators who have accounted for the impact of smoking, the weight of the evidence reviewed here implicates respirable crystalline silica as an independent risk factor for lung cancer mortality. This finding is further supported by animal studies demonstrating that exposure to silica alone can cause lung cancer (*e.g.,* Muhle et al., 1995).

3. Silicosis and Lung Cancer Risk

In general, studies of workers with silicosis, as well as meta-analyses that include these studies, have shown that workers with radiologic evidence of silicosis have higher lung cancer risk than those without radiologic abnormalities or mixed cohorts. Three meta-analyses attempted to look at the association of increasing ILO radiographic categories of silicosis with increasing lung cancer mortality. Two of these analyses (Kurihara and Wada, 2004; Tsuda et al., 1997) showed no association with increasing lung cancer mortality, while Lacasse et al. (2005) demonstrated a positive dose-response for lung cancer with increasing ILO radiographic category. A number of other studies, discussed above, found increased lung cancer risk among exposed workers absent radiological evidence of silicosis (Cassidy et al., 2007; Checkoway et al., 1999; Cherry et al., 1998; Hnizdo et al., 1997; McLaughlin et al., 1992). For example, the diatomaceous earth study by Checkoway et al. (1999) showed a statistically significant exposure-response for lung cancer among non-silicotics. Checkoway and Franzblau (2000), reviewing the international literature, found all epidemiological studies conducted to that date were insufficient to conclusively determine the role of silicosis in the etiology of lung cancer. OSHA preliminarily concludes that the more recent pooled and meta-analyses do not provide compelling evidence that silicosis is a necessary precursor to lung cancer. The analyses that do suggest an association between silicosis and lung cancer may simply reflect that more highly exposed individuals are at a higher risk for lung cancer.

Animal and *in vitro* studies have demonstrated that the early steps in the proposed mechanistic pathways that lead to silicosis and lung cancer seem to share some common features. This has led some of these researchers to also suggest that silicosis is a prerequisite to lung cancer. Some have suggested that any increased lung cancer risk associated with silica may be a consequence of the inflammation (and concomitant oxidative stress) and increased epithelial cell proliferation associated with the development of silicosis. However, other researchers have noted that other key factors and proposed mechanisms, such as direct damage to DNA by silica, inhibition of p53, loss of cell cycle regulation, stimulation of growth factors, and production of oncogenes, may also be involved in carcinogenesis induced by silica (*see* Section II.F of the background document for more information on these studies). Thus, OSHA preliminarily concludes that available animal and *in vitro* studies do not support the hypothesis that development of silicosis is necessary for silica exposure to cause lung cancer.

4. Relationship Between Silica Polymorphs and Lung Cancer Risk

OSHA's current PELs for respirable crystalline silica reflects a once-held belief that cristobalite is more toxic than quartz (*i.e.,* the existing general industry PEL for cristobalite is one-half the general industry PEL for quartz). Available evidence indicates that this does not appear to be the case with respect to the carcinogenicity of crystalline silica. A comparison between cohorts having principally been exposed to cristobalite (the diatomaceous earth study and the Italian refractory brick study) with other well conducted studies of quartz-exposed cohorts suggests no difference in the toxicity of cristobalite versus quartz. The data indicates that the SMRs for lung cancer mortality among workers in the diatomaceous earth (SMR = 141) and refractory brick (SMR=151) cohort studies are within the range of the SMR point estimates of other cohort studies with principally quartz exposures (quartz exposure of Vermont granite workers yielding an SMR of 117; quartz and possible post-firing cristobalite exposure of British pottery workers yielding an SMR of 129; quartz exposure among industrial sand workers yielding SMRs of 129, (McDonald et al., 2001) and 160 (Steenland and Sanderson, 2001)). Also, the SMR point estimates for the diatomaceous earth and refractory brick studies are similar to, and fall within the 95 percent confidence interval of, the odds ratio (OR=1.37, 95% CI 1.14–1.65) of the recently conducted multi-center case-control study in Europe (Cassidy et al., 2007).

OSHA believes that the current epidemiological literature provides little, if any, support for treating cristobalite as presenting a greater lung cancer risk than comparable exposure to respirable quartz. Furthermore, the weight of the available toxicological literature no longer supports the hypothesis that cristobalite has a higher toxicity than quartz, and quantitative

estimates of lung cancer risk do not suggest that cristobalite is more carcinogenic than quartz. (*See* Section I.F of the background document, Physical Factors that May Influence Toxicity of Crystalline Silica, for a fuller discussion of this issue.) OSHA preliminary concludes that respirable cristobalite and quartz dust have similar potencies for increasing lung cancer risk. Both IARC (1997) and NIOSH (2002) reached similar conclusions.

5. Cancers of Other Sites

Respirable crystalline silica exposure has also been investigated as a potential risk factor for cancer at other sites such as the larynx, nasopharynx and the digestive system including the esophagus and stomach. Although many of these studies suggest an association between exposure to crystalline silica and an excess risk of cancer mortality, most are too limited in terms of size, study design, or potential for confounding to be conclusive. Other than for lung cancer, cancer mortality studies demonstrating a dose-response relationship are quite limited. In their silica hazard review, NIOSH (2002) concluded that, exclusive of the lung, an association has not been established between silica exposure and excess mortality from cancer at other sites. A brief summary of the relevant literature is presented below.

a. Cancer of the Larynx and Nasopharynx

Several studies, including three of the better-quality lung cancer studies (Checkoway et al., 1997; Davis et al., 1983; McDonald et al., 2001) suggest an association between exposure to crystalline silica and increased mortality from laryngeal cancer. However, the evidence for an association is not strong due to the small number of cases reported and lack of statistical significance of most of the findings.

b. Gastric (Stomach) Cancer

In their 2002 hazard review of respirable crystalline silica, NIOSH identified numerous epidemiological studies and reported statistically significant increases in death rates due to gastric or stomach cancer. OSHA preliminarily concurs with observations made previously by Cocco et al. (1996) and the NIOSH (2002) crystalline silica hazard review that the vast majority of epidemiology studies of silica and stomach cancer have not sufficiently adjusted for the effects of confounding factors or have not been sufficiently designed to assess a dose-response relationship (*e.g.,* Finkelstein and Verma, 2005; Moshammer and Neuberger, 2004; Selikoff, 1978, Stern et al., 2001). Other studies did not demonstrate a statistically significant dose-response relationship (*e.g.,* Calvert et al., 2003; Tsuda et al., 2001). Therefore, OSHA believes the evidence is insufficient to conclude that silica is a gastric carcinogen.

c. Esophageal Cancer

Three well-conducted nested case-control studies of Chinese workers indicated an increased risk of esophageal cancer mortality attributed by the study's authors to respirable crystalline silica exposure in refractory brick production, boiler repair, and foundry workers (Pan et al., 1999; Wernli et al., 2006) and caisson construction work (Yu et al., 2005). Each study demonstrated a dose-response association with some surrogate measure of exposure, but confounding due to other occupational exposures is possible in all three work settings (heavy metal exposure in the repair of boilers in steel plants, PAH exposure in foundry workers, radon and radon daughter exposure in Hong Kong caisson workers). Other less well-constructed studies also indicated elevated rates of esophageal cancer mortality with silica exposure (Tsuda et al., 2001; Xu et al., 1996a).

In contrast, two large national mortality studies in Finland and the United States, using qualitatively ranked exposure estimates, did not show a positive association between silica exposure and esophageal cancer mortality (Calvert et al., 2003; Weiderpass et al., 2003). OSHA preliminarily concludes that the epidemiological literature is not sufficiently robust to attribute increased esophageal cancer mortality to exposure to respirable crystalline silica.

d. Other Miscellaneous Cancers

In 2002, NIOSH conducted a thorough literature review of the health effects potentially associated with crystalline silica exposure including a review of lung cancer and other carcinogens. NIOSH noted that for workers who may have been exposed to crystalline silica, there have been infrequent reports of statistically significant excesses of deaths for other cancers. A summary of these cancer studies as cited in NIOSH (2002) have been reported in the following organ systems (*see* NIOSH, 2002 for full bibliographic references): salivary gland; liver; bone; pancreatic; skin; lymphopoetic or hematopoietic; brain; and bladder.

According to NIOSH (2002), an association has not been established between these cancers and exposure to crystalline silica. OSHA believes that these isolated reports of excess cancer mortality at these sites are not sufficient to draw any inferences about the role of silica exposure. The findings have not been consistently seen among epidemiological studies and there is no evidence of an exposure response relationship.

C. Other Nonmalignant Respiratory Disease

In addition to causing silicosis, exposure to crystalline silica has been associated with increased risks of other non-malignant respiratory diseases (NMRD), primarily chronic obstructive pulmonary disease (COPD). COPD is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases. In patients with COPD, either chronic bronchitis or emphysema may be present or both conditions may be present together. The following presents OSHA's discussion of the literature describing the relationships between silica exposure and non-malignant respiratory disease.

1. Emphysema

OSHA has considered a series of longitudinal studies of white South African gold miners conducted by Hnizdo and co-workers. Hnizdo et al. (1991) found a significant association between emphysema (both panacinar and centriacinar) and years of employment in a high dust occupation (respirable dust was estimated to contain 30 percent free silica). There was no such association found for non-smokers, as there were only four non-smokers with a significant degree of emphysema found in the cohort. A further study by Hnizdo et al. (1994) looked at only life-long non-smoking South African gold miners. In this population, no significant degree of emphysema or association with years of exposure or cumulative dust exposure was found. However, the degree of emphysema was significantly associated with the degree of hilar gland nodules, which the authors suggested might act as a surrogate for exposure to silica. The authors concluded that the minimal degree of emphysema seen in non-smoking miners exposed to the cumulative dust levels found in this study (mean 6.8 mg/m^3, SD 2.4, range 0.5 to 20.2, 30 percent crystalline silica) was unlikely to cause meaningful impairment of lung function.

From the two studies above, Hnizdo et al. (1994) concluded that the statistically significant association between exposure to silica dust and the degree of emphysema in smokers suggests that tobacco smoking potentiates the effect of silica dust. In contrast to their previous studies, a later study by Hnizdo et al. (2000) of South African gold miners found that emphysema prevalence was decreased in relation to dust exposure. The authors suggested that selection bias was responsible for this finding.

The findings of several cross-sectional and case-control studies were more mixed. Becklake et al. (1987), in an unmatched case-control study of white South African gold miners, determined that a miner who had worked in high dust for 20 years had a greater chance of getting emphysema than a miner who had never worked in high dust. A reanalysis of this data (de Beer et al., 1992) including added-back cases and controls (because of possible selection bias in the original study), still found an increased risk for emphysema, although the reported odds ratio was smaller than previously reported by Becklake et al. (1987). Begin et al. (1995), in a study of the prevalence of emphysema in silica-exposed workers with and without silicosis, found that silica-exposed smokers without silicosis had a higher prevalence of emphysema than a group of asbestos-exposed workers with similar smoking history. In non-smokers, the prevalence of emphysema was much higher in those with silicosis than in those without silicosis. A study of black underground gold miners found that the presence and grade of emphysema were statistically significantly associated with the presence of silicosis but not with years of mining (Cowie et al., 1993).

Several of the above studies (Becklake et al., 1987; Begin et al., 1995; Hnizdo et al., 1994) found that emphysema can occur in silica-exposed workers who do not have silicosis and suggest that a causal relationship may exist between exposure to silica and emphysema. The findings of experimental (animal) studies that emphysema occurs at lower silica doses than does fibrosis in the airways or the appearance of early silicotic nodules (*e.g.,* Wright et al., 1988) tend to support the findings in human studies that silica-induced emphysema can occur absent signs of silicosis.

Others have also concluded that there is a relationship between emphysema and exposure to crystalline silica. Green and Vallyathan (1996) reviewed several studies of emphysema in workers exposed to silica. The authors stated that these studies show an association between cumulative dust exposure and death from emphysema. IARC (1997) has also briefly reviewed studies on emphysema in its monograph on crystalline silica carcinogenicity and concluded that exposure to crystalline silica increases the risk of emphysema. In their 2002 Hazard Review, NIOSH concluded that occupational exposure to respirable crystalline silica is associated with emphysema but that some epidemiologic studies suggested that this effect may be less frequent or absent in non-smokers.

Hnizdo and Vallyathan (2003) also conducted a review of studies addressing COPD due to occupational silica exposure and concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause emphysema.

Based on these findings, OSHA preliminarily concludes that exposure to respirable crystalline silica or silica-containing dust can increase the risk of emphysema, regardless of whether silicosis is present. This appears to be clearly the case for smokers. It is less clear whether nonsmokers exposed to silica would also be at higher risk and if so, at what levels of exposure. It is also possible that smoking potentiates the effect of silica dust in increasing emphysema risk.

2. Chronic Bronchitis

There were no longitudinal studies available designed to investigate the relationship between silica exposure and bronchitis. However, several cross-sectional studies provide useful information. Studies are about equally divided between those that have reported a relationship between silica exposure and bronchitis and those that have not. Several studies demonstrated a qualitative or semiquantitative relationship between silica exposure and chronic bronchitis. Sluis-Cremer et al. (1967) found a significant difference between the prevalence of chronic bronchitis in dust-exposed and non-dust exposed male residents of a South African gold mining town who smoked, but found no increased prevalence among non-smokers. In contrast, a different study of South African gold miners found that the prevalence of chronic bronchitis increased significantly with increasing dust concentration and cumulative dust exposure in smokers, nonsmokers, and ex-smokers (Wiles and Faure, 1977). Similarly, a study of Western Australia gold miners found that the prevalence of chronic bronchitis, as indicated by odds ratios (controlled for age and smoking), was significantly increased in those that had worked in the mines for 1 to 9 years, 10 to 19 years, and more than 20 years, as compared to lifetime non-miners (Holman et al., 1987). Chronic bronchitis was present in 62 percent of black South African gold miners and 45 percent of those who had never smoked in a study by Cowie and Mabena (1991). The prevalence of what the researchers called ''chronic bronchitic symptom complex'' reflected the intensity of dust exposure. A higher prevalence of respiratory symptoms, independent of smoking and age, was also found for granite quarry workers in Singapore in a high exposure group as compared to low exposure and control groups, even after excluding those with silicosis from the analysis (Ng et al., 1992b).

Other studies found no relationship between silica exposure and the prevalence of chronic bronchitis. Irwig and Rocks (1978) compared silicotic and non-silicotic South African gold miners and found no significant difference in symptoms of chronic bronchitis. The prevalence of symptoms of chronic bronchitis were also not found to be associated with years of mining, after adjusting for smoking, in a population of current underground uranium miners (Samet et al., 1984). Silica exposure was described in the study to be ''on occasion'' above the TLV. It was not possible to determine, however, whether miners with respiratory diseases had left the workforce, making the remaining population unrepresentative. Hard-rock (molybdenum) miners, with 27 and 49 percent of personal silica samples greater than 100 and 55 $\mu g/m^3$, respectively, also showed no increase in prevalence of chronic bronchitis in association with work in that industry (Kreiss et al., 1989). However, the authors thought that differential out-migration of symptomatic miners and retired miners from the industry and town might explain that finding. Finally, grinders of agate stones (with resulting dust containing 70.4 percent silica) in India also had no increase in the prevalence of chronic bronchitis compared to controls matched by socioeconomic status, age and smoking, although there was a significantly higher prevalence of acute bronchitis in female grinders. A significantly higher prevalence and increasing trend with exposure duration for pneumoconiosis in the agate workers indicated that had an increased prevalence in chronic bronchitis been present, it would have been detected (Rastogi et al., 1991). However, control workers in this study may also have been exposed to silica and the study and control workers both

had high tuberculosis prevalence, possibly masking an association of exposure with bronchitis (NIOSH, 2002). Furthermore, exposure durations were very short.

Thus, some prevalence studies supported a finding of increased bronchitis in workers exposed to silica-containing dust, while other studies did not support such a finding. However, OSHA believes that many of the studies that did not find such a relationship were likely to be biased towards the null. For example, some of the molybdenum miners studied by Kreiss et al. (1989), particularly retired and symptomatic miners, may have left the town and the industry before the time that the cross-sectional study was conducted, resulting in a survivor effect that could have interfered with detection of a possible association between silica exposure and bronchitis. This survivor effect may also have been operating in the study of uranium miners in New Mexico (Samet et al., 1984). In two of the negative studies, members of comparison and control groups were also exposed to crystalline silica (Irwig and Rocks, 1978; Rastogi et al., 1991), creating a potential bias toward the null. Additionally, tuberculosis in both exposed and control groups in the agate worker study (Rastogi et al., 1991)) may have masked an effect (NIOSH, 2002), and the exposure durations were very short. Several of the positive studies demonstrated a qualitative or semi-quantitative relationship between silica exposure and chronic bronchitis.

Others have reviewed relevant studies and also concluded that there is a relationship between exposure to crystalline silica and the development of bronchitis. The American Thoracic Society (ATS) (1997) published an official statement on the adverse effects of crystalline silica exposure that included a section that discussed studies on chronic bronchitis (defined by chronic sputum production). According to the ATS review, chronic bronchitis was found to be common among worker groups exposed to dusty environments contaminated with silica. In support of this conclusion, ATS cited studies with what they viewed as positive findings of South African (Hnizdo et al., 1990) and Australian (Holman et al., 1987) gold miners, Indonesian granite workers (Ng et al., 1992b), and Indian agate workers (Rastogi et al., 1991). ATS did not mention studies with negative findings.

A review published by NIOSH in 2002 discussed studies related to silica exposure and development of chronic bronchitis. NIOSH concluded, based on the same studies reviewed by OSHA, that occupational exposure to respirable crystalline silica is associated with bronchitis, but that some epidemiologic studies suggested that this effect may be less frequent or absent in non-smokers.

Hnizdo and Vallyathan (2003) also reviewed studies addressing COPD due to occupational silica exposure and concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause chronic bronchitis. They based this conclusion on studies that they cited as showing that the prevalence of chronic bronchitis increases with intensity of exposure. The cited studies were also reviewed by OSHA (Cowie and Mabena, 1991; Holman et al., 1987; Kreiss et al., 1989; Sluis-Cremer et al., 1967; Wiles and Faure, 1977).

OSHA preliminarily concludes that exposure to respirable crystalline silica may cause chronic bronchitis and an exposure-response relationship may exist. Smokers may be at increased risk as compared to non-smokers. Chronic bronchitis may occur in silica-exposed workers who do not have silicosis.

3. Pulmonary Function Impairment

OSHA has reviewed numerous studies on the relationship of silica exposure to pulmonary function impairment as measured by spirometry. There were several longitudinal studies available. Two groups of researchers conducted longitudinal studies of lung function impairment in Vermont granite workers and reached opposite conclusions. Graham et al (1981, 1994) examined stone shed workers, who had the highest exposures to respirable crystalline silica (between 50 and 100 $\mu g/m^3$), along with quarry workers (presumed to have lower exposure) and office workers (expected to have negligible exposure). The longitudinal losses of FVC and FEV_1 were not correlated with years employed, did not differ among shed, quarry, and office workers, and were similar, according to the authors, to other blue collar workers not exposed to occupational dust.

Eisen et al. (1983, 1995) found the opposite. They looked at lung function in two groups of granite workers: ''survivors'', who participated in each of five annual physical exams, and ''dropouts'', who did not participate in the final exam. There was a significant exposure-response relationship between exposure to crystalline silica and FEV_1 decline among the dropouts but not among the survivors. The dropout group had a steeper FEV_1 loss, and this was true for each smoking category. The authors concluded that exposures of about 50 ug/m^3 produced a measurable effect on pulmonary function in the dropouts. Eisen et al. (1995) felt that the ''healthy worker effect'' was apparent in this study and that studies that only looked at ''survivors'' would be less likely to see any effect of silica on pulmonary function.

A 12-year follow-up of age- and smoking-matched granite crushers and referents in Sweden found that over the follow-up period, the granite crushers had significantly greater decreases in FEV_1, FEV_1/FVC, maximum expiratory flow, and FEF_{50} than the referents (Malmberg et al., 1993). A longitudinal study of South African gold miners conducted by Hnizdo (1992) found that cumulative dust exposure was a significant predictor of most indices of decreases in lung function, including FEV_1 and FVC. A multiple linear regression analysis showed that the effects of silica exposure and smoking were additive. Another study of South African gold miners (Cowie, 1998) also found a loss of FEV_1 in those without silicosis. Finally, a study of U.S. automotive foundry workers (Hertzberg et al., 2002) found a consistent association with increased pulmonary function abnormalities and estimated measures of cumulative silica exposure within 0.1 mg/m^3. The Hnizdo (1992), Cowie et al. (1993), and Cowie (1998) studies of South African gold miners and the Malmberg et al. (1993) study of Swedish granite workers found very similar reductions in FEV_1 attributable to silica dust exposure.

A number of prevalence studies have described relationships between lung function loss and silica exposure or exposure measurement surrogates (*e.g.,* duration of exposure). These findings support those of the longitudinal studies. Such results have been found in studies of white South African gold miners (Hnizdo et al., 1990; Irwig and Rocks, 1978), black South African gold miners (Cowie and Mabena, 1991), Quebec silica-exposed workers (Begin, et al., 1995), Singapore rock drilling and crushing workers (Ng et al., 1992b), Vermont granite shed workers (Theriault et al., 1974a, 1974b), aggregate quarry workers and coal miners in Spain (Montes et al., 2004a, 2004b), concrete workers in The Netherlands (Meijer et al., 2001), Chinese refractory brick manufacturing workers in an iron-steel plant (Wang et al., 1997), Chinese gemstone workers (Ng et al., 1987b), hard-rock miners in Manitoba, Canada (Manfreda et al., 1982) and Colorado (Kreiss et al., 1989), pottery workers in France (Neukirch et al., 1994), potato sorters exposed to diatomaceous earth containing crystalline silica in The Netherlands

(Jorna et al., 1994), slate workers in Norway (Suhr et al., 2003), and men in a Norwegian community (Humerfelt et al., 1998). Two of these prevalence studies also addressed the role of smoking in lung function impairment associated with silica exposure. In contrast to the longitudinal study of South African gold miners discussed above (Hnizdo, 1992), another study of South African gold miners (Hnizdo et al., 1990) found that the joint effect of dust and tobacco smoking on lung function impairment was synergistic, rather than additive. Also, Montes et al. (2004b) found that the criteria for dust-tobacco interactions were satisfied for FEV_1 decline in a study of Spanish aggregate quarry workers.

One of the longitudinal studies and many of the prevalence studies discussed above directly addressed the question of whether silica-exposed workers can develop pulmonary function impairment in the absence of silicosis. These studies found that pulmonary function impairment: (1) Can occur in silica-exposed workers in the absence of silicosis, (2) was still evident when silicosis was controlled for in the analysis, and (3) was related to the magnitude and duration of silica exposure rather than to the presence or severity of silicosis.

Many researchers have concluded that a relationship exists between exposure to silica and lung function impairment. IARC (1997) has briefly reviewed studies on airways disease (*i.e.,* chronic airflow limitation and obstructive impairment of lung function) in its monograph on crystalline silica carcinogenicity and concluded that exposure to crystalline silica causes these effects. In its official statement on the adverse effects of crystalline silica exposure, the American Thoracic Society (ATS) (1997) included a section on airflow obstruction. The ATS noted that, in most of the studies reviewed, airflow limitation was associated with chronic bronchitis. The review of Hnizdo and Vallyathan (2003) also addressed COPD due to occupational silica exposure. They examined the epidemiological evidence for an exposure-response relationship for airflow obstruction in studies where silicosis was present or absent. Hnizdo and Vallyathan (2003) concluded that chronic exposure to silica dust at levels that do not cause silicosis may cause airflow obstruction.

Based on the evidence discussed above from a number of longitudinal studies and numerous cross-sectional studies, OSHA preliminarily concludes that there is an exposure-response relationship between exposure to respirable crystalline silica and the development of impaired lung function. The effect of tobacco smoking on this relationship may be additive or synergistic. Also, pulmonary function impairment has been shown to occur among silica-exposed workers who do not show signs of silicosis.

4. Non-malignant Respiratory Disease Mortality

In this section, OSHA reviews studies on NMRD mortality that focused on causes of death other than from silicosis. Two studies of gold miners, a study of diatomaceous earth workers, and a case-control analysis of death certificate data provide useful information.

Wyndham et al. (1986) found a significant excess mortality for chronic respiratory diseases in a cohort of white South African gold miners. Although these data did include silicosis mortality, the authors found evidence demonstrating that none of the miners certified on the death certificate as dying from silicosis actually died from that disease. Instead, pneumoconiosis was always an incidental finding in those dying from some other cause, the most common of which was chronic obstructive lung disease. A case-referent analysis found that, although the major risk factor for chronic respiratory disease was smoking, there was a statistically significant additional effect of cumulative dust exposure, with the relative risk estimated to be 2.48 per ten units of 1000 particle years of exposure.

A synergistic effect of smoking and cumulative dust exposure on mortality from COPD was found in another study of white South African gold miners (Hnizdo, 1990). Analysis of various combinations of dust exposure and smoking found a trend in odds ratios that indicated this synergism. There was a statistically significant increasing trend for dust particle-years and for cigarette-years of smoking. For cumulative dust exposure, an exposure-response relationship was found, with the analysis estimating that those with exposures of 10,000, 17,500, or 20,000 particle-years of exposure had a 2.5-, 5.06-, or 6.4-times higher mortality risk for COPD, respectively, than those with the lowest dust exposure of less than 5000 particle-years. The authors concluded that dust alone would not lead to increased COPD mortality but that dust and smoking act synergistically to cause COPD and were thus the main risk factor for death from COPD in their study.

Park et al. (2002) analyzed the California diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994, to quantify the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park et al. (2002) to at least partially adjust for smoking. Using the exposure estimates developed for the cohort by Rice et al. (2001) in their exposure-response study of lung cancer risks, Park et al. (2002) evaluated the quantitative exposure-response relationship for LDOC mortality and found a strong positive relationship with exposure to respirable crystalline silica. OSHA finds this study particularly compelling because of the strengths of the study design and availability of smoking history data on part of the cohort and high-quality exposure and job history data; consequently, OSHA has included this study in its Preliminary Quantitative Risk Assessment.

In a case-control analysis of death certificate data drawn from 27 U.S. states, Calvert et al. (2003) found increased mortality odds ratios among those in the medium and higher crystalline silica exposure categories, a significant trend of increased risk for COPD mortality with increasing silica exposures, and a significantly increased odds ratio for COPD mortality in silicotics as compared to those without silicosis.

Green and Vallyathan (1996) also reviewed several studies of NMRD mortality in workers exposed to silica. The authors stated that these studies showed an association between cumulative dust exposure and death from the chronic respiratory diseases.

Based on the evidence presented in the studies above, OSHA preliminarily concludes that respirable crystalline silica increases the risk for mortality from non-malignant respiratory disease (not including silicosis) in an exposure-related manner. However, it appears that the risk is strongly influenced by smoking, and the effects of smoking and silica exposure may be synergistic.

D. Renal and Autoimmune Effects

In recent years, evidence has accumulated that suggests an association between exposure to crystalline silica and an increased risk

of renal disease. Over the past 10 years, epidemiologic studies have been conducted that provide evidence of exposure-response trends to support this association. There is also suggestive evidence that silica can increase the risk of rheumatoid arthritis and other autoimmune diseases (Steenland, 2005b). In fact, an autoimmune mechanism has been postulated for some silica-associated renal disease (Calvert et al., 1997). This section will discuss the evidence supporting an association of silica exposure with renal and autoimmune diseases.

Overall, there is substantial evidence suggesting an association between exposure to crystalline silica and increased risks of renal and autoimmune diseases. In addition to a number of case reports, epidemiologic studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (*e.g.,* Calvert et al., 1997), subclinical renal changes (*e.g.,* Ng et al., 1992c), end-stage renal disease morbidity (*e.g.,* Steenland et al., 1990), chronic renal disease mortality (Steenland et al., 2001b, 2002a), and Wegener's granulomatosis (Nuyts et al., 1995). In other findings, silica-exposed individuals, both with and without silicosis, had an increased prevalence of abnormal renal function (Hotz et al., 1995), and renal effects have been reported to persist after cessation of silica exposure (Ng et al., 1992c). Possible mechanisms suggested for silica-induced renal disease include a direct toxic effect on the kidney, deposition in the kidney of immune complexes (IgA) following silica-related pulmonary inflammation, or an autoimmune mechanism (Calvert et al., 1997; Gregorini et al., 1993).

Several studies of exposed worker populations reported finding excess renal disease mortality and morbidity. Wyndham et al. (1986) reported finding excess mortality from acute and chronic nephritis among South African goldminers that had been followed for 9 years. Italian ceramic workers experienced an overall increase in the prevalence of end-stage renal disease (ESRD) cases compared to regional rates; the six cases that occurred among the workers had cumulative exposures to crystalline silica of between 0.2 and 3.8 mg/m^3-years (Rapiti et al., 1999).

Calvert et al. (1997) found an increased incidence of non-systemic ESRD cases among 2,412 South Dakota gold miners exposed to a median crystalline silica concentration of 0.09 mg/m^3. In another study of South Dakota gold miners, Steenland and Brown (1995a) reported a positive trend of chronic renal disease mortality risk and cumulative exposure to respirable crystalline silica, but most of the excess deaths were concentrated among workers hired before 1930 when exposures were likely higher than in more recent years.

Excess renal disease mortality has also been described among North American industrial sand workers. McDonald et al., (2001, 2005) found that nephritis/nephrosis mortality was elevated overall among 2,670 industrial sand workers hired 20 or more years prior to follow-up, but there was no apparent relationship with either cumulative or average exposure to crystalline silica. However, Steenland et al. (2001b) did find that increased mortality from acute and chronic renal disease was related to increasing quartiles of cumulative exposure among a larger cohort of 4,626 industrial sand workers. In addition, they also found a positive trend for ESRD case incidence and quartiles of cumulative exposure.

In a pooled cohort analysis, Steenland et al. (2002a) combined the industrial sand cohort from Steenland et al. (2001b), gold mining cohort from Steenland and Brown (1995a), and the Vermont granite cohort studies by Costello and Graham (1988). In all, the combined cohort consisted of 13,382 workers with exposure information available for 12,783. The exposure estimates were validated by the monotonically increasing exposure-response trends seen in analyses of silicosis, since cumulative silica levels are known to predict silicosis risk. The mean duration of exposure, cumulative exposure, and concentration of respirable silica for the cohort were 13.6 years, 1.2 mg/m^3-years, and 0.07 mg/m^3, respectively.

The analysis demonstrated statistically significant exposure-response trends for acute and chronic renal disease mortality with quartiles of cumulative exposure to respirable crystalline silica. In a nested case-control study design, a positive exposure-response relationship was found across the three cohorts for both multiple-cause mortality (*i.e.,* any mention of renal disease on the death certificate) and underlying cause mortality. Renal disease risk was most prevalent among workers with cumulative exposures of 0.5 mg/m^3 or more (Steenland et al., 2002a).

Other studies failed to find an excess renal disease risk among silica-exposed workers. Davis et al. (1983) found an elevated, but not a statistically significant increase, in mortality from diseases of the genitourinary system among Vermont granite shed workers. There was no observed relationship between mortality from this cause and cumulative exposure. A similar finding was reported by Koskela et al. (1987) among Finnish granite workers, where there were 4 deaths due to urinary tract disease compared to 1.8 expected. Both Carta et al. (1994) and Cocco et al. (1994) reported finding no increased mortality from urinary tract disease among workers in an Italian lead mine and a zinc mine. However, Cocco et al. (1994) commented that exposures to respirable crystalline silica were low, averaging 0.007 and 0.09 mg/m^3 in the two mines, respectively, and that their study in particular had low statistical power to detect excess mortality.

There are many case series, case-control, and cohort studies that provide support for a causal relationship between exposure to respirable crystalline silica and an increased renal disease risk (Kolev et al., 1970; Osorio et al., 1987; Steenland et al., 1990; Gregorini et al., 1993; Nuyts et al., 1995). In addition, a number of studies have demonstrated early clinical signs of renal dysfunction (*i.e.,* urinary excretion of low- and high-molecular weight proteins and other markers of renal glomerular and tubular disruption) in workers exposed to crystalline silica, both with and without silicosis (Ng et al., 1992c; Hotz et al., 1995; Boujemaa, 1994; Rosenman et al., 2000).

OSHA believes that there is substantial evidence on which to base a finding that exposure to respirable crystalline silica increases the risk of renal disease mortality and morbidity. In particular, OSHA believes that the 3-cohort pooled analysis conducted by Steenland et al. (2002a) is particularly convincing. OSHA believes that the findings of this pooled analysis seem credible because the analysis involved a large number of workers from three cohorts with well-documented, validated job-exposure matrices and found a positive and monotonic increase in renal disease risk with increasing exposure for both underlying and multiple cause data. However, there are considerably less data, and thus the findings based on them are less robust, than what is available for silicosis mortality or lung cancer mortality. Nevertheless, OSHA preliminarily concludes that the underlying data are sufficient to provide useful estimates of risk and has included the Steenland et al. (2002a) analysis in its Preliminary Quantitative Risk Assessment.

Several studies of different designs, including case series, cohort, registry linkage and case-control, conducted in a variety of exposed groups suggest an association between silica exposure and

increased risk of systemic autoimmune disease (Parks et al., 1999). Studies have found that the most common autoimmune diseases associated with silica exposure are scleroderma (*e.g.,* Sluis-Cremer et al., 1985); rheumatoid arthritis (*e.g.* Klockars et al., 1987; Rosenman and Zhu, 1995); and systemic lupus erythematosus (*e.g.,* Brown et al., 1997). Mechanisms suggested for silica-related autoimmune disease include an adjuvant effect of silica (Parks et al., 1999), activation of the immune system by the fibrogenic proteins and growth factors released as a result of the interaction of silica particles with macrophages (*e.g.,* Haustein and Anderegg, 1998), and a direct local effect of non-respirable silica particles penetrating the skin and producing scleroderma (Green and Vallyathan, 1996). However, there are no quantitative exposure-response data available at this time on which to base a quantitative risk assessment for autoimmune diseases.

Therefore, OSHA preliminarily concludes that there is substantial evidence that silica exposure increases the risks of renal and autoimmune disease. The positive and monotonic exposure-response trends demonstrated for silica exposure and renal disease risk more strongly suggest a causal link. The studies by Steenland et al. (2001b, 2002a) and Steenland and Brown (1995a) provide evidence of a positive exposure-response relationship. For autoimmune diseases, the available data did not provide an adequate basis for assessing exposure-response relationships. However, OSHA believes that the available exposure-response data on silica exposure and renal disease is sufficient to allow for quantitative estimates of risk.

E. Physical Factors That May Influence Toxicity of Crystalline Silica

Much research has been conducted to investigate the influence of various physical factors on the toxicologic potency of crystalline silica. Such factors examined include crystal polymorphism; the age of fractured surfaces of the crystal particle; the presence of impurities, particularly metals, on particle surfaces; and clay occlusion of the particle. These factors likely vary among different workplace settings suggesting that the risk to workers exposed to a given level of respirable crystalline silica may not be equivalent in different work environments. In this section, OSHA examines the research demonstrating the effects of these factors on the toxicologic potency of silica.

The modification of surface characteristics by the physical factors noted above may alter the toxicity of silica by affecting the physical and biochemical pathways of the mechanistic process. Thus, OSHA has reviewed the proposed mechanisms by which silica exposure leads to silicosis and lung cancer. It has been proposed that silicosis results from a cycle of cell damage, oxidant generation, inflammation, scarring and fibrosis. A silica particle entering the lung can cause lung damage by two major mechanisms: direct damage to lung cells due to the silica particle's unique surface properties or by the activation or stimulation of alveolar macrophages (after phagocytosis) and/or alveolar epithelial cells. In either case, an elevated production of reactive oxygen and nitrogen species (ROS/RNS) results in oxidant damage to lung cells. The oxidative stress and lung injury stimulates alveolar macrophages and/or alveolar epithelial cells to produce growth factors and fibrogenic mediators, resulting in fibroblast activation and pulmonary fibrosis. A continuous ingestion-reingestion cycle, with cell activation and death, is established.

OSHA has examined evidence on the comparative toxicity of the silica polymorphs (quartz, cristobalite, and tridymite). A number of animal studies appear to suggest that cristobalite and tridymite are more toxic to the lung than quartz and more tumorigenic (*e.g.,* King et al., 1953; Wagner et al., 1980). However, in contrast to these findings, several authors have reviewed the studies done in this area and concluded that cristobalite and tridymite are not more toxic than quartz (*e.g.,* Bolsaitis and Wallace, 1996; Guthrie and Heaney, 1995). Furthermore, a difference in toxicity between cristobalite and quartz has not been observed in epidemiologic studies (tridymite has not been studied) (NIOSH, 2002). In an analysis of exposure-response for lung cancer, Steenland et al. (2001a) found similar exposure-response trends between cristobalite-exposed workers and other cohorts exposed to quartz.

A number of studies have compared the toxicity of freshly fractured versus aged silica. Although animal studies have demonstrated that freshly fractured silica is more toxic than aged silica, aged silica still retains significant toxicity (Porter et al., 2002; Shoemaker et al., 1995; Vallyathan et al., 1995). Studies of workers exposed to freshly fractured silica have demonstrated that these workers exhibit the same cellular effects as seen in animals exposed to freshly fractured silica (Castranova et al., 1998; Goodman et al., 1992). There have been no studies, however, comparing workers exposed to freshly fractured silica to those exposed to aged silica. Animal studies also suggest that pulmonary reactions of rats to short-duration exposure to freshly fractured silica mimic those seen in acute silicosis in humans (Vallyathan et al., 1995).

Surface impurities, particularly metals, have been shown to alter silica toxicity. Iron, depending on its state and quantity, has been shown to either increase or decrease toxicity. Aluminum has been shown to decrease toxicity (Castranova et al., 1997; Donaldson and Borm, 1998; Fubini, 1998). Silica coated with aluminosilicate clay exhibits lower toxicity, possibly as a result of reduced bioavailability of the silica particle surface (Donaldson and Borm, 1998; Fubini, 1998). This reduced bioavailability may be due to aluminum ions left on the silica surface by the clay (Bruch et al., 2004; Cakmak et al., 2004; Fubini et al., 2004). Aluminum and other metal ions are thought to modify silanol groups on the silica surface, thus decreasing the membranolytic and cytotoxic potency and resulting in enhanced particle clearance from the lung before damage can take place (Fubini, 1998). An epidemiologic study found that the risk of silicosis was less in pottery workers than in tin and tungsten miners (Chen et al., 2005; Harrison et al., 2005), possibly reflecting that pottery workers were exposed to silica particles having less biologically available, non-clay-occluded surface area than was the case for miners. The authors concluded that clay occlusion of silica particles can be a factor in reducing disease risk.

Although it is evident that a number of factors can act to mediate the toxicological potency of crystalline silica, it is not clear how such considerations should be taken into account to evaluate lung cancer and silicosis risks to exposed workers. After evaluating many *in vitro* studies that had been conducted to investigate the surface characteristics of crystalline silica particles and their influence on fibrogenic activity, NIOSH (2002) concluded that further research is needed to associate specific surface characteristics that can affect toxicity with specific occupational exposure situations and consequent health risks to workers. According to NIOSH (2002), such exposures may include work processes that produce freshly fractured silica surfaces or that involve quartz contaminated with trace elements such as iron. NIOSH called for further *in vitro* and *in vivo* studies of the toxicity and pathogenicity of alpha quartz compared with its polymorphs, quartz

contaminated with trace elements, and further research on the association of surface properties with specific work practices and health effects.

In discussing the ''considerable'' heterogeneity shown across the 10 studies used in the pooled lung cancer risk analysis, Steenland et al. (2001a) pointed to hypotheses that physical differences in silica exposure (*e.g.,* freshness of particle cleavage) between cohorts may be a partial explanation of observed differences in exposure-response coefficients derived from those cohort studies. However, the authors did not have specific information on whether or how these factors might have actually influenced the observed differences. Similarly, in the pooled analysis and risk assessments for silicosis mortality conducted by Mannetje et al. (2002b), differences in biological activity of different types of silica dust could not be specifically taken into account. Mannetje et al. (2002b) determined that the exposure-response relationship between silicosis and log-transformed cumulative exposure to crystalline silica was comparable between studies and no significant heterogeneity was found. The authors therefore concluded that their findings were relevant for different circumstances of occupational exposure to crystalline silica. Both the Steenland et al. (2001a) and Mannetje et al. (2002b) studies are discussed in detail in OSHA's Preliminary Quantitative Risk Assessment (section II of the background document and summarized in section VI of this preamble).

OSHA preliminarily concludes that there is considerable evidence to support the hypothesis that surface activity of crystalline silica particles plays an important role in producing disease, and that several environmental influences can modify surface activity to either enhance or diminish the toxicity of silica. However, OSHA believes that the available information is insufficient to determine in any quantitative way how these influences may affect disease risk to workers in any particular workplace setting.

VI. Summary of OSHA's Preliminary Quantitative Risk Assessment

A. Introduction

The Occupational Safety and Health Act (OSH Act or Act) and some landmark court cases have led OSHA to rely on quantitative risk assessment, to the extent possible, to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. A determining factor in the decision to perform a quantitative risk assessment is the availability of suitable data for such an assessment. In the case of crystalline silica, there has been extensive research on its health effects, and several quantitative risk assessments have been published in the peer-reviewed scientific literature that describe the risk to exposed workers of lung cancer mortality, silicosis mortality and morbidity, non-malignant respiratory disease mortality, and renal disease mortality. These assessments were based on several studies of occupational cohorts in a variety of industry sectors, the underlying studies of which are described in OSHA's review of the health effects literature (*see* section V of this preamble). In this section, OSHA summarizes its Preliminary Quantitative Risk Assessment (QRA) for crystalline silica, which is presented in Section II of the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (placed in Docket OSHA–2010–0034).

OSHA has done what it believes to be a comprehensive review of the literature to provide quantitative estimates of risk for crystalline silica-related diseases. Quantitative risk assessments for lung cancer and silicosis mortality were published after the International Agency for Research on Cancer (IARC) determined more than a decade ago that there was sufficient evidence to regard crystalline silica as a human carcinogen (IARC, 1997). This finding was based on several studies of worker cohorts demonstrating associations between exposure to crystalline silica and an increased risk of lung cancer. Although IARC judged the overall evidence as being sufficient to support this conclusion, IARC also noted that some studies of crystalline silica-exposed workers did not demonstrate an excess risk of lung cancer and that exposure-response trends were not always consistent among studies that were able to describe such trends. These findings led Steenland et al. (2001a) and Mannetje et al. (2002b) to conduct comprehensive exposure-response analyses of the risk of lung cancer and silicosis mortality associated with exposure to crystalline silica. These studies, referred to as the IARC multi-center studies of lung cancer and silicosis mortality, relied on all available cohort data from previously published epidemiological studies for which there were adequate quantitative data on worker exposures to crystalline silica to derive pooled estimates of disease risk. In addition, OSHA identified four single-cohort studies of lung cancer mortality that it judged suitable for quantitative risk assessment; two of these cohorts (Attfield and Costello, 2004; Rice et al., 2001) were included among the 10 used in the IARC multi-center study and studies of two other cohorts appeared later (Hughes et al., 2001; McDonald et al., 2001, 2005; Miller and MacCalman, 2009). For non-malignant respiratory disease mortality, in addition to the silicosis mortality study by Mannetje et al. (2002b), Park et al. (2002) conducted an exposure-response analysis of non-malignant respiratory disease mortality (including silicosis and other chronic obstructive pulmonary diseases) among diatomaceous earth workers. Exposure-response analyses for silicosis morbidity have been published in several single-cohort studies (Chen et al., 2005; Hnizdo and Sluis-Cremer, 1993; Steenland and Brown, 1995b; Miller et al., 1998; Buchanan et al., 2003). Finally, a quantitative assessment of end-stage renal disease mortality based on data from three worker cohorts was developed by Steenland et al. (2002a).

In addition to these published studies, OSHA's contractor, Toxichemica, Inc., commissioned Drs. Kyle Steenland and Scott Bartell of Emory University to perform an uncertainty analysis to examine the effect on lung cancer and silicosis mortality risk estimates of uncertainties that exist in the exposure assessments underlying the two IARC multi-center analyses (Toxichemica, Inc., 2004).

OSHA's Preliminary QRA presents estimates of the risk of silica-related diseases assuming exposure over a working life (45 years) to the proposed 8-hour time-weighted average (TWA) PEL and action level of 0.05 and 0.025 mg/m^3, respectively, of respirable crystalline silica, as well as to OSHA's current PELs. OSHA's current general industry PEL for respirable quartz is expressed both in terms of a particle count formula and a gravimetric concentration formula, while the current construction and shipyard employment PELs for respirable quartz are only expressed in terms of a particle count formula. The current PELs limit exposure to respirable dust; the specific limit in any given instance depends on the concentration of crystalline silica in the dust. For quartz, the gravimetric general industry PEL approaches a limit of 0.1 mg/m^3 as respirable quartz as the quartz content increases (*see* discussion in Section XVI of this preamble, Summary and Explanation for paragraph (c)). OSHA's Preliminary QRA presents risk estimates for

exposure over a working lifetime to 0.1 mg/m³ to represent the risk associated with exposure to the current general industry PEL. OSHA's current PEL for construction and shipyard employment is a formula PEL that limits exposure to respirable dust expressed as a respirable particle count concentration. As with the gravimetric general industry PEL, the limit varies depending on quartz content of the dust. There is no single mass concentration equivalent for the construction and shipyard PELs; OSHA's Preliminary QRA reviews several studies that suggest that the current construction/shipyard PEL likely lies in the range between 0.25 and 0.5 mg/m³ respirable quartz, and OSHA presents risk estimates for this range of exposure to represent the risks associated with exposure to the current construction/shipyard PEL. In general industry, for both the gravimetric and particle count PELs, OSHA's current PEL for cristobalite and tridymite are half the value for quartz. Thus, OSHA's Preliminary QRA presents risk estimates associated with exposure over a working lifetime to 0.025, 0.05, 0.1, 0.25, and 0.5 mg/m³ respirable silica (corresponding to cumulative exposures over 45 years to 1.125, 2.25, 4.5, 11.25, and 22.5 mg/m³-years).

Risk estimates for lung cancer mortality, silicosis and non-malignant respiratory disease mortality, and renal disease mortality are presented in terms of lifetime (up to age 85) excess risk per 1,000 workers for exposure over an 8-hour working day, 250 days per year, and a 45-year working life. For silicosis morbidity, OSHA based its risk estimates on cumulative risk models used by the various investigators to develop quantitative exposure-response relationships. These models characterized the risk of developing silicosis (as detected by chest radiography) up to the time that cohort members (including both active and retired workers) were last examined. Thus, risk estimates derived from these studies represent less-than-lifetime risks of developing radiographic silicosis. OSHA did not attempt to estimate lifetime risk (*i.e.,* up to age 85) for silicosis morbidity because the relationships between age, time, and disease onset post-exposure have not been well characterized.

A draft preliminary quantitative risk assessment document was submitted for external scientific peer review in accordance with the Office of Management and Budget's ''Final Information Quality Bulletin for Peer Review'' (OMB, 2004). A summary of OSHA's responses to the peer reviewers' comments appears in Section III of the background document.

In the sections below, OSHA describes the studies and the published risk assessments it uses to estimate the occupational risk of crystalline silica-related disease. (The Preliminary QRA itself also discusses several other available studies that OSHA does not include and OSHA's reasons for not including these studies.)

B. Lung Cancer Mortality

1. Summary of Studies

In its Preliminary QRA, OSHA discusses risk assessments from six published studies that quantitatively analyzed exposure-response relationships for crystalline silica and lung cancer; some of these also provided estimates of risks associated with exposure to OSHA's current PEL or NIOSH's Recommended Exposure Limit (REL) of 0.05 mg/m³. These studies include: (1) A quantitative analysis by Steenland et al. (2001a) of worker cohort data pooled from ten studies; (2) an exposure-response analysis by Rice et al. (2001) of a cohort of diatomaceous earth workers primarily exposed to cristobalite; (3) an analysis by Attfield and Costello (2004) of U.S. granite workers; (4) a risk assessment by Kuempel et al. (2001), who employed a kinetic rat lung model to describe the relationship between quartz lung burden and cancer risk, then calibrated and validated that model using the diatomaceous earth worker and granite worker cohort mortality data; (5) an exposure-response analysis by Hughes et al., (2001) of U.S. industrial sand workers; and (6) a risk analysis by Miller et al. (2007) and Miller and MacCalman (2009) of British coal miners. These six studies are described briefly below and are followed by a summary of the lung cancer risk estimates derived from these studies.

a. Steenland et al. (2001a) Pooled Cohort Analysis

OSHA considers the lung cancer analysis conducted by Steenland et al. (2001a) to be of prime importance for risk estimation because of its size, incorporation of data from multiple cohorts, and availability of detailed exposure and job history data. Subsequent to its publication, Steenland and Bartell (Toxichemica, Inc., 2004) conducted a quantitative uncertainty analysis on the pooled data set to evaluate the potential impact on the risk estimates of random and systematic exposure misclassification, and Steenland (personal communication, 2010) conducted additional exposure-response modeling.

The original study consisted of a pooled exposure-response analysis and risk assessment based on raw data obtained from ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths). Steenland et al. (2001a) initially identified 13 cohort studies as containing exposure information sufficient to develop a quantitative exposure assessment; the 10 studies included in the pooled analysis were those for which data on exposure and health outcome could be obtained for individual workers. The cohorts in the pooled analysis included U.S. gold miners (Steenland and Brown, 1995a), U.S. diatomaceous earth workers (Checkoway et al., 1997), Australian gold miners (de Klerk and Musk, 1998), Finnish granite workers (Koskela et al., 1994), U.S. industrial sand employees (Steenland and Sanderson, 2001), Vermont granite workers (Costello and Graham, 1988), South African gold miners (Hnizdo and Sluis-Cremer, 1991; Hnizdo et al., 1997), and Chinese pottery workers, tin miners, and tungsten miners (Chen et al., 1992).

The exposure assessments developed for the pooled analysis are described by Mannetje et al. (2002a). The exposure information and measurement methods used to assess exposure from each of the 10 cohort studies varied by cohort and by time and included dust measurements representing particle counts, mass of total dust, and respirable dust mass. All exposure information was converted to units of mg/m³ respirable crystalline silica by generating cohort-specific conversion factors based on the silica content of the dust to which workers were exposed.

A case-control study design was employed for which cases and controls were matched for race, sex, age (within 5 years) and study; 100 controls were matched to each case. To test the reasonableness of the cumulative exposure estimates for cohort members, Mannetje et al. (2002a) examined exposure-response relationships for silicosis mortality by performing a nested case-control analysis for silicosis or unspecified pneumoconiosis using conditional logistic regression. Each cohort was stratified into quartiles by cumulative exposure, and standardized rate ratios (SRR) for silicosis were calculated using the lowest-exposure quartile as the baseline. Odds ratios (OR) for silicosis were also calculated for the pooled data set overall, which was stratified into quintiles based on cumulative exposure.

For the pooled data set, the relationship between odds ratio for silicosis mortality and increasing cumulative exposure was ''positive and reasonably monotonic'', ranging from 3.1 for the lowest quartile of exposure to 4.8 for the highest. In addition, in seven of the ten individual cohorts, there were statistically significant trends between silicosis mortality rate ratios (SRR) and cumulative exposure. For two of the cohorts (U.S. granite workers and U.S. gold miners), the trend test was not statistically significant (p=0.10). A trend analysis could not be performed on the South African gold miner cohort since silicosis was not coded as an underlying cause of death in that country. A more rigorous analysis of silicosis mortality on pooled data from six of these cohorts also showed a strong, statistically significant increasing trend with increasing decile of cumulative exposure (Mannetje et al., 2002b), providing additional evidence for the reasonableness of the exposure assessment used for the Steenland et al (2001a) lung cancer analysis.

For the pooled lung cancer mortality analysis, Steenland et al. (2001a) conducted a nested case-control analysis via Cox regression, in which there were 100 controls chosen for each case randomly selected from among cohort members who survived past the age at which the case died, and matched on age (the time variable in Cox regression), study, race/ethnicity, sex, and date of birth within 5 years (which, in effect, matched on calendar time given the matching on age). Using alternative continuous exposure variables in a log-linear relative risk model (log RR=βx, where x represents the exposure variable and β the coefficient to be estimated), Steenland et al. (2001a) found that the use of either 1) cumulative exposure with a 15-year lag, 2) the log of cumulative exposure with a 15-year lag, or 3) average exposure resulted in positive statistically significant ($p \leq 0.05$) exposure-response coefficients. The models that provided the best fit to the data were those that used cumulative exposure and log-transformed cumulative exposure. The fit of the log-linear model with average exposure was clearly inferior to those using cumulative and log-cumulative exposure metrics.

There was significant heterogeneity among studies (cohorts) using either cumulative exposure or average exposure. The authors suggested a number of possible reasons for such heterogeneity, including errors in measurement of high exposures (which tends to have strong influence on the exposure-response curve when untransformed exposure measures are used), the differential toxicity of silica depending on the crystalline polymorph, the presence of coatings or trace minerals that alter the reactivity of the crystal surfaces, and the age of the fractured surfaces. Models that used the log transform of cumulative exposure showed no statistically significant heterogeneity among cohorts (p=0.36), possibly because they are less influenced by very high exposures than models using untransformed cumulative exposure. For this reason, as well as the good fit of the model using log-cumulative exposure, Steenland et al. (2001a) conducted much of their analysis using log-transformed cumulative exposure. The sensitivity analysis by Toxichemica, Inc. (2004) repeated this analysis after correcting some errors in the original coding of the data set. At OSHA's request, Steenland (2010) also conducted a categorical analysis of the pooled data set and additional analyses using linear relative risk models (with and without log-transformation of cumulative exposure) as well as a 2-piece spline model.

The cohort studies included in the pooled analysis relied in part on particle count data and the use of conversion factors to estimate exposures of workers to mass respirable quartz. A few studies were able to include at least some respirable mass sampling data. OSHA believes that uncertainty in the exposure assessments that underlie each of the 10 studies included in the pooled analysis is likely to represent one of the most important sources of uncertainty in the risk estimates. To evaluate the potential impact of uncertainties in the underlying exposure assessments on estimates of the risk, OSHA's contractor, Toxichemica, Inc. (2004), commissioned Drs. Kyle Steenland and Scott Bartell of Emory University to conduct an uncertainty analysis using the raw data from the pooled cancer risk assessment. The uncertainty analysis employed a Monte Carlo technique in which two kinds of random exposure measurement error were considered; these were (1) random variation in respirable dust measurements and (2) random error in estimating respirable quartz exposures from historical data on particle count concentration, total dust mass concentration, and respirable dust mass concentration measurements. Based on the results of this uncertainty analysis, OSHA does not have reason to believe that random error in the underlying exposure estimates in the Steenland et al. (2001a) pooled cohort study of lung cancer is likely to have substantially influenced the original findings, although a few individual cohorts (particularly the South African and Australian gold miner cohorts) appeared to be sensitive to measurement errors.

The sensitivity analysis also examined the potential effect of systematic bias in the use of conversion factors to estimate respirable crystalline silica exposures from historical data. Absent *a priori* reasons to suspect bias in a specific direction (with the possible exception of the South African cohort), Toxichemica, Inc. (2004) considered possible biases in either direction by assuming that exposure was under-estimated by 100% (*i.e.,* the true exposure was twice the estimated) or over-estimated by 100% (*i.e.,* the true exposure was half the estimated) for any given cohort in the original pooled dataset. For the conditional logistic regression model using log cumulative exposure with a 15-year lag, doubling or halving the exposure for a specific study resulted in virtually no change in the exposure-response coefficient for that study or for the pooled analysis overall. Therefore, based on the results of the uncertainty analysis, OSHA believes that misclassification errors of a reasonable magnitude in the estimation of historical exposures for the 10 cohort studies were not likely to have substantially biased risk estimates derived from the exposure-response model used by Steenland et al. (2001a).

b. Rice et al. (2001) Analysis of Diatomaceous Earth Workers

Rice et al. (2001) applied a variety of exposure-response models to the same California diatomaceous earth cohort data originally reported on by Checkoway et al. (1993, 1996, 1997) and included in the pooled analysis conducted by Steenland et al. (2001a) described above. The cohort consisted of 2,342 white males employed for at least one year between 1942 and 1987 in a California diatomaceous earth mining and processing plant. The cohort was followed until 1994, and included 77 lung cancer deaths. Rice et al. (2001) relied on the dust exposure assessment developed by Seixas et al. (1997) from company records of over 6,000 samples collected from 1948 to 1988; cristobalite was the predominate form of crystalline silica to which the cohort was exposed. Analysis was based on both Poisson regression models Cox's proportional hazards models with various functions of cumulative silica exposure in mg/m^3-years to estimate the relationship between silica exposure and lung cancer mortality rate. Rice et al. (2001) reported that exposure to crystalline silica was a significant predictor of lung cancer

mortality for nearly all of the models employed, with the linear relative risk model providing the best fit to the data in the Poisson regression analysis.

c. Attfield and Costello (2004) Analysis of Granite Workers

Attfield and Costello (2004) analyzed the same U.S. granite cohort originally studied by Costello and Graham (1988) and Davis et al. (1983) and included in the Steenland et al. (2001a) pooled analysis, consisting of 5,414 male granite workers who were employed in the Vermont granite industry between 1950 and 1982 and who had received at least one chest x-ray from the surveillance program of the Vermont Department of Industrial Hygiene. Their 2004 report extended follow-up from 1982 to 1994, and found 201 deaths. Workers' cumulative exposures were estimated by Davis et al. (1983) based on historical exposure data collected in six environmental surveys conducted between 1924 and 1977, plus work history information.

Using Poisson regression models and seven cumulative exposure categories, the authors reported that the results of the categorical analysis showed a generally increasing trend of lung cancer rate ratios with increasing cumulative exposure, with seven lung cancer death rate ratios ranging from 1.18 to 2.6. A complication of this analysis was that the rate ratio for the highest exposure group in the analysis (cumulative exposures of 6.0 mg/m^3-years or higher) was substantially lower than those for other exposure groups. Attfield and Costello (2004) reported that the best-fitting model was based on a 15-year lag, use of untransformed cumulative exposure, and omission of the highest exposure group.

The authors argued that it was appropriate to base their risk estimates on a model that was fitted without the highest exposure group for several reasons. They believed the underlying exposure data for the high-exposure group was weaker than for the others, and that there was a greater likelihood that competing causes of death and misdiagnoses of causes of death attenuated the lung cancer death rate. Second, all of the remaining groups comprised 85 percent of the deaths in the cohort and showed a strong linear increase in lung cancer mortality with increasing exposure. Third, Attfield and Costello (2004) believed that the exposure-response relationship seen in the lower exposure groups was more relevant given that the exposures of these groups were within the range of current occupational standards. Finally, the authors stated that risk estimates derived from the model after excluding the highest exposure group were more consistent with other published risk estimates than was the case for estimates derived from the model using all exposure groups. Because of these reasons, OSHA believes it is appropriate to rely on the model employed by Attfield and Costello (2004) after omitting the highest exposure group.

d. Kuempel et al. (2001) Rat-Based Model for Human Lung Cancer

Kuempel et al. (2001) published a rat-based toxicokinetic/toxicodynamic model for silica exposure for predicting human lung cancer, based on lung burden concentrations necessary to cause the precursor events that can lead to adverse physiological effects in the lung. These adverse physiological effects can then lead to lung fibrosis and an indirect genotoxic cause of lung cancer. The hypothesized first step, or earliest expected response, in these disease processes is chronic lung inflammation, which the authors consider as a disease limiting step. Since the NOAEL of lung burden associated with this inflammation, based on the authors' rat-to-human lung model conversion, is the equivalent of exposure to 0.036 mg/m^3 (M_{crit}) for 45 years, exposures below this level would presumably not lead to (based on an indirect genotoxic mechanism) lung cancer, at least in the ''average individual.'' Since silicosis also is inflammation mediated, this exposure could also be considered to be an average threshold level for that disease as well.

Kuempel et al. (2001) have used their rat-based lung cancer model with human data, both to validate their model and to estimate the lung cancer risk as a function of quartz lung burden. First they ''calibrated'' human lung burdens from those in rats based on exposure estimates and lung autopsy reports of U.S. coal miners. Then they validated these lung burden estimates using quartz exposure data from U.K. coal miners. Using these human lung burden/exposure concentration equivalence relationships, they then converted the cumulative exposure-lung cancer response slope estimates from both the California diatomaceous earth workers (Rice et al., 2001) and Vermont granite workers (Attfield and Costello, 2001) to lung burden-lung cancer response slope estimates. Finally, they used these latter slope estimates in a life table program to estimate lung cancer risk associated with their ''threshold'' exposure of 0.036 mg/m^3 and to the OSHA PEL and NIOSH REL. Comparing the estimates from the two epidemiology studies with those based on a male rat chronic silica exposure study the authors found that, '' the lung cancer excess risk estimates based on male rat data are approximately three times higher than those based on the male human data.'' Based on this modeling and validation exercise, Keumpel et al. concluded, ''the rat-based estimates of excess lung cancer risk in humans exposed to crystalline silica are reasonably similar to those based on two human occupational epidemiology studies.''

Toxichemica, Inc. (2004) investigated whether use of the dosimetry model would substantially affect the results of the pooled lung cancer data analysis initially conducted by Steenland et al. (2001a). They replicated the lung dosimetry model using Kuempel et al.'s (2001) reported median fit parameter values, and compared the relationship between log cumulative exposure and 15-year lagged lung burden at the age of death in case subjects selected for the pooled case-control analysis. The two dose metrics were found to be highly correlated (r=0.99), and models based on either log silica lung burden or log cumulative exposure were similarly good predictors of lung cancer risk in the pooled analysis (nearly identical log-likelihoods of –4843.96 and—4843.996, respectively). OSHA believes that the Kuempel et al. (2001) analysis is a credible attempt to quantitatively describe the retention and accumulation of quartz in the lung, and to relate the external exposure and its associated lung burden to the inflammatory process. However, using the lung burden model to convert the cumulative exposure coefficients to a different exposure metric appears to add little additional information or insight to the risk assessments conducted on the diatomaceous earth and granite cohort studies. Therefore, for the purpose of quantitatively evaluating lung cancer risk in exposed workers, OSHA has chosen to rely on the epidemiology studies themselves and the cumulative exposure metrics used in those studies.

e. Hughes et al. (2001), McDonald et al. (2001), and McDonald et al. (2005) Study of North American Industrial Sand Workers

McDonald et al. (2001), Hughes et al. (2001) and McDonald et al. (2005) followed up on a cohort study of North American industrial sand workers that overlapped with the industrial sand cohort (18 plants, 4,626 workers) studied by Steenland and Sanderson (2001) and included in Steenland et al.'s (2001a) pooled cohort analysis. The McDonald et al. (2001) follow-up cohort

included 2,670 men employed before 1980 for three years or more in one of nine North American (8 U.S. and 1 Canadian) sand-producing plants, including 1 large associated office complex. Information on cause of death was obtained, from 1960 through 1994, for 99 percent of the deceased workers for a total 1,025 deaths representing 38 percent of the cohort. A nested case-control study and analysis based on 90 lung cancer deaths from this cohort was also conducted by Hughes et al. (2001). A later update through 2000, of both the cohort and nested case-control studies by McDonald et al. (2005), eliminated the Canadian plant, following 2,452 men from the eight U.S. plants. For the lung cancer case-control part of the study the update included 105 lung cancer deaths. Both the initial and updated case control studies used up to two controls per case.

Although the cohort studies provided evidence of increased risk of lung cancer (SMR = 150, p = 0.001, based on U.S. rates) for deaths occurring 20 or more years from hire, the nested case-control studies, Hughes et al. (2001) and McDonald et al. (2005), allowed for individual job, exposure, and smoking histories to be taken into account in the exposure-response analysis for lung cancer. Both of these case-control analyses relied on an analysis of exposure information reported by Sanderson et al. (2000) and by Rando et al. (2001) to provide individual estimates of average and cumulative exposure. Statistically significant positive exposure-response trends for lung cancer were found for both cumulative exposure (lagged 15 years) and average exposure concentration, but not for duration of employment, after controlling for smoking. A monotonic increase was seen for both lagged and unlagged cumulative exposure when the four upper exposure categories were collapsed into two. With exposure lagged 15 years and after adjusting for smoking, increasing quartiles of cumulative silica exposure were associated with lung cancer mortality (odds ratios of 1.00, 0.84, 2.02 and 2.07, p-value for trend=0.04). There was no indication of an interaction effect of smoking and cumulative silica exposure (Hughes et al., 2001).

OSHA considers this Hughes et al. (2001) study and analysis to be of high enough quality to provide risk estimates for excess lung cancer for silica exposure to industrial sand workers. Using the median cumulative exposure levels of 0, 0.758, 2.229 and 6.183 mg/m^3-years, Hughes et al. estimated lung cancer odds ratios, ORs (no. of deaths), for these categories of 1.00 (14), 0.84 (15), 2.02 (31), and 2.07 (30), respectively, on a 15-year lag basis (p-value for trend=0.04.) For the updated nested case control analysis, McDonald et al. (2005) found very similar results, with exposure lagged 15 years and, after adjusting for smoking, increasing quartiles of cumulative silica exposure were associated with lung cancer ORs (no. of deaths) of 1.00 (13), 0.94 (17), 2.24 (38), and 2.66 (37) (p-value for trend=0.006). Because the Hughes et al. (2001) report contained information that allowed OSHA to better calculate exposure-response estimates and because of otherwise very similar results in the two papers, OSHA has chosen to base its lifetime excess lung cancer risk estimate for these industrial sand workers on the Hughes et al. (2001) case-control study. Using the median exposure levels of 0, 0.758, 2.229 and 6.183 mg-years/m^3, respectively, for each of the four categories described above, and using the model: $\ln OR = \alpha + \beta \times$ Cumulative Exposure, the coefficient for the exposure estimate was $\beta = 0.13$ per (mg/m^3-years), with a standard error of $\beta = 0.074$ (calculated from the trend test p-value in the same paper). In this model, with background lung cancer risks of about 5 percent, the OR provides a suitable estimate of the relative risk.

f. Miller et al. (2007) and Miller and MacCalman (2009) Study of British Coal Workers Exposed to Respirable Quartz

Miller et al. (2007) and Miller and MacCalman (2009) continued a follow-up mortality study, begun in 1970, of 18,166 coalminers from 10 British coalmines initially followed through the end of 1992 (Miller et al., 1997). The two recent reports on mortality analyzed the cohort of 17,800 miners and extended the analysis through the end of 2005. By that time there were 516,431 person years of observation, an average of 29 years per miner, with 10,698 deaths from all causes. Causes of deaths of interest included pneumoconiosis, other non-malignant respiratory diseases (NMRD), lung cancer, stomach cancer, and tuberculosis. Three of the strengths of this study are its use of detailed time-exposure measurements of both quartz and total mine dust, detailed individual work histories, and individual smoking histories. However, the authors noted that no additional exposure measurements were included in the updated analysis, since all the mines had closed by the mid 1980's.

For this cohort mortality study there were analyses using both external (regional age-time and cause specific mortality rates) internal controls. For the analysis from external mortality rates, the all-cause mortality SMR from 1959 through 2005 was 100.9 (95% C.I., 99.0–102.8), based on all 10,698 deaths. However, these death ratios were not uniform over time. For the period from 1990 to 2005, the all-cause SMR was 109.6 (95% C.I., 106.5–112.8), while the ratios for previous periods were less than 100. This pattern of recent increasing SMRs was also seen in the recent cause-specific death rate for lung cancer, SMR=115.7 (95% C.I., 104.8–127.7). For the analysis based on internal rates and using Cox regression methods, the relative risk for lung cancer risk based on a cumulative quartz exposure equivalent to approximately 0.055 mg/m^3 for 45 years was RR = 1.14 (95% C.I., 1.04 to 1.25). This risk is adjusted for concurrent coal dust exposure and smoking status, and incorporated a 15-year lag in quartz exposures. The analysis showed a strong effect for smoking (independent of quartz exposure) on lung cancer. For lung cancer, OSHA believes that the analyses based on the Cox regression method provides strong evidence that for these coal miners' quartz exposures were associated with increased lung cancer risk, but that simultaneous exposures to coal dust did not cause increased lung cancer risk. To estimate lung cancer risk from this study, OSHA estimated the regression slope for a log-linear relative risk model based on the Miller and MacCalman's (2009) finding of a relative risk of 1.14 for a cumulative exposure of 0.055 mg/m^3-years.

2. Summary of OSHA's Estimates of Lung Cancer Mortality Risk

Tables VI–1 and VI–2 summarize the excess lung cancer risk estimates from occupational exposure to crystalline silica, based on five of the six lung cancer risk assessments discussed above. OSHA's estimates of lifetime excess lung cancer risk associated with 45 years of exposure to crystalline silica at 0.1 mg/m^3 (approximately the current general industry PEL) range from 13 to 60 deaths per 1,000 workers. For exposure to the proposed PEL of 0.05 mg/m^3, the lifetime risk estimates calculated by OSHA are in the range of 6 to 26 deaths per 1,000 workers. For a 45-year exposure at the proposed action level of 0.025 mg/m^3, OSHA estimates the risk to range from 3 to 23 deaths per 1,000 workers. The results from these assessments are reasonably consistent despite the use of data from different cohorts and the reliance on different analytical techniques for evaluating dose-response relationships. Furthermore, OSHA notes that in this range of exposure, 0.025—0.1 mg/m^3, there is statistical consistency between

the risk estimates, as evidenced by the considerable overlap in the 95-percent confidence intervals of the risk estimates presented in Table VI–1.

OSHA also estimates the lung cancer risk associated with 45 years of exposure to the current construction/shipyard PEL (in the range of 0.25 to 0.5 mg/m^3) to range from 37 to 653 deaths per 1,000 workers. Exposure to 0.25 or 0.5 mg/m^3 over 45 years represents cumulative exposures of 11.25 and 22.5 mg-years/m^3, respectively. This range of cumulative exposure is well above the median cumulative exposure for most of the cohorts used in the risk assessment, primarily because most of the individuals in these cohorts had not been exposed for as long as 45 years. Thus, estimating lung cancer excess risks over this higher range of cumulative exposures of interest to OSHA required some degree of extrapolation and adds uncertainty to the estimates.

C. Silicosis and Non-Malignant Respiratory Disease Mortality

There are two published quantitative risk assessment studies of silicosis and non-malignant respiratory disease (NMRD) mortality; a pooled analysis of silicosis mortality by Mannetje et al. (2002b) of data from six epidemiological studies, and an exposure-response analysis of NMRD mortality among diatomaceous earth workers (Park et al., 2002).

1. Mannetje et al. (2002b) Six Cohort Pooled Analysis

The Mannetje et al. (2002b) silicosis analysis was part of the IARC ten cohort pooled study included in the Steenland et al. (2001a) lung cancer mortality analysis above. These studies included 18,634 subjects and 170 silicosis deaths (n = 150 for silicosis, and n = 20 unspecified pneumoconiosis). The silicosis deaths had a median duration of exposure of 28 years, a median cumulative exposure of 7.2 mg/m^3-years, and a median average exposure of 0.26 mg/m^3, while the respective values of the whole cohort were 10 years, 0.62 mg/m^3-years, and 0.07 mg/m^3. Rates for silicosis adjusted for age, calendar time, and study were estimated by Poisson regression; rates increased nearly monotonically with deciles of cumulative exposure, from a mortality rate of 5/100,000 person-years in the lowest exposure category (0–0.99 mg/m^3-years) to 299/100,000 person-years in the highest category (>28.10 mg/m^3-years). Quantitative estimates of exposure to respirable silica (mg/m^3) were available for all six cohorts (Mannetje et al. 2002a). Lifetime risk of silicosis mortality was estimated by accumulating mortality rates over time using the formula

$$\text{Risk} = 1 - \exp(-\Sigma \text{time} * \text{rate}).$$

To estimate the risk of silicosis mortality at the current and proposed PELs, OSHA used the model described by Mannetje et al. (2002b) to estimate risk to age 85 but used rate ratios that were estimated from a nested case-control design that was part of a sensitivity analysis conducted by Toxichemica, Inc. (2004), rather than the Poisson regression originally conducted by Mannetje et al. (2002b). The case-control design was selected because it was expected to better control for age; in addition, the rate ratios derived from the case-control study reflect exposure measurement uncertainty via conduct of a Monte Carlo analysis (Toxichemica, Inc., 2004).

2. Park et al. (2002) Study of Diatomaceous Earth Workers

Park et al. (2002) analyzed the California diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994, to quantify the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Industrial hygiene data for the cohort were available from the employer for total dust, silica (mostly cristobalite), and asbestos. Park et al. (2002) used the exposure assessment previously reported by Seixas et al. (1997) and used by Rice et al. (2001) to estimate cumulative crystalline silica exposures for each worker in the cohort based on detailed work history files. The mean silica concentration for the cohort overall was 0.29 mg/m^3 over the period of employment (Seixas et al., 1997). The mean cumulative exposure values for total respirable dust and respirable crystalline silica were 7.31 and 2.16 mg/m^3-year, respectively. Similar cumulative exposure estimates were made for asbestos. Smoking information was available for about 50 percent of the cohort and for 22 of the 67 LDOC deaths available for analysis, permitting Park et al. (2002) to at least partially adjust for smoking. Estimates of LDOC mortality risks were derived via Poisson and Cox's proportional hazards models; a variety of relative rate model forms were fit to the data, with a linear relative rate model being selected for risk estimation.

3. Summary Risk Estimates for Silicosis and NMRD Mortality

Table VI–2 presents OSHA's risk estimates for silicosis and NMRD mortality derived from the Mannetje et al. (2002b) and Park et al. (2002) studies, respectively. For 45 years of exposure to the current general industry PEL (approximately 0.1 mg/m^3 respirable crystalline silica), OSHA's estimates of excess lifetime risk are 11 deaths per 1,000 workers for the pooled analysis and 83 deaths per 1,000 workers based on Park et al.'s (2002) estimates. At the proposed PEL, estimates of silicosis and NMRD mortality are 7 and 43 deaths per 1,000, respectively. For exposures up to 0.25 mg/m^3, the estimates based on Park et al. are about 5 to 11 times as great as those calculated for the pooled analysis of silicosis mortality (Mannetje et al., 2002b). However, these two sets of risk estimates are not directly comparable. First, the Park et al. analysis used untransformed cumulative exposure as the exposure metric, whereas the Mannertje et al. analysis used *log* cumulative exposure, which causes the exposure-response to flatten out in the higher exposure ranges. Second, the mortality endpoint for the Park et al. (2002) analysis is death from all non-cancer lung diseases, including pneumoconiosis, emphysema, and chronic bronchitis, whereas the pooled analysis by Mannetje et al. (2002b) included only deaths coded as silicosis or other pneumoconiosis. Less than 25 percent of the LDOC deaths in the Park et al. (2002) analysis were coded as silicosis or other pneumoconiosis (15 of 67). As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis; thus, Mannetje et al.'s (2002b) selection of deaths may tend to underestimate the true risk of silicosis mortality, and Park et al.'s (2002) analysis would more fairly capture the total respiratory mortality risk from all non-malignant causes, including silicosis and chronic obstructive pulmonary disease.

D. Renal Disease Mortality

Steenland et al. (2002a) examined renal disease mortality in three cohorts and evaluated exposure-response relationships from the pooled cohort data. The three cohorts included U.S. gold miners (Steenland and Brown, 1995a), U.S. industrial sand workers (Steenland et al., 2001b), and Vermont granite workers (Costello and Graham, 1988), all three of which are included in both the lung cancer mortality and silicosis mortality pooled analyses reported above. Follow up for the U.S.

gold miners study was extended six years from that in the other pooled analyses. Steenland et al. (2002a) reported that these cohorts were chosen because data were available for both underlying cause mortality and multiple cause mortality; this was believed important because renal disease is often listed on death certificates without being identified as an underlying cause of death. In the three cohorts, there were 51 total renal disease deaths using underlying cause, and 204 total renal deaths using multiple cause mortality.

The combined cohort for the pooled analysis (Steenland et al., 2002a) consisted of 13,382 workers with exposure information available for 12,783 (95 percent). Exposure matrices for the three cohorts had been used in previous studies (Steenland and Brown, 1995a; Attfield and Costello, 2001; Steenland et al., 2001b). The mean duration of exposure, the mean cumulative exposure, and the mean concentration of respirable silica for the pooled cohort were 13.6 years, 1.2 mg/m^3-years, and 0.07 mg/m^3, respectively. SMRs (compared to the U.S. population) for renal disease (acute and chronic glomerulonephritis, nephrotic syndrome, acute and chronic renal failure, renal sclerosis, and nephritis/nephropathy) were statistically significantly elevated using multiple cause data (SMR 1.29, 95% CI 1.10–1.47, 193 deaths) and underlying cause data (SMR 1.41, 95% CI 1.05–1.85, 51 observed deaths).

OSHA's estimates of renal disease mortality appear in Table VI–2. Based on the life table analysis, OSHA estimates that exposure to the current (0.10 mg/m^3) and proposed general industry PEL (0.0.05 mg/m^3) over a working life would result in a lifetime excess renal disease risk of 39 (95% CI 2–200) and 32 (95% CI 1.7–147) deaths per 1,000, respectively. For exposure to the current construction/shipyard PEL, OSHA estimates the excess lifetime risk to range from 52 (95% CI 2.2–289) to 63 (95% CI 2.5–368) deaths per 1,000 workers.

E. Silicosis Morbidity

OSHA's Preliminary QRA summarizes the principal cross-sectional and cohort studies that have quantitatively characterized relationships between exposure to crystalline silica and development of radiographic evidence of silicosis. Each of these studies relied on estimates of cumulative exposure to evaluate the relationship between exposure and silicosis prevalence in the worker populations examined. The health endpoint of interest in these studies is the appearance of opacities on chest roentgenograms indicative of pulmonary fibrosis.

The International Labour Organization's (ILO) 1980 International Classification of Radiographs of the Pneumoconioses is accepted as the standard against which chest radiographs are measured in epidemiologic studies, for medical surveillance and for clinical evaluation. According to this standard, if radiographic findings are or may be consistent with pneumoconiosis, then the size, shape, and extent of profusion of opacities are characterized by comparing the radiograph to standard films. Classification by shape (rounded vs. irregular) and size involves identifying primary and secondary types of small opacities on the radiograph and classifying them into one of six size/shape categories. The extent of profusion is judged from the concentrations of opacities as compared with that on the standard radiographs and is graded on a 12-point scale of four major categories (0–3, with Category 0 representing absence of opacities), each with three subcategories. Most of the studies reviewed by OSHA considered a finding consistent with an ILO classification of 1/1 to be a positive diagnosis of silicosis, although some also considered an x-ray classification of 1/0 or 0/1 to be positive.

Chest radiography is not the most sensitive tool used to diagnose or detect silicosis. In 1993, Hnizdo et al. reported the results of a study that compared autopsy and radiological findings of silicosis in a cohort of 557 white South African gold miners. The average period from last x-ray to autopsy was 2.7 years. Silicosis was not diagnosed radiographically for over 60 percent of the miners for whom pathological examination of lung tissue showed slight to marked silicosis. The likelihood of false negatives (negative by x-ray, but silicosis is actually present) increased with years of mining and average dust exposure of the miners. The low sensitivity seen for radiographic evaluation suggests that risk estimates derived from radiographic evidence likely understate the true risk of developing fibrotic lesions as a result of exposure to crystalline silica.

OSHA's Preliminary QRA examines multiple studies from which silicosis occupational morbidity risks can be estimated. The studies evaluated fall into three major types. Some are cross-sectional studies in which radiographs taken at a point in time were examined to ascertain cases (Kreiss and Zhen, 1996; Love et al., 1999; Ng and Chan, 1994; Rosenman et al., 1996; Churchyard et al., 2003, 2004); these radiographs may have been taken as part of a health survey conducted by the investigators or represent the most recent chest x-ray available for study subjects. Other studies were designed to examine radiographs over time in an effort to determine onset of disease. Some of these studies examined primarily active, or current, workers (Hughes et al., 1998; Muir et al., 1989a, 1989b; Park et al., 2002), while others included both active and retired workers (Chen et al., 2001, 2005; Hnizdo and Sluis-Cremer, 1993; Miller et al., 1998; Buchanan et al., 2003; Steenland and Brown, 1995b).

Even though OSHA has presented silicosis risk estimates for all of the studies identified, the Agency is relying primarily on those studies that examined radiographs over time and included both active and retired workers. It has been pointed out by others (Chen et al., 2001; Finkelstein, 2000; NIOSH, 2002) that lack of follow-up of retired workers consistently resulted in lower risk estimates compared to studies that included retired workers. OSHA believes that the most reliable estimates of silicosis morbidity, as detected by chest radiographs, come from the studies that evaluated radiographs over time, included radiographic evaluation of workers after they left employment, and derived cumulative or lifetime estimates of silicosis disease risk. Brief descriptions of these cumulative risk studies used to estimate silicosis morbidity risks are presented below.

1. Hnizdo and Sluis Cremer (1993) Study of South African White Gold Miners

Hnizdo and Sluis-Cremer (1993) described the results of a retrospective cohort study of 2,235 white gold miners in South Africa. These workers had received annual examinations and chest x-rays while employed; most returned for occasional examinations after employment. A case was defined as one with an x-ray classification of ILO 1/1 or greater. A total of 313 miners had developed silicosis and had been exposed for an average of 27 years at the time of diagnosis. Forty-three percent of the cases were diagnosed while employed and the remaining 57 percent were diagnosed an average of 7.4 years after leaving the mines. The average latency for the cohort was 35 years (range of 18–50 years) from start of exposure to diagnosis.

The average respirable dust exposure for the cohort overall was 0.29 mg/m^3 (range 0.11–0.47), corresponding to an estimated average respirable silica concentration of 0.09 mg/m^3 (range

0.033–0.14). The average cumulative dust exposure for the overall cohort was 6.6 mg/m^3-years (range 1.2–18.7), or an average cumulative silica exposure of 1.98 mg/m^3-years (range 0.36–5.61). OSHA believes that the exposure estimates for the cohort are uncertain given the need to rely on particle count data generated over a fairly narrow production period.

Silicosis risk increased exponentially with cumulative exposure to respirable dust and was modeled using log-logistic regression. Using the exposure-response relationship developed by Hnizdo and Sluis-Cremer (1993), and assuming a quartz content of 30 percent in respirable dust, Rice and Stayner (1995) and NIOSH (2002) estimated the risk of silicosis to be 70 percent and 13 percent for a 45-year exposure to 0.1 and 0.05 mg/m^3 respirable crystalline silica, respectively.

2. Steenland and Brown (1995b) Study of South Dakota Gold Miners

Three thousand three hundred thirty South Dakota gold miners who had worked at least a year underground between 1940 and 1965 were studied by Steenland and Brown (1995b). Workers were followed though 1990 with 1,551 having died; loss to follow up was low (2 percent). Chest x-rays taken in cross-sectional surveys in 1960 and 1976 and death certificates were used to ascertain cases of silicosis. One hundred twenty eight cases were found via death certificate, 29 by x-ray (defined as ILO 1/1 or greater), and 13 by both. Nine percent of deaths had silicosis mentioned on the death certificate. Inclusion of death certificate diagnoses probably increases the risk estimates from this study compared to those that rely exclusively on radiographic findings to evaluate silicosis morbidity risk (*see* discussion of Hnizdo et al. (1993) above).

Exposure was estimated by conversion of impinger (particle count) data and was based on measurements indicating an average of 13 percent silica in the dust. Based on these data, the authors estimated the mean exposure concentration to be 0.05 mg/m^3 for the overall cohort, with those hired before 1930 exposed to an average of 0.15 mg/m^3. The average duration of exposure for cases was 20 years (s.d = 8.7) compared to 8.2 years (s.d = 7.9) for the rest of the cohort. This study found that cumulative exposure was the best disease predictor, followed by duration of exposure and average exposure. Lifetime risks were estimated from Poisson regression models using standard life table techniques. The authors estimated a risk of 47 percent associated with 45 years of exposure to 0.09 mg/m^3 respirable crystalline silica, which reduced to 35 percent after adjustment for age and calendar time.

3. Miller et al. (1995, 1998) and Buchanan et al. (2003) Study of Scottish Coal Miners

Miller et al. (1995, 1998) and Buchanan et al. (2003) reported on a 1990/1991 follow-up study of 547 survivors of a 1,416 member cohort of Scottish coal workers from a single mine. These men had all worked in the mine during a period between early 1971 and mid 1976, during which they had experienced ''unusually high concentrations of freshly cut quartz in mixed coalmine dust. The population's exposures to both coal and quartz dust had been measured in unique detail, for a substantial proportion of the men's working lives.'' Thus, this cohort allowed for the study of the effects of both higher and lower silica concentrations, and exposure-rate effects on the development of silicosis. The 1,416 men had all had previous radiographs dating from before, during, or just after this high concentration period, and the 547 participating survivors received their follow-up chest x-rays between November 1990 and April 1991. Follow-up interviews consisted of questions on current and past smoking habits, and occupational history since leaving the coal mine, which closed in 1981.

Silicosis cases were identified as such if the median classification of the three readers indicated an ILO (1980) classification of 1/0 or greater, plus a progression from the earlier reading. Of the 547 men, 203 (38 percent) showed progression of at least one ILO category from the 1970's surveys to the 1990–91 survey; in 128 of these (24 percent) there was progression of two or more steps. In the 1970's survey 504 men had a profusion score of 0; of these, 120 (24 percent) progressed to an ILO classification of 1/0 or greater. Of the 36 men who had shown earlier profusions of 1/0 or greater, 27 (75 percent) showed further progression at the 1990/1991 follow-up. Only one subject showed a regression from any earlier reading, and that was slight, from ILO 1/0 to 0/1.

To study the effects of exposure to high concentrations of quartz dust, the Buchanan et al. (2003) analysis presented the results of logistic regression modeling that incorporated two independent terms for cumulative exposure, one arising from exposure to concentrations less than 2 mg/m^3 respirable quartz and the other from exposure to concentrations greater than or equal to 2 mg/m^3. Both of the cumulative quartz exposure concentration variables were ''highly statistically significant in the presence of the other,'' and independent of the presence of coal dust. Since these quartz variables were in the same units, g–hr/m^3, the authors noted that coefficient for exposure concentrations equal to or above 2.0 mg/m^3 was 3 times that of the coefficient for concentrations less than 2.0 mg/m^3. From this, the authors concluded that their analysis showed that ''the risk of silicosis over a working lifetime can rise dramatically with exposure to such high concentrations over a timescale of merely a few months.''

Buchanan et al., (2003) provided analysis and risk estimates only for silicosis cases defined as having an x-ray classified as ILO 2/1+, after adjusting for the disproportionately severe effect of exposure to high concentrations on silicosis risk. Estimating the risk of acquiring a chest x-ray classified as ILO 1/0+ from the Buchanan (2003) or the earlier Miller et al. (1995, 1998) publications can only be roughly approximated because of the limited summary information included; this information suggests that the risk of silicosis defined as an ILO classification of 1/0+ could be about three times higher than the risk of silicosis defined as an ILO 2/1+ x-ray. OSHA has a high degree of confidence in the estimates of progression to stages 2/1+ from this Scotland coal mine study, mainly because of the highly detailed and extensive exposure measurements, the radiographic records, and the detailed analyses of high exposure-rate effects.

4. Chen et al. (2001) Study of Tin Miners

Chen et al. (2001) reported the results of a retrospective study of a Chinese cohort of 3,010 underground miners who had worked in tin mines at least one year between 1960 and 1965. They were followed through 1994, by which time 2,426 (80.6%) workers had either retired or died, and only 400 (13.3%) remained employed at the mines.

The study incorporated occupational histories, dust measurements and medical examination records. Exposure data consisted of high-flow, short-term gravimetric total dust measurements made routinely since 1950; the authors used data from 1950 to represent earlier exposures since dust control measures were not implemented until 1958. Results from a 1998–1999 survey indicated that respirable silica measurements were 3.6 percent (s.d = 2.5 percent) of total dust measurements. Annual radiographs were taken since 1963 and all cohort members continued

to have chest x-rays taken every 2 or 3 years after leaving work. Silicosis was diagnosed when at least 2 of 3 radiologists classified a radiograph as being a ''suspected case'' or at Stage I, II, or III under the 1986 Chinese pneumoconiosis roentgen diagnostic criteria. According to Chen et al. (2001), these four categories under the Chinese system were found to agree closely with ILO categories 0/1, Category 1, Category 2, and Category 3, respectively, based on studies comparing the Chinese and ILO classification systems. Silicosis was observed in 33.7 percent of the group; 67.4 percent of the cases developed after exposure ended.

5. Chen et al. (2005) Study of Chinese Pottery Workers, Tin Miners, and Tungsten Miners

In a later study, Chen et al. (2005) investigated silicosis morbidity risks among three cohorts to determine if the risk varied among workers exposed to silica dust having different characteristics. The cohorts consisted of 4,547 pottery workers, 4,028 tin miners, and 14,427 tungsten miners selected from a total of 20 workplaces. Cohort members included all males employed after January 1, 1950 and who worked for at least one year between 1960 and 1974. Radiological follow-up was through December 31, 1994 and x-rays were scored according to the Chinese classification system as described above by Chen et al. (2001) for the tin miner study. Exposure estimates of cohort members to respirable crystalline silica were based on the same data as described by Chen et al. (2001). In addition, the investigators measured the extent of surface occlusion of crystalline silica particles by alumino-silicate from 47 dust samples taken at 13 worksites using multiple-voltage scanning electron microscopy and energy dispersive X-ray spectroscopy (Harrison et al., 2005); this method yielded estimates of the percent of particle surface that is occluded.

Compared to tin and tungsten miners, pottery workers were exposed to significantly higher mean total dust concentrations (8.2 mg/m^3, compared to 3.9 mg/m^3 for tin miners and 4.0 mg/m^3 for tungsten miners), worked more net years in dusty occupations (mean of 24.9 years compared to 16.4 years for tin miners and 16.5 years for tungsten miners), and had higher mean cumulative dust exposures (205.6 mg/m^3-years compared to 62.3 mg/m^3-years for tin miners and 64.9 mg/m^3-years for tungsten miners) (Chen et al., 2005). Applying the authors' conversion factors to estimate respirable crystalline silica from Chinese total dust measurements, the approximate mean cumulative exposures to respirable silica for pottery, tin, and tungsten workers are 6.4 mg/m^3-years, 2.4 mg/m^3-years, and 3.2 mg/m^3-years, respectively. Measurement of particle surface occlusion indicated that, on average, 45 percent of the surface area of respirable particles collected from pottery factory samples was occluded, compared to 18 percent of the particle surface area for tin mine samples and 13 percent of particle surface area for tungsten mines.

Based on Chen et al. (2005), OSHA estimated the cumulative silicosis risk associated with 45 years of exposure to 0.1 mg/m^3 respirable crystalline silica (a cumulative exposure of 4.5 mg/m^3-years) to be 6 percent for pottery workers, 12 percent for tungsten miners, and 40 percent for tin miners. For a cumulative exposure of 2.25 mg/m^3-years (*i.e.,* 45 years of exposure to 0.05 mg/m^3), cumulative silicosis morbidity risks were estimated to be 2, 2, and 10 percent for pottery workers, tungsten miners, and tin miners, respectively. When cumulative silica exposure was adjusted to reflect exposure to surface-active quartz particles (*i.e.,* not occluded), the estimated cumulative risk among pottery workers more closely approximated those of the tin and tungsten miners, suggesting to the authors that alumino-silicate occlusion of the crystalline particles in pottery factories at least partially explained the lower risk seen among workers, despite their having been more heavily exposed.

6. Summary of Silicosis Morbidity Risk Estimates.

Table VI–2 presents OSHA's risk estimates for silicosis morbidity that are derived from each of the studies described above. Estimates of silicosis morbidity derived from the seven cohorts in cumulative risk studies with post-employment follow-up range from 60 to 773 per 1,000 workers for 45-year exposures to the current general industry PEL of 0.10 mg/m^3, and from 20 to 170 per 1,000 workers for a 45-year exposure to the proposed PEL of 0.05 mg/m^3. The study results provide substantial evidence that the disease can progress for years after exposure ends. Results from an autopsy study (Hnizdo et al., 1993), which found pathological evidence of silicosis absent radiological signs, suggest that silicosis cases based on radiographic diagnosis alone tend to underestimate risk since pathological evidence of silicosis. Other results (Chen et al., 2005) suggest that surface properties among various types of silica dusts can have different silicosis potencies. Results from the Buchanan et al. (2003) study of Scottish coal miners suggest that short-term exposures to >2 mg/m^3 silica can cause a disproportionately higher risk of silicosis than would be predicted by cumulative exposure alone, suggesting a dose-rate effect for exposures to concentrations above this level. OSHA believes that, given the consistent finding of a monotonic exposure-response relationship for silicosis morbidity with cumulative exposure in the studies reviewed, that cumulative exposure is a reasonable exposure metric upon which to base risk estimates in the exposure range of interest to OSHA (*i.e.,* between 0.025 and 0.5 mg/m^3 respirable crystalline silica).

F. Other Considerations in OSHA's Risk Analysis

Uncertainties are inherent to any risk modeling process and analysis; assessing risk and associated complexities of silica exposure among workers is no different. However, the Agency has a high level of confidence that the preliminary risk assessment results reasonably reflect the range of risks experienced by workers exposed to silica in all occupational settings. First, the preliminary assessment is based on an analysis of a wide range of studies, conducted in multiple industries across a wide range of exposure distributions, which included cumulative exposures equivalent to 45 years of exposure to and below the current PEL.

Second, risk models employed in this assessment are based on a cumulative exposure metric, which is the product of average daily silica concentration and duration of worker exposure for a specific job. Consequently, these models predict the same risk for a given cumulative exposure regardless of the pattern of exposure. For example, a manufacturing plant worker exposed to silica at 0.05 mg/m^3 for eight hours per day will have the same cumulative exposure over a given period of time as a construction worker who is exposed each day to silica at 0.1 mg/m^3 for one hour, at 0.075 mg/m^3 for four hours and not exposed to silica for three hours. The cumulative exposure metric thus reflects a worker's long-term average exposure without regard to the pattern of exposure experienced by the worker, and is therefore generally applicable to all workers who are exposed to silica in the various industries. For example, at construction sites, conditions may change often since the nature of work can be intermittent and involve working with a variety of materials that contain different concentrations of quartz. Additionally, workers may perform

construction operations for relatively short periods of time where they are exposed to concentrations of silica that may be significantly higher than many continuous operations in general industry. However, these differences are taken into account by the use of the cumulative exposure metric that relates exposure to disease risk. OSHA believes that use of cumulative exposure is the most appropriate dose-metric because each of the studies that provide the basis for the risk assessment demonstrated strong exposure-response relationships between cumulative exposure and disease risk. This metric is especially important in terms of progression of silica-related disease, as discussed in Section VII of the preamble, Significance of Risk, in section B.1.a.

OSHA's risk assessment relied upon many studies that utilized cumulative exposures of cohort members. Table VI–3 summarizes these lung cancer studies, including worker exposure quartile data across a number of industry sectors. The cumulative exposures exhibited in these studies are equivalent to the cumulative exposure that would result from 45 years of exposure to the current and proposed PELs (*i.e.,* 4.5 and 2,25 mg/m^3, respectively). For this reason, OSHA has a high degree of confidence in the risk estimates associated with exposure to the current and proposed PELs; additionally, the risk assessment does not require significant low-dose extrapolation of the model beyond the observed range of exposures. OSHA acknowledges there is greater uncertainty in the risk estimates for the proposed action level of 0.025 mg/m^3, particularly given some evidence of a threshold for silicosis between the proposed PEL and action level. Given the Agency's findings that controlling exposures below the proposed PEL would not be technologically feasible for employers, OSHA believes that estimating risk for exposures below the proposed action level, which becomes increasingly more uncertain, is not necessary to further inform the Agency's regulatory action.

Although the Agency believes that the results of its risk assessment are broadly relevant to all occupational exposure situations involving crystalline silica, OSHA acknowledges that differences exist in the relative toxicity of crystalline silica particles present in different work settings due to factors such as the presence of mineral or metal impurities on quartz particle surfaces, whether the particles have been freshly fractured or are aged, and size distribution of particles. At this time, however, OSHA preliminarily concludes that it is not yet possible to use available information on factors that mediate the potency of silica to refine available quantitative estimates of the lung cancer and silicosis mortality risks, and that the estimates from the studies and analyses relied upon are fairly representative of a wide range of workplaces reflecting differences in silica polymorphism, surface properties, and impurities.

TABLE VI–1—ESTIMATES OF LIFETIME [A] LUNG CANCER MORTALITY RISK RESULTING FROM 45-YEARS OF EXPOSURE TO CRYSTALLINE SILICA

[Deaths per 1,000 workers (95% confidence interval)]

Cohort	Model	Exposure lag (years)	Model parameters (standard error)	Exposure level (mg/m^3)				
				0.025	0.05	0.10	0.25	0.50
Ten pooled cohorts (*see* Table II–1).	Log-linear [b]	15	β = 0.60 (0.015)	22 (11–36)	26 (12–41)	29 (13–48)	34 (15–56)	38 (17–63)
	Linear [b]	15	β = 0.074950 (0.024121).	23 (9–38)	26 (10–43)	29 (11–47)	33 (12–53)	36 (14–58)
	Linear	15	β_1 = 0.16498 (0.0653) and.	9 (2–16)	18 (4–31)	22 (6–38)	27 (12–43)	36 (20–51)
	Spline§ [c d]		β_2 = −0.1493 (0.0657).					
Range from 10 cohorts.		15	Various	0.21–13	0.41–28	0.83–69	2.1–298	4.2–687
	Log-linear [c]							
Diatomaceous earth workers.	Linear [c]	10	β = 0.1441 [e]	9 (2–21)	17 (5–41)	34 (10–79)	81 (24–180)	152 (46–312)
U.S.Granite workers.	Log-linear [c]	15	β = 0.19 [e]	11 (4–18)	25 (9–42)	60 (19–111)	250 (59–502)	653 (167–760)
North American industrial sand workers.	Log-linear [c]	15	β = 0.13 (0.074) [f]	7 (0–16)	15 (0–37)	34 (0–93)	120 (0–425)	387 (0–750)
British coal miners	Log-linear [c]	15	B = 0.0524 (0.0188).	3 (1–5)	6 (2–11)	13 (4–23)	37 (9–75)	95 (20–224)

[a] Risk to age 85 and based on 2006 background mortality rates for all males (*see* Appendix for life table method).
[b] Model with log cumulative exposure (mg/m^3-days + 1).
[c] Model with cumulative exposure (mg/m^3-years).
[d] 95% confidence interval calculated as follows (where CE = cumulative exposure in mg/m^3-years and SE is standard error of the parameter estimate):
For CE ≤ 2.19: $1 + [(\beta_1 \pm (1.96 * SE_1)) * CE]$.
For CE > 2.19: $1 + [(\beta_1 * CE) + (\beta_2 * (CE-2.19))] \pm 1.96 * SQRT[(CE^2 * SE_1^2) + ((CE-2.19)^2 * SE_2^2) + (2*CE*(CE-3.29)*-0.00429)]$.
[e] Standard error not reported, upper and lower confidence limit on beta estimated from confidence interval of risk estimate reported in original article.
[f] Standard error of the coefficient was estimated from the p-value for trend.

TABLE VI–2—SUMMARY OF LIFETIME OR CUMULATIVE RISK ESTIMATES FOR CRYSTALLINE SILICA

Health endpoint (source)	Risk associated with 45 years of occupational exposure (per 1,000 workers)				
	Respirable crystalline silica exposure level (mg/m^3)				
	0.025	0.05	0.100	0.250	0.500
Lung Cancer Mortality (Lifetime Risk):					
Pooled Analysis, Toxichemica, Inc (2004) [a b]	9–23	18–26	22–29	27–34	36–38

TABLE VI–2—SUMMARY OF LIFETIME OR CUMULATIVE RISK ESTIMATES FOR CRYSTALLINE SILICA—Continued

Health endpoint (source)	Risk associated with 45 years of occupational exposure (per 1,000 workers)				
	Respirable crystalline silica exposure level (mg/m³)				
	0.025	0.05	0.100	0.250	0.500
Diatomaceous Earth Worker study (Rice et al., 2001) [a c]	9	17	34	81	152
U.S. Granite Worker study (Attfield and Costello, 2004) [a d]	11	25	60	250	653
North American Industrial Sand Worker study (Hughes et al., 2001) [a e]	7	15	34	120	387
British Coal Miner study (Miller and MacCalman, 2009) [a f]	3	6	13	37	95
Silicosis and Non-Malignant Lung Disease Mortality (Lifetime Risk):					
Pooled Analysis (Toxichemica, Inc., 2004) (silicosis) [g]	4	7	11	17	22
Diatomaceous Earth Worker study (Park et al., 2002) (NMRD) [h]	22	43	83	188	321
Renal Disease Mortality (Lifetime Risk):					
Pooled Cohort study (Steenland et al., 2002a)	25	32	39	52	63
Silicosis Morbidity (Cumulative Risk):					
Chest x-ray category of 2/1 or greater (Buchanan et al., 2003) [j]	21	55	301	994	1000
Silicosis mortality and/or x-ray of 1/1 or greater (Steenland and Brown, 1995b) [k]	31	74	431	593	626
Chest x-ray category of 1/1 or greater (Hnizdo and Sluis-Cremer, 1993) [l]	6	127	773	995	1000
Chest x-ray category of 1 or greater (Chen et al., 2001) [m]	40	170	590	1000	1000
Chest x-ray category of 1 or greater (Chen et al., 2005) [n]					
Tin miners	40	100	400	950	1000
Tungsten miners	5	20	120	750	1000
Pottery workers	5	20	60	300	700

From Table II–12, ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (Docket OSHA–2010–0034).

TABLE VI–3—EXPOSURE DISTRIBUTION IN LUNG CANCER STUDIES

Study	n	Primary exposure (as described in study)	No. of deaths from lung cancer	*Cum(exp) (mg/m³-y)*				*Average* exposure (mg/m³)*				Mean respirable crystalline silica exposure over employment period (mg/m∧3)
				q¹	median (q²)	q³	max	25th (q¹)	median (q²)	75th (q³)	max	
U.S. diatomaceous earth workers [1] (Checkoway et al., 1997).	2,342	cristobalite	77	0.37	1.05	2.48	62.52	0.11	0.18	0.46	2.43	n/a
S. African gold miners [1] (Hnizdo and Sluis-cremer, 1991 & Hnizdo et al., 1997).	2,260	quartz and other silicates.	77	n/a	4.23	n/a	n/a	0.15	0.19	0.22	0.31	n/a
U.S. gold miners [1] (Steenland and Brown, 1995a).	3,328	silica dust	156	0.1	0.23	0.74	6.2	0.02	0.05	0.1	0.24	n/a
Australian gold miners [1] (de Klerk and Musk, 1998).	2,297	silica dust	135	6.52	11.37	17.31	50.22	0.25	0.43	0.65	1.55	n/a
U.S. granite workers (Costello and Graham, 1988).	5,414	silica dust from granite.	124	0.14	0.71	2.19	50	0.02	0.05	0.08	1.01	n/a
Finnish granite workers (Koskela et al., 1994).	1,026	quartz dust	38	0.84	4.63	15.42	100.98	0.39	0.59	1.29	3.6	n/a

TABLE VI–3—EXPOSURE DISTRIBUTION IN LUNG CANCER STUDIES—Continued

Study	n	Primary exposure (as described in study)	No. of deaths from lung cancer	*Cum(exp) (mg/m³-y)*				*Average* exposure (mg/m³)*				Mean respirable crystalline silica exposure over employment period (mg/m∧3)
				q[1]	median (q[2])	q[3]	max	25th (q[1])	median (q[2])	75th (q[3])	max	
U.S. industrial sand workers [1] (Steenland et al., 2001b).	4,626	silica dust	85	0.03	0.13	5.2	8.265	0.02	0.04	0.06	0.4	n/a
North American industrial sand workers [1] (Hughes et al., 2001).	90	crystalline silica.	95	1.11	2.73	5.20	n/a	0.069	0.15	0.025	n/a	n/a
Ch. Tungsten (Chen et al., 1992).	28,442	silica dust	174	3.49	8.56	29.79	232.26	0.15	0.32	1.28	4.98	6.1
Ch. Pottery (Chen et al., 1992).	13,719	silica dust	81	3.89	6.07	9.44	63.15	0.18	0.22	0.34	2.1	11.4
Ch. Tin (Chen et al., 1992).	7,849	silica dust	119	2.79	5.27	5.29	83.09	0.12	0.19	0.49	1.95	7.7
British coal workers [1] (Miller and MacCalman, 2009).	17,820	quartz	973	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

[1] Study adjusted for effects smoking.
* Average exposure is cumulative exposure averaged over the entire exposure period.
n/a Data not available.

VII. Significance of Risk

A. Legal Requirements

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.'' 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.

The Agency's burden to establish significant risk derives from the OSH Act, 29 U.S.C. 651 et seq. Section 3(8) of the Act requires that workplace safety and health standards be ''reasonably necessary and appropriate to provide safe or healthful employment.'' 29 U.S.C. 652(8). The Supreme Court, in the ''benzene'' decision, stated that section 3(8) ''implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe.'' *Indus. Union Dep't, AFL–CIO* v. *Am.* Petroleum Inst., 448 U.S. 607, 642 (1980). Examining section 3(8) more closely, the Court described OSHA's obligation to demonstrate significant risk:

> ''[S]afe'' is not the equivalent of ''risk-free.'' A workplace can hardly be considered ''unsafe'' unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate *any* permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices.

Id. While clarifying OSHA's responsibilities, the Court emphasized the Agency's discretion in determining what constitutes significant risk, stating, ''[the Agency's] determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' *Benzene,* 448 U.S. at 655, n. 62. The Court explained that significant risk is not a ''mathematical straitjacket,'' and maintained that OSHA could meet its burden without ''wait[ing] for deaths to occur before taking any action.'' *Benzene,* 448 U.S. at 655.

Because section 6(b)(5) of the Act requires that the Agency base its findings on the ''best available evidence,'' 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. Thus, while OSHA's significant risk determination must be supported by substantial evidence, the Agency ''is not required to support the finding that a significant risk exists with anything approaching scientific certainty.'' *Id.* Furthermore, ''the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of over protection rather than under protection,'' so long as such assumptions are based in ''a body of reputable scientific thought.'' *Id.*

The Act also requires that the Agency make a finding that the toxic material or harmful physical agent at issue causes material impairment to workers' health. Section 6(b)(5) of the Act directs the Secretary of Labor 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 . . . for the period of his working life.'' 29 U.S.C. 655(b)(5). As with significant risk, what constitutes material impairment in any given case is a policy determination for which OSHA is given substantial leeway. ''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—and that OSHA may act with a ''pronounced bias towards worker safety.'' *Id; Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (D.C. Cir. 1988).

It is the Agency's practice to estimate risk to workers by using quantitative

risk assessment and determining the significance of that risk based on judicial guidance, the language of the OSH Act, and Agency policy considerations. Thus, using the best available evidence, OSHA identifies material health impairments associated with potentially hazardous occupational exposures, and, when possible, provides a quantitative assessment of exposed workers' risk of these impairments. The Agency then evaluates whether these risks are severe enough to warrant regulatory action and determines whether a new or revised rule will substantially reduce these risks.

In this case, OSHA has reviewed extensive toxicological, epidemiological, and experimental research pertaining to adverse health effects of occupational exposure to respirable crystalline silica, including silicosis, other non-malignant respiratory disease, lung cancer, and autoimmune and renal diseases. As a result of this review, the Agency has developed preliminary quantitative estimates of the excess risk of mortality and morbidity that is attributable to currently allowable respirable crystalline silica exposure concentrations. The Agency is proposing a new PEL of 0.05 mg/m^3 because exposures at and above this level present a significant risk to workers' health. Even though OSHA's preliminary risk assessment indicates that a significant risk exists at the proposed action level of 0.025 mg/m^3, the Agency is not proposing a PEL below the proposed 0.05 mg/m^3 limit because OSHA must also consider technological and economic feasibility in determining exposure limits. As explained in the Summary and Explanation for paragraph (c), Permissible Exposure Limit (PEL), OSHA has preliminary determined that the proposed PEL of 0.05 mg/m^3 is technologically and economically feasible, but that a lower PEL of 0.025 mg/m^3 is not technologically feasible. OSHA has preliminarily determined that long-term exposure at the current PEL presents a significant risk of material harm to workers' health, and that adoption of the proposed PEL will substantially reduce this risk to the extent feasible.

As discussed in Section V of this preamble (Health Effects Summary), inhalation exposure to respirable crystalline silica increases the risk of a variety of adverse health effects, including silicosis, chronic obstructive pulmonary disease (COPD), lung cancer, immunological effects, kidney disease, and infectious tuberculosis (TB). OSHA considers each of these conditions to be a material impairment of health. These diseases result in significant discomfort, permanent functional limitations including permanent disability or reduced ability to work, reduced quality of life, and decreased life expectancy. When these diseases coexist, as is common, the effects are particularly debilitating (Rice and Stayner, 1995; Rosenman et al., 1999). Based on these findings and on the scientific evidence that respirable crystalline silica substantially increases the risk of each of these conditions, OSHA preliminarily concludes that workers who are exposed to respirable crystalline silica at the current PEL are at significant risk of material impairment of health or functional capacity.

B. OSHA's Preliminary Findings

1. Material Impairments of Health

Section I of OSHA's Health Effects Literature Review and Preliminary Quantitative Risk Assessment (available in Docket OSHA–2010–0034) describes in detail the adverse health conditions that workers who are exposed to respirable crystalline silica are at risk of developing. The Agency's findings are summarized in Section V of this preamble (Health Effects Summary). The adverse health effects discussed include lung cancer, silicosis, other non-malignant respiratory disease (NMRD), and immunological and renal effects.

a. Silicosis

Silicosis refers to a spectrum of lung diseases attributable to the inhalation of respirable crystalline silica. As described in Section V (Health Effects Summary), the three types of silicosis are acute, accelerated, and chronic. Acute silicosis can occur within a few weeks to months after inhalation exposure to extremely high levels of respirable crystalline silica. Death from acute silicosis can occur within months to a few years of disease onset, with the exposed person drowning in their own lung fluid (NIOSH, 1996). Accelerated silicosis results from exposure to high levels of airborne respirable crystalline silica, and disease usually occurs within 5 to 10 years of initial exposure (NIOSH, 1996). Both acute and accelerated silicosis are associated with exposures that are substantially above the current general industry PEL, although precise information on the relationships between exposure and occurrence of disease are not available.

Chronic silicosis is the most common form of silicosis seen today, and is a progressive and irreversible condition characterized as a diffuse nodular pulmonary fibrosis (NIOSH, 1996). Chronic silicosis generally occurs after 10 years or more of inhalation exposure to respirable crystalline silica at levels below those associated with acute and accelerated silicosis. Affected workers may have a dry chronic cough, sputum production, shortness of breath, and reduced pulmonary function. These symptoms result from airway restriction caused by the development of fibrotic scarring in the alveolar sacs and the ends of the lung tissue. The scarring can be detected in chest x-ray films when the lesions become large enough to appear as visible opacities. The result is restriction of lung volumes and decreased pulmonary compliance with concomitant reduced gas transfer (Balaan and Banks, 1992). Chronic silicosis is characterized by small, rounded opacities that are symmetrically distributed in the upper lung zones on chest radiograph.

The diagnosis of silicosis is based on a history of exposure to respirable crystalline silica, chest radiograph findings, and the exclusion of other conditions, including tuberculosis (TB). Because workers affected by early stages of chronic silicosis are often asymptomatic, the finding of opacities in the lung is key to detecting silicosis and characterizing its severity. The International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses (ILO, 1980, 2002, 2011) is the currently accepted standard against which chest radiographs are evaluated in epidemiologic studies, for medical surveillance, and for clinical evaluation. The ILO system standardizes the description of chest x-rays, and is based on a 12-step scale of severity and extent of silicosis as evidenced by the size, shape, and density of opacities seen on the x-ray film. Profusion (frequency) of small opacities is classified on a 4-point major category scale (0–3), with each major category divided into three, giving a 12-point scale between 0/− and 3/+. Large opacities are defined as any opacity greater than 1 cm that is present in a film.

The small rounded opacities seen in early stage chronic silicosis (*i.e.,* ILO major category 1 profusion) may progress (through ILO major categories 2 and/or 3) and develop into large fibrotic masses that destroy the lung architecture, resulting in progressive massive fibrosis (PMF). This stage of advanced silicosis is usually characterized by impaired pulmonary function, disability, and premature death. In cases involving PMF, death is commonly attributable to progressive respiratory insufficiency (Balaan and Banks, 1992).

The appearance of ILO category 2 or 3 background profusion of small opacities has been shown to increase the risk of developing large opacities characteristic of PMF. In one study of silicosis patients in Hong Kong, Ng and Chan (1991) found the risk of PMF increased by 42 and 64 percent among patients whose chest x-ray films were classified as ILO major category 2 or 3, respectively. Research has shown that people with silicosis advanced beyond ILO major category 1 have reduced median survival times compared to the general population (Infante-Rivard et al., 1991; Ng et al., 1992a; Westerholm, 1980).

Silicosis is the oldest known occupational lung disease and is still today the cause of significant premature mortality. In 2005, there were 161 deaths in the U.S. where silicosis was recorded as an underlying or contributing cause of death on a death certificate (NIOSH, 2008c). Between 1996 and 2005, deaths attributed to silicosis resulted in an average of 11.6 years of life lost by affected workers (NIOSH, 2007). In addition, exposure to respirable crystalline silica remains an important cause of morbidity and hospitalizations. State-based hospital discharge data show that in the year 2000, 1,128 silicosis-related hospitalizations occurred, indicating that silicosis continues to be a significant health issue in the U.S. (CSTE, 2005). Although there is no national silicosis disease surveillance system in the U.S., a published analysis of state-based surveillance data from the time period 1987–1996 estimated that between 3,600–7,000 new cases of silicosis occurred in the U.S. each year (Rosenman et al., 2003). It has been widely reported that available statistics on silicosis-related mortality and morbidity are likely to be understated due to misclassification of causes of death (for example, as tuberculosis, chronic bronchitis, emphysema, or cor pulmonale), errors in recording occupation on death certificates, or misdiagnosis of disease by health care providers (Goodwin, 2003; Windau et al., 1991; Rosenman et al., 2003). Furthermore, reliance on chest x-ray findings may miss cases of silicosis because fibrotic changes in the lung may not be visible on chest radiograph; thus, silicosis may be present absent x-ray signs or may be more severe than indicated by x-ray (Hnizdo et al., 1993; Craighead and Vallyathan, 1980; Rosenman et al., 1997).

Although most workers with early-stage silicosis (ILO categories 0/1 or 1/0) typically do not experience respiratory symptoms, the primary risk to the affected worker is progression of disease with progressive decline of lung function. Several studies of workers exposed to crystalline silica have shown that, once silicosis is detected by x-ray, a substantial proportion of affected workers can progress beyond ILO category 1 silicosis, even after exposure has ceased (for example, Hughes et al., 1982; Hessel et al., 1988; Miller et al., 1998; Ng et al., 1987a; Yang et al., 2006). In a population of coal miners whose last chest x-ray while employed was classified as major category 0, and who were examined again 10 years after the mine had closed, 20 percent had developed opacities consistent with a classification of at least 1/0, and 4 percent progressed further to at least 2/1 (Miller et al., 1998). Although there were periods of extremely high exposure to respirable quartz in the mine (greater than 2 mg/m^3 in some jobs between 1972 and 1976, and more than 10 percent of exposures between 1969 and 1977 were greater than 1 mg/m^3), the mean cumulative exposure for the cohort over the period 1964–1978 was 1.8 mg/m^3-years, corresponding to an average silica concentration of 0.12 mg/m^3. In a population of granite quarry workers exposed to an average respirable silica concentration of 0.48 mg/m^3 (mean length of employment was 23.4 years), 45 percent of those diagnosed with simple silicosis showed radiological progression of disease after 2 to 10 years of follow up (Ng et al., 1987a). Among a population of gold miners, 92 percent progressed in 14 years; exposures of high-, medium-, and low-exposure groups were 0.97, 0.45, and 0.24 mg/m^3, respectively (Hessel et al., 1988). Chinese mine and factory workers categorized under the Chinese system of x-ray classification as ''suspected'' silicosis cases (analogous to ILO 0/1) had a progression rate to stage I (analogous to ILO major category 1) of 48.7 percent and the average interval was about 5.1 years (Yang et al., 2006). These and other studies discussed in the Health Effects section are of populations of workers exposed to average concentrations of respirable crystalline silica above those permitted by OSHA's current general industry PEL. The studies, however, are of interest to OSHA because the Agency's current enforcement data indicate that exposures in this range are still common in some industry sectors. Furthermore, the Agency's preliminary risk assessment is based on use of an exposure metric that is less influenced by exposure pattern and, instead, characterizes the accumulated exposure of workers over time. Further, the use of a cumulative exposure metric reflects the progression of silica-related diseases: While it is not known that silicosis is a precursor to lung cancer, continued exposure to respirable crystalline silica among workers with silicosis has been shown to be associated with malignant respiratory disease (Chen et al., 1992). The Chinese pottery workers study offers an example of silicosis-associated lung cancer among workers in the clay industry, reflecting the variety of health outcomes associated with diverse silica exposures across industrial settings.

The risk of silicosis, and particularly its progression, carries with it an increased risk of reduced lung function. There is strong evidence in the literature for the finding that lung function deteriorates more rapidly in workers exposed to silica, especially those with silicosis, than what is expected from a normal aging process (Cowie 1998; Hughes et al., 1982; Malmberg et al., 1993; Ng and Chan, 1992). The rates of decline in lung function are greater in those whose disease showed evidence of radiologic progression (Bégin et al., 1987a; Cowie 1998; Ng and Chan, 1992; Ng et al., 1987a). Additionally, the average deterioration of lung function exceeds that in smokers (Hughes et al., 1982).

Several studies have reported no decrease in pulmonary function with an ILO category 1 level of profusion of small opacities but found declines in pulmonary function with categories 2 and 3 (Ng et al., 1987a; Begin et al., 1988; Moore et al., 1988). A study by Cowie (1998), however, found a statistically significantly greater annual loss in FVC and FEV_1 among those with category 1 profusion compared to category 0. In another study, Cowie and Mabena (1991) found that the degree of profusion of opacities was associated with reductions in several pulmonary function metrics. Still, other studies have reported no associations between radiographic silicosis and decreases in pulmonary function (Ng et al., 1987a; Wiles et al., 1992; Hnizdo, 1992), with some studies (Ng et al., 1987a; Wang et al., 1997) finding that measurable changes in pulmonary function are evident well before the changes seen on chest x-ray. This may reflect the general insensitivity of chest radiography in detecting lung fibrosis, and/or may reflect that exposure to respirable silica has also been shown to increase the risk of chronic obstructive pulmonary disease (COPD) (*see* Section V, Health Effects Summary).

Finally, silicosis, and exposure to respirable crystalline silica in and of itself, increases the risk that latent

tuberculosis infection can convert to active disease. Early descriptions of dust diseases of the lung did not distinguish between TB and silicosis, and most fatal cases described in the first half of this century were a combination of silicosis and TB (Castranova et al., 1996). More recent findings demonstrate that exposure to silica, even without silicosis, increases the risk of infectious (*i.e.,* active) pulmonary TB (Sherson et al., 1990; Cowie, 1994; Hnizdo and Murray, 1998; WaterNaude et al., 2006). Both conditions together can hasten the development of respiratory impairment and increase mortality risk even beyond that experienced by unexposed persons with active TB (Banks, 2005).

Based on the information presented above and in its review of the health literature, OSHA preliminarily concludes that silicosis remains a significant cause of early mortality and of serious morbidity, despite the existence of an enforceable exposure limit over the past 40 years. Silicosis in its later stages of progression (*i.e.,* with chest x-ray findings of ILO category 2 or 3 profusion of small opacities, or the presence of large opacities) is characterized by the likely appearance of respiratory symptoms and decreased pulmonary function, as well as increased risk of progression to PMF, disability, and early mortality. Early-stage silicosis, although without symptoms among many who are affected, nevertheless reflects the formation of fibrotic lesions in the lung and increases the risk of progression to later stages, even after exposure to respirable crystalline silica ceases. In addition, the presence of silicosis increases the risk of pulmonary infections, including conversion of latent TB infection to active TB. Silicosis is not a reversible condition and there is no specific treatment for the disease, other than administration of drugs to alleviate inflammation and maintain open airways, or administration of oxygen therapy in severe cases. Based on these considerations, OSHA preliminarily finds that silicosis of any form, and at any stage, is a material impairment of health and that fibrotic scarring of the lungs represents loss of functional respiratory capacity.

b. Lung Cancer

OSHA considers lung cancer, an irreversible and usually fatal disease, to be a clear material impairment of health. According to the National Cancer Institute (Horner et al., 2009), the five-year survival rate for all forms of lung cancer is only 15.6 percent, a rate that has not improved in nearly two decades. OSHA's preliminary finding that respirable crystalline silica exposure substantially increases the risk of lung cancer mortality is based on the best available toxicological and epidemiological data, reflects substantial supportive evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations, including the International Agency for Research on Cancer (IARC, 1997), the National Toxicology Program (NTP, 2000), the National Institute for Occupational Safety and Health (NIOSH, 2002), the American Thoracic Society (1997), and the American Conference of Governmental Industrial Hygienists (ACGIH, 2001). The Agency's primary evidence comes from evaluation of more than 50 studies of occupational cohorts from many different industry sectors in which exposure to respirable crystalline silica occurs, including granite and stone quarrying; the refractory brick industry; gold, tin, and tungsten mining; the diatomaceous earth industry; the industrial sand industry; and construction. Studies key to OSHA's risk assessment are outlined in Table VII–1, which summarizes exposure characterization and related lung cancer risk across several different industries. In addition, the association between exposure to respirable crystalline silica and lung cancer risk was reported in a national mortality surveillance study (Calvert et al., 2003) and in two community-based studies (Pukkala et al., 2005; Cassidy et al., 2007), as well as in a pooled analysis of 10 occupational cohort studies (Steenland et al., 2001a).

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
U.S. Diatomaceous earth workers.	Cohort study. Same as Checkoway et al., 1993, excluding 317 workers whose exposures could not be characterized, and including 89 workers with asbestos exposure who were previously excluded from the 1993 study. Follow up through 1994.	Assessment based on almost 6,400 samples taken from 1948–1988; about 57 percent of samples represented particle counts, 17 percent were personal respirable dust samples. JEM included 135 jobs over 4 time periods (Seixas et al., 1997).	77	SMR 129 (CI 101–161) based on national rates, and SMR 144 (CI 114–180) based on local rates. Risk ratios by exposure quintile were 1.00, 0.96, 0.77, 1.26, and 2.15, with the latter being stat. sig. RR= 2.15 and 1.67.	Smoking history available for half cohort. Under worst-case assumptions, the risk ratio for the high-exposure group would be reduced to 1.67 after accounting for smoking.	Checkoway et al., 1997.
South African gold miners.	Cohort study. N=2,209 white male miners employed between 1936 and 1943. Followed from 1968–1986.	Particle count data from Beadle (1971).	77	RR 1.023 (CI 1.005–1.042) per 1,000 particle-years of exposure based on Cox proportional hazards model.	Model adjusted for smoking and year of birth. Lung cancer was associated with silicosis of the hilar glands not silicosis of lung or pleura. Possible confounding by radon exposure among miners with 20 or more years experience.	Hnizdo and Sluis-Cremer, 1991.

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES—Continued

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
South African gold miners.	Nested case-control study from population study by Hnizdo and Sluis-Cremer,1991. N=78 cases, 386 controls.	Particle count data converted to respirable dust mass (Beadle and Bradley, 1970, and Page-Shipp and Harris, 1972).	78	RR 2.45 (CI 1.2–5.2) when silicosis was included in model.	Lung cancer mortality associated with smoking, cumulative dust exposure, and duration of underground work. Latter two factors were most significantly associated with lung cancer with exposure lagged 20 years.	Hnizdo et al., 1997.
US gold miners.	Cohort and nested case-control study, same population as Brown et al. (1986); workers with at least 1 year underground work between 1940 and 1965. Follow up through 1990.	Particle count data, conversion to mass concentration based on Vt. Granite study, construction of JEM. Median quartz exposures were 0.15, 0.07, and 0.02 mg/m^3 prior to 1930, from 1930–1950, and after 1950 respectively.	115	SMR 113 (CI 94–136) overall. SMRs increased for workers with 30 or more years of latency, and when local cancer rates used as referents. Case-control study showed no relationship of risk to cumulative exposure to dust.	Smoking data available for part of cohort, habits comparable to general US population; attributable smoking-related cancer risk estimated to be 1.07.	Steenland and Brown, 1995a, 1995b
Australian gold miners.	Cohort and nested case-control study. N=2,297, follow up of Armstrong et al. (1979). Follow up through 1993.	Expert ranking of dustiness by job.	Nested case control of 138 lung cancer deaths.	SMR 126 (CI 107–159) lower bound; SMR 149 (CI 126–176) upper bound. From case-control, RR 1.31 (CI 1.10–1.7) per unit exposure score.	Association between exposure and lung cancer mortality not stat. sig. after adjusting for smoking, bronchitis, and silicosis. Authors concluded lung cancer restricted to miners who received compensation for silicosis..	de Klerk and Musk, 1998
U.S. (Vermont) granite shed and quarry workers –.	Cohort study. N=5,414 employed at least 1 year between 1950 and 1982.	Exposure data not used in analysis.	53 deaths among those hired before 1930; 43 deaths among those hired after 1940.	SMR 129 for pre-1930 hires (not stat. sig.); SMR 95 for post-1940 hires (not stat. sig). SMR 181 (stat. sig) for shed workers hired before 1930 and with long tenure and latency.	Dust controls employed between 1938 and 1940 with continuing improvement afterwards.	Costello and Graham, 1988.
Finnish granite workers.	Cohort and nested case-control studies. N=1,026, follow up from 1972–1981, extended to 1985 (Koskella et al., 1990) and 1989 (Koskella et al., 1994).	Personal sampling data collected from 1970–1972 included total and respirable dust and respirable silica sampling. Average silica concentrations ranged form 0.3–4.9 mg/m^3.	31 through 1989	Through 1989, SMR 140 (CI 98–193). For workers in two regions where silica content of rock was highest, SMRs were 126 (CI 71–208) and 211 (CI 120–342), respectively.	Smoking habits similar to other Finnish occupational groups. Minimal work-related exposures to other carcinogens.	Koskela et al., 1987, 1990, 1994.
North American industrial sand workers.	Case-control study from McDonald et al. (2001) cohort.	Assessment based on 14,249 respirable dust and silica samples taken from 1974 to 1998. Exposures prior to this based on particle count data. Adjustments made for respirator use (Rando et al., 2001).	95 cases, two controls per case.	OR 1.00, 0.84, 2.02 and 2.07 for increasing quartiles of exposure p for trend=0.04).	Adjusted for smoking. Positive association between silica exposure and lung cancer. Median exposure for cases and controls were 0.148 and 0.110 mg/m^3 respirable silica, respectively.	Hughes et al., 2001.

TABLE VII–1— SUMMARY OF KEY LUNG CANCER STUDIES—Continued

Industry sector/population	Type of study and description of population	Exposure characterization	No. of lung cancer deaths/cases	Risk ratios (95% CI)	Additional information	Source
U.S. industrial sand workers.	Cohort and nested case-control study. N=4,626 workers. Follow up from 1960–1996.	Exposure assessment based on 4,269 compliance dust samples taken from 1974–1996 and analyzed for respirable quartz. Exposures prior to 1974 based on particle count data and quartz analysis of settled dust and dust collected by high-volume air samplers, and use of a conversion factor (1 mppcf=0.1 mg/m^3).	109 deaths overall	SMR 160 (CI 131–193) overall. Positive trends seen with cumulative silica exposure (p=0.04 for unlagged, p=0.08 for lagged).	Smoking data from 358 workers suggested that smoking could not explain the observed increase in lung cancer mortality rates.	Steenland and Sanderson, 2001.
Chinese Tin, Tungsten, and Copper miners.	Cohort study. N=54,522 workers employed 1 yr. or more between 1972 and 1974. Follow up through 1989.	Measurements for total dust, quartz content, and particle size taken from 1950's-1980's. Exposures categorized as high, medium, low, or non-exposed.	.....	SMRs 198 for tin workers (no CI reported but stat. sig.). No stat. sig. increased SMR for tungsten or copper miners.	Non-statistically significantly increased risk ratio for lung cancer among silicotics. No increased gradient in risk observed with exposure.	Chen et al., 1992.
Chinese Pottery workers.	Cohort study. N=13,719 workers employed in 1972–1974. Follow up through 1989.	Measurements of job-specific total dust and quartz content of settled dust used to classify workers into one of four total dust exposure groups.	.....	SMR 58 (p<0.05) overall. RR 1.63 (CI 0.8–3.4) among silicotics compared to non-silicotics.	No reported increase in lung cancer with increasing exposure.	Chen et al., 1992.
British Coal workers.	Cohort study. N=17,820 miners from 10 collieries..	Quartz exposure assessed from personal respirable dust samples.	973	Significant relationship between cumulative silica exposure (lagged 15 years) and lung cancer mortality VIA Cox regression.	Adjusted for smoking ..	Miller et al, 2007; Miller and MacCalman, 2009

Toxicity studies provide additional evidence of the carcinogenic potential of crystalline silica (Health Effects Summary, Section V). Acellular studies using DNA exposed directly to freshly fractured crystalline silica demonstrate the direct effect silica has on DNA breakage. Cell culture research has investigated the processes by which crystalline silica disrupts normal gene expression and replication (Section V). Studies demonstrate that chronic inflammatory and fibrotic processes resulting in oxidative and cellular damage set up another possible mechanism that leads to neoplastic changes in the lung (Goldsmith, 1997; *see also* Health Effects discussion in Section V). In addition, the biologically damaging physical characteristics of crystalline silica, and the direct and indirect genotoxicity of crystalline silica (Schins, 2002; Borm and Driscoll, 1996), support the Agency's preliminary position that respirable crystalline silica should be considered as an occupational carcinogen that causes lung cancer, a clear material impairment of health.

c. Non-Malignant Respiratory Disease (Other Than Silicosis)

Exposure to respirable crystalline silica increases the risk of developing chronic obstructive pulmonary disease (COPD), in particular chronic bronchitis and emphysema. COPD results in loss of pulmonary function that restricts normal activity in individuals afflicted with these conditions (ATS, 2003). Both chronic bronchitis and emphysema can occur in conjunction with development of silicosis. Several studies have documented increased prevalence of chronic bronchitis and emphysema among silica-exposed workers even absent evidence of silicosis (*see* Section I of the Health Effects Literature Review and Preliminary Quantitative Risk Assessment; NIOSH, 2002; ATS, 1997). There is evidence that smoking may have an additive or synergistic effect on silica-related COPD morbidity or mortality (Hnizdo, 1990; Hnizdo et al., 1990; Wyndham et al., 1986; NIOSH, 2002). In a study of diatomaceous earth workers, Park et al. (2002) found a positive exposure-response relationship between exposure to respirable cristobalite and increased mortality from non-malignant respiratory disease.

Decrements in pulmonary function have often been found among workers exposed to respirable crystalline silica absent radiologic evidence of silicosis. Several cross-sectional studies have reported such findings among granite workers (Theriault, 1974a, 1974b; Ng et al., 1992b; Montes et al., 2004b), South African gold miners (Irwig and Rocks, 1978; Hnizdo et al., 1990; Cowie and Mabena, 1991), gemstone cutters (Ng et al., 1987b), concrete workers (Meijer et al., 2001), refractory brick workers (Wang et al., 1997), hard rock miners (Manfreda et al., 1982; Kreiss et al., 1989), pottery workers (Neukirch et al., 1994), slate workers (Suhr et al., 2003), and potato sorters (Jorna et al., 1994).

OSHA also evaluated several longitudinal studies where exposed workers were examined over a period of time to track changes in pulmonary function. Among both active and retired Vermont granite workers exposed to an average of 60 μg/m^3, Graham did not find exposure-related decrements in pulmonary function (Graham et al., 1981, 1994). However, Eisen et al.

(1995) did find significant pulmonary decrements among a subset of granite workers (termed ''dropouts'') who left work and consequently did not voluntarily participate in the last of a series of annual pulmonary function tests. This group of workers experienced steeper declines in FEV_1 compared to the subset of workers who remained at work and participated in all tests (termed ''survivors''), and these declines were significantly related to dust exposure. Thus, in this study, workers who had left work had exposure-related declines in pulmonary function to a greater extent than did workers who remained on the job, clearly demonstrating a survivor effect among the active workers. Exposure-related changes in lung function were also reported in a 12-year study of granite workers (Malmberg et al., 1993), in two 5-year studies of South African miners (Hnizdo, 1992; Cowie, 1998), and in a study of foundry workers whose lung function was assessed between 1978 and 1992 (Hertzberg et al., 2002).

Each of these studies reported their findings in terms of rates of decline in any of several pulmonary function measures, such as FVC, FEV_1, and FEV_1/FVC. To put these declines in perspective, Eisen et al. (1995), reported that the rate of decline in FEV_1 seen among the dropout subgroup of Vermont granite workers was 4 ml per mg/m^3-year of exposure to respirable granite dust; by comparison, FEV_1 declines at a rate of 10 ml/year from smoking one pack of cigarettes daily. From their study of foundry workers, Hertzberg et al., (2002) reported finding a 1.1 ml/year decline in FEV_1 and a 1.6 ml/year decline in FVC for each mg/m^3-year of respirable silica exposure after controlling for ethnicity and smoking. From these rates of decline, they estimated that exposure to the current OSHA quartz standard of 0.1 mg/m^3 for 40 years would result in a total loss of FEV_1 and FVC that is less than but still comparable to smoking a pack of cigarettes daily for 40 years. Hertzberg et al. (2002) also estimated that exposure to the current standard for 40 years would increase the risk of developing abnormal FEV_1 or FVC by factors of 1.68 and 1.42, respectively. OSHA believes that this magnitude of reduced pulmonary function, as well as the increased morbidity and mortality from non-malignant respiratory disease that has been documented in the studies summarized above, constitute material impairments of health and loss of functional respiratory capacity.

d. Renal and Autoimmune Effects

OSHA's review of the literature summarized in Section V, Health Effects Summary, reflects substantial evidence that exposure to crystalline silica increases the risk of renal and autoimmune diseases. Epidemiologic studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease (*e.g.,* Calvert et al., 1997), subclinical renal changes including proteinurea and elevated serum creatinine (*e.g.,* Ng et al., 1992c; Rosenman et al., 2000; Hotz et al., 1995), end-stage renal disease morbidity (*e.g.,* Steenland et al., 1990), chronic renal disease mortality (Steenland et al., 2001b, 2002a), and Wegener's granulomatosis (Nuyts et al., 1995), the latter of which represents severe injury to the glomeruli that, if untreated, rapidly leads to renal failure. Possible mechanisms suggested for silica-induced renal disease include a direct toxic effect on the kidney, deposition in the kidney of immune complexes (IgA) following silica-related pulmonary inflammation, or an autoimmune mechanism (Calvert et al., 1997; Gregorini et al., 1993). Steenland et al. (2002a) demonstrated a positive exposure-response relationship between exposure to respirable crystalline silica and end-stage renal disease mortality.

In addition, there are a number of studies that show exposure to be related to increased risks of autoimmune disease, including scleroderma (*e.g.,* Sluis-Cremer et al., 1985), rheumatoid arthritis (*e.g.* Klockars et al., 1987; Rosenman and Zhu, 1995), and systemic lupus erythematosus (*e.g.,* Brown et al., 1997). Scleroderma is a degenerative disorder that leads to over-production of collagen in connective tissue that can cause a wide variety of symptoms including skin discoloration and ulceration, joint pain, swelling and discomfort in the extremities, breathing problems, and digestive problems. Rheumatoid arthritis is characterized by joint pain and tenderness, fatigue, fever, and weight loss. Systemic lupus erythematosus is a chronic disease of connective tissue that can present a wide range of symptoms including skin rash, fever, malaise, joint pain, and, in many cases, anemia and iron deficiency. OSHA believes that chronic renal disease, end-stage renal disease mortality, Wegener's granulomatosis, scleroderma, rheumatoid arthritis, and systemic lupus erythematosus clearly represent material impairments of health.

2. Significance of Risk

To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on toxicological, epidemiological, and experimental data, as well as statistical methods. The Agency uses these data and methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime at levels of exposure reflecting both compliance with current standards and compliance with the new standard being proposed. In the case of crystalline silica, the current general industry, construction, and shipyard PELs are formulas that limit 8-hour TWA exposures to respirable dust; the limit on exposure decreases with increasing crystalline silica content of the dust. OSHA's current general industry PEL for respirable quartz is expressed both in terms of a particle count as well as a gravimetric concentration, while the current construction and shipyard employment PELs for respirable quartz are only expressed in terms of a particle count formula. For general industry, the gravimetric formula PEL for quartz approaches 0.1 mg/m^3 (100 μg/m^3) of respirable crystalline silica when the quartz content of the dust is about 10 percent or greater. For the construction and shipyard industries, the current PEL is a formula that is based on concentration of respirable particles in the air; on a mass concentration basis, it is believed by OSHA to lie within a range of between about 0.25 mg/m^3 (250 μg/m^3) to 0.5 mg/m^3 (500 μg/m^3) expressed as respirable quartz (*see* Section VI). In general industry, the current PELs for cristobalite and tridymite are one-half the PEL for quartz.

OSHA is proposing to revise the current PELs for general industry, construction, and shipyards to 0.05 mg/m^3 (50 μg/m^3) of respirable crystalline silica. OSHA is also proposing an action level of 0.025 mg/m^3 (25 μg/m^3). In the Summary of the Preliminary Quantitative Risk Assessment (Section VI of the preamble), OSHA presents estimates of health risks associated with 45 years of exposure to 0.025, 0.05, and 0.1 mg/m^3 respirable crystalline silica to represent the risks associated with exposure over a working lifetime to the proposed action level, proposed PEL, and current general industry PEL, respectively. OSHA also presents estimates associated with exposure to 0.25 and 0.5 mg/m^3 to represent a range of risks likely to be associated with exposure to the current construction and shipyard PELs. Risk estimates are

presented for mortality due to lung cancer, silicosis and other non-malignant lung disease, and end-stage renal disease, as well as silicosis morbidity. The preliminary findings from this assessment are summarized below.

a. Summary of Excess Risk Estimates for Excess Lung Cancer Mortality

For preliminary estimates of lung cancer risk from crystalline silica exposure, OSHA has relied upon studies of exposure-response relationships presented in a pooled analysis of 10 cohort studies (Steenland, et al. 2001a; Toxichemica, Inc., 2004) as well as on individual studies of granite (Attfield and Costello, 2004), diatomaceous earth (Rice et al., 2001), and industrial sand (Hughes et al., 2001) worker cohorts, and a study of coal miners exposed to respirable quartz (Miller et al., 2007; Miller and MacCalman, 2009). OSHA believes these studies are suitable for use to quantitatively characterize health risks to exposed workers because (1) study populations were of sufficient size to provide adequate power to detect low levels of risk, (2) sufficient quantitative exposure data were available to characterize cumulative exposures of cohort members to respirable crystalline silica, (3) the studies either adjusted for or otherwise adequately addressed confounding factors such as smoking and exposure to other carcinogens, and (4) investigators developed quantitative assessments of exposure-response relationships using appropriate statistical models or otherwise provided sufficient information that permits OSHA to do so. Where investigators estimated excess lung cancer risks associated with exposure to the current PEL or NIOSH recommended exposure limit, OSHA provided these estimates in its Preliminary Quantitative Risk Assessment. However, OSHA implemented all risk models in its own life table analysis so that the use of background lung cancer rates and assumptions regarding length of exposure and lifetime were constant across each of the models, and so OSHA could estimate lung cancer risks associated with exposure to specific levels of silica of interest to the Agency.

The Steenland et al. (2001a) study consisted of a pooled exposure-response analysis and risk assessment based on raw data obtained for ten cohorts of silica-exposed workers (65,980 workers, 1,072 lung cancer deaths). The cohorts in this pooled analysis include U.S. gold miners (Steenland and Brown, 1995a), U.S. diatomaceous earth workers (Checkoway et al., 1997), Australian gold miners (deKlerk and Musk, 1998), Finnish granite workers (Koskela et al., 1994), South African gold miners (Hnizdo et al., 1997), U.S. industrial sand employees (Steenland et al., 2001b), Vermont granite workers (Costello and Graham, 1988), and Chinese pottery workers, tin miners, and tungsten miners (Chen et al., 1992). The investigators used a nested case-control design with cases and controls matched for race, sex, age (within five years) and study; 100 controls were matched for each case. An extensive exposure assessment for this pooled analysis was developed and published by Mannetje et al. (2002a). Exposure measurement data were available for all 10 cohorts and included measurements of particle counts, total dust mass, respirable dust mass, and, for one cohort, respirable quartz. Cohort-specific conversion factors were used to estimate cumulative exposures to respirable crystalline silica. A case-control analysis of silicosis mortality (Mannetje et al., 2002b) showed a strong positive exposure-response trend, indicating that cumulative exposure estimates for the cohorts were not subject to random misclassification errors of such a magnitude so as to obscure observing an exposure-response relationship between silica and silicosis despite the variety of dust measurement metrics relied upon and the need to make assumptions to convert the data to a single exposure metric (*i.e.,* mass concentration of respirable crystalline silica). In effect, the known relationship between exposure to respirable silica and silicosis served as a positive control to assess the validity of exposure estimates. Quantitative assessment of lung cancer risks were based on use of a log-linear model (log RR = βx, where x represents the exposure variable and β the coefficient to be estimated) with a 15-year exposure lag providing the best fit. Models based on untransformed or log-transformed cumulative dose metrics provided an acceptable fit to the pooled data, with the model using untransformed cumulative dose providing a slightly better fit. However, there was substantial heterogeneity among the exposure-response coefficients derived from the individual cohorts when untransformed cumulative dose was used, which could result in one or a few of the cohorts unduly influencing the pooled exposure-response coefficient. For this reason, the authors preferred the use of log-transformed cumulative exposure in the model to derive the pooled coefficient since heterogeneity was substantially reduced.

OSHA's implementation of this model is based on a re-analysis conducted by Steenland and Bartow (Toxichemica, 2004), which corrected small errors in the assignment of exposure estimates in the original analysis. In addition, subsequent to the Toxichemica report, and in response to suggestions made by external peer reviewers, Steenland and Bartow conducted additional analyses based on use of a linear relative risk model having the general form RR = 1 + βx, as well as a categorical analysis (personal communication, Steenland 2010). The linear model was implemented with both untransformed and log-transformed cumulative exposure metrics, and was also implemented as a 2-piece spline model.

The categorical analysis indicates that, for the pooled data set, lung cancer relative risks increase steeply at low exposures, after which the rate of increase in relative risk declines and the exposure-response curve becomes flat (*see* Figure II–2 of the Preliminary Quantitative Risk Assessment). Use of either the linear relative risk or log-linear relative risk model with untransformed cumulative exposure (with or without a 15-year lag) failed to capture this initial steep slope, resulting in an underestimate of the relative risk compared to that suggested by the categorical analysis. In contrast, use of log-transformed cumulative exposure with the linear or log-linear model, and use of the 2-piece linear spline model with untransformed exposure, better reflected the initial rise and subsequent leveling out of the exposure-response curve, with the spline model fitting somewhat better than either the linear or log-linear models (all models incorporated a 15-year exposure lag). Of the three models that best reflect the shape of the underlying exposure-response curve suggested by the categorical analysis, there is no clear rationale to prefer one over the other. Use of log-transformed cumulative exposure in either the linear or log-linear models has the advantage of reducing heterogeneity among the 10 pooled studies, lessening the likelihood that the pooled coefficient would be overtly influenced by outliers; however, use of a log-transformed exposure metric complicates comparing results with those from other risk analyses considered by OSHA that are based on untransformed exposure metrics. Since all three of these models yield comparable estimates of risk the choice of model is not critical for the purpose of assessing significance of the risk, and therefore OSHA believes that the risk estimates derived from the pooled study

are best represented as a range of estimates based on all three of these models.

From these models, the estimated lung cancer risk associated with 45 years of exposure to 0.1 mg/m^3 (about equal to the current general industry PEL) is between 22 and 29 deaths per 1,000 workers. The estimated risk associated with exposure to silica concentrations in the range of 0.25 and 0.5 mg/m^3 (about equal to the current construction and shipyard PELs) is between 27 and 38 deaths per 1,000. At the proposed PEL of 0.05 mg/m^3, the estimated excess risk ranges from 18 to 26 deaths per 1,000, and, at the proposed action level of 0.025 mg/m^3, from 9 to 23 deaths per 1,000.

As previously discussed, the exposure-response coefficients derived from each of the 10 cohorts exhibited significant heterogeneity; risk estimates based on the coefficients derived from the individual studies for untransformed cumulative exposure varied by almost two orders of magnitude, with estimated risks associated with exposure over a working lifetime to the current general industry PEL ranging from a low of 0.8 deaths per 1,000 (from the Chinese pottery worker study) to a high of 69 deaths per 1,000 (from the South African miner study). It is possible that the differences seen in the slopes of the exposure-response relationships reflect physical differences in the nature of crystalline silica particles generated in these workplaces and/or the presence of different substances on the crystal surfaces that could mitigate or enhance their toxicity (*see* Section V, Health Effects Summary). It may also be that exposure estimates for some cohorts were subject to systematic misclassification errors resulting in under- or over-estimation of exposures due to the use of assumptions and conversion factors that were necessary to estimate mass respirable crystalline silica concentrations from exposure samples analyzed as particle counts or total and respirable dust mass. OSHA believes that, given the wide range of risk estimates derived from these 10 studies, use of log-transformed cumulative exposure or the 2-piece spline model is a reasonable approach for deriving a single summary statistic that represents the lung cancer risk across the range of workplaces and exposure conditions represented by the studies. However, use of these approaches results in a non-linear exposure-response and suggests that the relative risk of silica-related lung cancer begins to attenuate at cumulative exposures in the range of those represented by the current PELs. Although such exposure-response relationships have been described for some carcinogens (for example, from metabolic saturation or a healthy worker survivor effect, *see* Staynor et al., 2003), OSHA is not aware of any specific evidence that would suggest that such a result is biologically plausible for silica, except perhaps the possibility that lung cancer risks increase more slowly with increasing exposure because of competing risks from other silica-related diseases. Attenuation of the exposure-response can also result from misclassification of exposure estimates for the more highly-exposed cohort members (Staynor et al., 2003). OSHA's evaluation of individual cohort studies discussed below indicates that, with the exception of the Vermont granite cohort, attenuation of exposure-related lung cancer response has not been directly observed.

In addition to the pooled cohort study, OSHA's Preliminary Quantitative Risk Assessment presents risk estimates derived from four individual studies where investigators presented either lung cancer risk estimates or exposure-response coefficients. Two of these studies, one on diatomaceous earth workers (Rice et al., 2001) and one on Vermont granite workers (Attfield and Costello, 2004), were included in the 10-cohort pooled study (Steenland et al., 2001a; Toxichemica, 2004). The other two were of British coal miners (Miller et al., 2007; Miller and MacCalman, 2010) and North American industrial sand workers (Hughes et al., 2001).

Rice et al. (2001) presents an exposure-response analysis of the diatomaceous worker cohort studied by Checkoway et al. (1993, 1996, 1997), who found a significant relationship between exposure to respirable cristobalite and increased lung cancer mortality. The cohort consisted of 2,342 white males employed for at least one year between 1942 and 1987 in a California diatomaceous earth mining and processing plant. The cohort was followed until 1994, and included 77 lung cancer deaths. The risk analysis relied on an extensive job-specific exposure assessment developed by Sexias et al. (1997), which included use of over 6,000 samples taken during the period 1948 through 1988. The mean cumulative exposure for the cohort was 2.16 mg/m^3-years for respirable crystalline silica dust. Rice et al. (2001) evaluated several model forms for the exposure-response analysis and found exposure to respirable cristobalite to be a significant predictor of lung cancer mortality with the best-fitting model being a linear relative risk model (with a 15-year exposure lag). From this model, the estimates of the excess risk of lung cancer mortality are 34, 17, and 9 deaths per 1,000 workers for 45-years of exposure to 0.1, 0.05, and 0.025 mg/m^3, respectively. For exposures in the range of the current construction and shipyard PELs over 45 years, estimated risks lie in a range between 81 and 152 deaths per 1,000 workers.

Somewhat higher risk estimates are derived from the analysis presented by Attfield and Costello (2004) of Vermont granite workers. This study involved a cohort of 5,414 male granite workers who were employed in the Vermont granite industry between 1950 and 1982 and who were followed through 1994. Workers' cumulative exposures were estimated by Davis et al. (1983) based on historical exposure data collected in six environmental surveys conducted between 1924 and 1977. A categorical analysis showed an increasing trend of lung cancer risk ratios with increasing exposure, and Poisson regression was used to evaluate several exposure-response models with varying exposure lags and use of either untransformed or log-transformed exposure metrics. The best-fitting model was based on use of a 15-year lag, use of untransformed cumulative exposure, and omission of the highest exposure group. The investigators believed that the omission of the highest exposure group was appropriate since: (1) The underlying exposure data for the high-exposure group was weaker than for the others; (2) there was a greater likelihood that competing causes of death and misdiagnoses of causes of death attenuated the lung cancer death rate in the highest exposure group; (3) all of the remaining groups comprised 85 percent of the deaths in the cohort and showed a strong linear increase in lung cancer mortality with increasing exposure; and (4) the exposure-response relationship seen in the lower exposure groups was more relevant given that the exposures of these groups were within the range of current occupational standards. OSHA's use of the exposure coefficient from this analysis in a log-linear relative risk model yielded a risk estimate of 60 deaths per 1,000 workers for 45 years of exposure to the current general industry PEL of 0.1 mg/m^3, 25 deaths per 1,000 for 45 years of exposure to the proposed PEL of 0.05 mg/m^3, and 11 deaths per 1,000 for 45 years of exposure at the proposed action level of 0.025 mg/m^3. Estimated risks associated with 45 years of exposure at the current construction PEL range from 250 to 653 deaths per 1,000.

Hughes et al. (2001) conducted a nested case-control study of 95 lung cancer deaths from a cohort of 2,670

industrial sand workers in the U.S. and Canada studied by McDonald et al. (2001). (This cohort overlaps with the cohort studied by Steenland and Sanderson (2001), which was included in the 10-cohort pooled study by Steenland et al., 2001a). Both categorical analyses and conditional logistic regression were used to examine relationships with cumulative exposure, log of cumulative exposure, and average exposure. Exposure levels over time were estimated via a job-exposure matrix developed for this study (Rando et al., 2001). The 50th percentile (median) exposure level of cases and controls for lung cancer were 0.149 and 0.110 mg/m^3 respirable crystalline silica, respectively, slightly above the current OSHA general industry standard. There did not appear to be substantial misclassification of exposures, as evidenced by silicosis mortality showing a positive exposure-response trend with cumulative exposure and average exposure concentration. Statistically significant positive exposure-response trends for lung cancer were found for both cumulative exposure (lagged 15 years) and average exposure concentration, but not for duration of employment, after controlling for smoking. There was no indication of an interaction effect of smoking and cumulative silica exposure. Hughes et al. (2001) reported the exposure coefficients for both lagged and unlagged cumulative exposure; there was no significant difference between the two (0.13 per mg/m^3-year for lagged vs. 0.14 per mg/m^3-year for unlagged). Use of the coefficient from Hughes et al. (2001) that incorporated a 15-year lag generates estimated cancer risks of 34, 15, and 7 deaths per 1,000 for 45 years exposure to the current general industry PEL of 0.1, the proposed PEL of 0.05 mg/m^3, and the proposed action level of 0.025 mg/m^3 respirable silica, respectively. For 45 years of exposure to the construction PEL, estimated risks range from 120 to 387 deaths per 1,000 workers.

Miller and MacCalman (2010, also reported in Miller et al., 2007) extended the follow-up of a previously published cohort mortality study (Miller and Buchanan, 1997). The follow-up study included 17,800 miners from 10 coal mines in the U.K. who were followed through the end of 2005; observation in the original study began in 1970. By 2005, there were 516,431 person years of observation, an average of 29 years per miner, with 10,698 deaths from all causes. Exposure estimates of cohort members were not updated from the earlier study since the mines closed in the 1980s; however, some of these men might have had additional exposure at other mines or facilities. An analysis of cause-specific mortality was performed using external controls; it demonstrated that lung cancer mortality was statistically significantly elevated for coal miners exposed to silica. An analysis using internal controls was performed via Cox proportional hazards regression methods, which allowed for each individual miner's measurements of age and smoking status, as well as the individual's detailed dust and quartz time-dependent exposure measurements. From the Cox regression, Miller and MacCalman (2009) estimated that cumulative exposure of 5 g-h/m^3 respirable quartz (incorporating a 15-year lag) was associated with a relative risk of 1.14 for lung cancer. This cumulative exposure is about equivalent to 45 years of exposure to 0.055 mg/m^3 respirable quartz, or a cumulative exposure of 2.25 mg/m^3-yr, assuming 2,000 hours of exposure per year. OSHA applied this slope factor in a log-relative risk model and estimated the lifetime lung cancer mortality risk to be 13 per 1,000 for 45 years of exposure to 0.1 mg/m^3 respirable crystalline silica. For the proposed PEL of 0.05 mg/m^3 and proposed action level of 0.025 mg/m^3, the lifetime risks are estimated to be 6 and 3 deaths per 1,000, respectively. The range of risks estimated to result from 45 years of exposure to the current construction and shipyard PELs is from 37 to 95 deaths per 1,000 workers.

The analysis from the Miller and MacCalman (2009) study yields risk estimates that are lower than those obtained from the other cohort studies described above. Possible explanations for this include: (1) Unlike the studies on diatomaceous earth workers and granite workers, the mortality analysis of the coal miners was adjusted for smoking; (2) lung cancer risks might have been lower among the coal miners due to high competing mortality risks observed in the cohort (mortality was significantly increased for several diseases, including tuberculosis, chronic bronchitis, and non-malignant respiratory disease); and (3) the lower risk estimates derived from the coal miner study could reflect an actual difference in the cancer potency of the quartz dust in the coal mines compared to that present in the work environments studied elsewhere. OSHA believes that the risk estimates derived from this study are credible. In terms of design, the cohort was based on union rolls with very good participation rates and good reporting. The study group was the largest of any of the individual cohort studies reviewed here (over 17,000 workers) and there was an average of nearly 30 years of follow-up, with about 60 percent of the cohort having died by the end of follow-up. Just as important were the high quality and detail of the exposure measurements, both of total dust and quartz.

b. Summary of Risk Estimates for Silicosis and Other Chronic Lung Disease Mortality

OSHA based its quantitative assessment of silicosis mortality risks on a pooled analysis conducted by Mannetje et al. (2002b) of data from six of the ten epidemiological studies in the Steenland et al. (2001a) pooled analysis of lung cancer mortality. Cohorts included in the silicosis study were U.S. diatomaceous earth workers (Checkoway et al., 1997); Finnish granite workers (Koskela et al., 1994); U.S. granite workers (Costello and Graham, 1988); U.S. industrial sand workers (Steenland and Sanderson, 2001); U.S. gold miners (Steenland and Brown, 1995b); and Australian gold miners (deKlerk and Musk, 1998). These six cohorts contained 18,634 subjects and 170 silicosis deaths, where silicosis mortality was defined as death from silicosis (ICD–9 502, n=150) or from unspecified pneumoconiosis (ICD–9 505, n = 20). Analysis of exposure-response was performed in a categorical analysis where the cohort was divided into cumulative exposure deciles and Poisson regression was used to estimate silicosis rate ratios for each category, adjusted for age, calendar period, and study. Exposure-response was examined in more detail using a nested case-control design and logistic regression. Although Mannetje et al. (2002b) estimated silicosis risks at the current OSHA PEL from the Poisson regression, a subsequent analysis based on the case-control design was conducted by Steenland and Bartow (Toxichemica, 2004), which resulted in slightly lower estimates of risk. Based on the Toxichemica analysis, OSHA estimates that the lifetime risk (over 85 years) of silicosis mortality associated with 45 years of exposure to the current general industry PEL of 0.1 mg/m^3 is 11 deaths per 1,000 workers. Exposure for 45 years to the proposed PEL of 0.05 mg/m^3 and action level of 0.025 mg/m^3 results in an estimated 7 and 4 silicosis deaths per 1,000, respectively. Lifetime risks associated with exposure at the current construction and shipyard PELs range from 17 to 22 deaths per 1,000 workers.

To study non-malignant respiratory diseases, of which silicosis is one, Park et al. (2002) analyzed the California

diatomaceous earth cohort data originally studied by Checkoway et al. (1997), consisting of 2,570 diatomaceous earth workers employed for 12 months or more from 1942 to 1994. The authors quantified the relationship between exposure to cristobalite and mortality from chronic lung disease other than cancer (LDOC). Diseases in this category included pneumoconiosis (which included silicosis), chronic bronchitis, and emphysema, but excluded pneumonia and other infectious diseases. Less than 25 percent of the LDOC deaths in the analysis were coded as silicosis or other pneumoconiosis (15 of 67). As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis. Exposure-response relationships were explored using both Poisson regression models and Cox's proportional hazards models fit to the same series of relative rate exposure-response models that were evaluated by Rice et al. (2001) for lung cancer (*i.e.,* log-linear, log-square root, log-quadratic, linear relative rate, a power function, and a shape function). Relative or excess rates were modeled using internal controls and adjusting for age, calendar time, ethnicity (Hispanic versus white), and time since first entry into the cohort, or using age- and calendar time-adjusted external standardization to U.S. population mortality rates. There were no LDOC deaths recorded among workers having cumulative exposures above 32 mg/m^3-years, causing the response to level off or decline in the highest exposure range; possible explanations considered included survivor selection, depletion of susceptible populations in high dust areas, and/or a higher degree of misclassification of exposures in the earlier years where exposure data were lacking and when exposures were presumably the highest. Therefore, Park et al. (2002) performed exposure-response analyses that restricted the dataset to observations where cumulative exposures were below 10 mg/m^3-years, a level more than four times higher than that resulting from 45 years of exposure to the current general industry PEL for cristobalite (which is about 0.05 mg/m^3), as well as analyses using the full dataset. Among the models based on the restricted dataset, the best-fitting model with a single exposure term was the linear relative rate model using external adjustment.

OSHA's estimates of the lifetime chronic lung disease mortality risk based on this model are substantially higher than those that OSHA derived from the Mannetje et al. (2002b) silicosis analysis. For the current general industry PEL of 0.1 mg/m^3, exposure for 45 years is estimated to result in 83 deaths per 1,000 workers. At the proposed PEL of 0.05 mg/m^3 and action level of 0.025 mg/m^3, OSHA estimates the lifetime risk from 45 years of exposure to be 43 and 22 deaths per 1,000, respectively. The range of risks associated with exposure at the construction and shipyard PELs over a working lifetime is from 188 to 321 deaths per 1,000 workers. It should be noted that the Mannetje study (2002b) was not adjusted for smoking while the Park study (2002) had data on smoking habits for about one-third of the workers who died from LDOC and about half of the entire cohort. The Poisson regression on which the risk model is based was partially stratified on smoking. Furthermore, analyses without adjustment for smoking suggested to the authors that smoking was acting as a negative confounder.

c. Summary of Risk Estimates for Renal Disease Mortality

OSHA's analysis of the health effects literature included several studies that have demonstrated that exposure to crystalline silica increases the risk of renal and autoimmune disease (*see* Section V, Health Effects Summary). Studies have found statistically significant associations between occupational exposure to silica dust and chronic renal disease, sub-clinical renal changes, end-stage renal disease morbidity, chronic renal disease mortality, and Wegener's granulomatosis. A strong exposure-response association for renal disease mortality and silica exposure has also been demonstrated.

OSHA's assessment of the renal disease risks that result from exposure to respirable crystalline silica are based on an analysis of pooled data from three cohort studies (Steenland et al., 2002a). The combined cohort for the pooled analysis (Steenland et al., 2002a) consisted of 13,382 workers and included industrial sand workers (Steenland et al., 2001b), U.S. gold miners (Steenland and Brown, 1995a), and Vermont granite workers (Costello and Graham, 1998). Exposure data were available for 12,783 workers and analyses conducted by the original investigators demonstrated monotonically increasing exposure-response trends for silicosis, indicating that exposure estimates were not likely subject to significant random misclassification. The mean duration of exposure, cumulative exposure, and concentration of respirable silica for the combined cohort were 13.6 years, 1.2 mg/m^3-years, and 0.07 mg/m^3, respectively. There were highly statistically significant trends for increasing renal disease mortality with increasing cumulative exposure for both multiple cause analysis of mortality ($p<0.000001$) and underlying cause analysis ($p = 0.0007$). Exposure-response analysis was also conducted as part of a nested case-control study, which showed statistically significant monotonic trends of increasing risk with increasing exposure again for both multiple cause ($p = 0.004$ linear trend, 0.0002 log trend) and underlying cause ($p = 0.21$ linear trend, 0.03 log trend) analysis. The authors found that use of log-cumulative dose in a log relative risk model fit the pooled data better than cumulative exposure, average exposure, or lagged exposure. OSHA's estimates of renal disease mortality risk, which are based on the log relative risk model with log cumulative exposure, are 39 deaths per 1,000 for 45 years of exposure at the current general industry PEL of 0.1 mg/m^3, 32 deaths per 1,000 for exposure at the proposed PEL of 0.05 mg/m^3, and 25 deaths per 1,000 at the proposed action level of 0.025 mg/m^3. OSHA also estimates that 45 years of exposure at the current construction and shipyard PELs would result in a renal disease mortality risk ranging from 52 to 63 deaths per 1,000 workers.

d. Summary of Risk Estimates for Silicosis Morbidity

OSHA's Preliminary Quantitative Risk Assessment reviewed several cross-sectional studies designed to characterize relationships between exposure to respirable crystalline silica and development of silicosis as determined by chest radiography. Several of these studies could not provide information on exposure or length of employment prior to disease onset. Others did have access to sufficient historical medical data to retrospectively determine time of disease onset but included medical examination at follow up of primarily active workers with little or no post-employment follow-up. Although OSHA presents silicosis risk estimates that were reported by the investigators of these studies, OSHA believes that such estimates are likely to understate lifetime risk of developing radiological silicosis; in fact, the risk estimates reported in these studies are generally lower than those derived from studies that included retired workers in follow up medical examinations.

Therefore, OSHA believes that the most useful studies for characterizing lifetime risk of silicosis morbidity are retrospective cohort studies that

included a large proportion of retired workers in the cohort and that were able to evaluate disease status over time, including post-retirement. OSHA identified studies of six cohorts for which the inclusion of retirees was deemed sufficient to adequately characterize silicosis morbidity risks well past employment (Hnizdo and Sluis-Cremer, 1993; Steenland and Brown, 1995b; Miller et al., 1998; Buchanan et al., 2003; Chen et al., 2001; Chen et al., 2005). Study populations included five mining cohorts and a Chinese pottery worker cohort. Except for the Chinese studies (Chen et al., 2001; Chen et al., 2005), chest radiographs were interpreted in accordance with the ILO system described earlier in this section, and x-ray films were read by panels of B-readers. In the Chinese studies, films were evaluated using a Chinese system of classification that is analogous to the ILO system. In addition, the Steenland and Brown (1995b) study of U.S. gold miners included silicosis mortality as well as morbidity in its analysis. OSHA's estimates of silicosis morbidity risks are based on implementing the various exposure-response models reported by the investigators; these are considered to be cumulative risk models in the sense that they represent the risk observed in the cohort at the time of the last medical evaluation and do not reflect all of the risk that may become manifest over a lifetime. With the exception of a coal miner study (Buchanan et al., 2003), risk estimates reflect the risk that a worker will acquire an abnormal chest x-ray classified as ILO major category 1 or greater; the coal miner study evaluated the risk of acquiring an abnormal chest x-ray classified as major category 2 or higher.

For miners exposed to freshly cut crystalline silica, the estimated risk of developing lesions consistent with an ILO classification of category 1 or greater is estimated to range from 120 to 773 cases per 1,000 workers exposed at the current general industry PEL of 0.1 mg/m^3 for 45 years. For 45 years of exposure to the proposed PEL of 0.05 mg/m^3, the range in estimated risk is from 20 to 170 cases per 1,000 workers. The risk predicted from exposure to the proposed action level of 0.025 mg/m^3 ranges from 5 to 40 cases per 1,000. From the coal miner study of Buchanan et al. (2003), the estimated risks of acquiring an abnormal chest x-ray classified as ILO category 2 or higher are 301, 55, and 21 cases per 1,000 workers exposed for 45 years to 0.1, 0.05, and 0.025 mg/m^3, respectively. These estimates are within the range of risks obtained from the other mining studies. At exposures at or above 0.25 mg/m^3 for 45 years (equivalent to the current construction and shipyard PELs), the risk of acquiring an abnormal chest x-ray approaches unity. Risk estimates based on the pottery cohort are 60, 20, and 5 cases per 1,000 workers exposed for 45 years to 0.1, 0.05, and 0.025 mg/m^3, respectively, which is generally below the range of risks estimated from the other studies and may reflect a lower toxicity of quartz particles in that work environment due to the presence of alumino-silicates on the particle surfaces. According to Chen et al. (2005), adjustment of the exposure metric to reflect the unoccluded surface area of silica particles resulted in an exposure-response of pottery workers that was similar to the mining cohorts. The finding of a reduced silicosis risk among pottery workers is consistent with other studies of clay and brick industries that have reported finding a lower prevalence of silicosis compared to that experienced in other industry sectors (Love et al., 1999; Hessel, 2006; Miller and Soutar, 2007) as well as a lower silicosis risk per unit of cumulative exposure (Love et al., 1999; Miller and Soutar, 2007).

3. Significance of Risk and Risk Reduction

The Supreme Court's benzene decision of 1980, discussed above in this section, states that ''before he can promulgate *any* permanent health or safety standard, the Secretary [of Labor] is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices.'' Benzene, 448 U.S. at 642. While making it clear that it is up to the Agency to determine what constitutes a significant risk, the Court offered general guidance on the level of risk OSHA might determine to be significant.

> It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, 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 and take appropriate steps to decrease or eliminate it.

Benzene, 448 U.S. at 655. The Court further stated that the determination of significant risk is not a mathematical straitjacket and that ''the Agency has no duty to calculate the exact probability of harm.'' *Id.*

In this section, OSHA presents its preliminary findings with respect to the significance of the risks summarized above, and the potential of the proposed standard to reduce those risks. Findings related to mortality risk will be presented first, followed by silicosis morbidity risks.

a. Mortality Risks

OSHA's Preliminary Quantitative Risk Assessment (and the Summary of the Preliminary Quantitative Risk Assessment in section VI) presents risk estimates for four causes of excess mortality: Lung cancer, silicosis, non-malignant respiratory disease (including silicosis and COPD), and renal disease. Table VII–2 presents the estimated excess lifetime risks (*i.e.,* to age 85) of these fatal diseases associated with various levels of crystalline silica exposure allowed under the current rule, based on OSHA's risk assessment and assuming 45 years of occupational exposure to crystalline silica.

TABLE VII–2—EXPECTED EXCESS DEATHS PER 1,000 WORKERS

Fatal health outcome	Current general industry PEL (0.1 mg/m^3)	Current construction/ shipyard PEL (0.25–0.5 mg/m^3)	Proposed PEL (0.05 mg/m^3)
Lung Cancer:			
10-cohort pooled analysis	22–29	27–38	18–26
Single cohort study-lowest estimate	13	37–95	6
Single cohort study-highest estimate	60	250–653	25
Silicosis	11	17–22	7
Non-Malignant Respiratory Disease (including silicosis)	83	188–321	43

TABLE VII–2—EXPECTED EXCESS DEATHS PER 1,000 WORKERS—Continued

Fatal health outcome	Current general industry PEL (0.1 mg/m³)	Current construction/ shipyard PEL (0.25–0.5 mg/m³)	Proposed PEL (0.05 mg/m³)
Renal Disease	39	52–63	32

The purpose of the OSH Act, as stated in Section 6(b), is to ensure ''that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.'' 29 U.S.C. 655(b)(5). Assuming a 45-year working life, as OSHA has done in significant risk determinations for previous standards, the Agency preliminarily finds that the excess risk of disease mortality related to exposure to respirable crystalline silica at levels permitted by current OSHA standards is clearly significant. The Agency's estimate of such risk falls well above the level of risk the Supreme Court indicated a reasonable person might consider unacceptable. *Benzene,* 448 U.S. at 655. For lung cancer, OSHA estimates the range of risk at the current general industry PEL to be between 13 and 60 deaths per 1,000 workers. The estimated risk for silicosis mortality is lower, at 11 deaths per 1,000 workers; however, the estimated lifetime risk for non-malignant respiratory disease mortality, including silicosis, is about 8-fold higher than that for silicosis alone, at 83 deaths per 1,000. OSHA believes that the estimate for non-malignant respiratory disease mortality is better than the estimate for silicosis mortality at capturing the total respiratory disease burden associated with exposure to crystalline silica dust. The former captures deaths related to COPD, for which there is strong evidence of a causal relationship with exposure to silica, and is also more likely to capture those deaths where silicosis was a contributing factor but where the cause of death was misclassified. Finally, there is an estimated lifetime risk of renal disease mortality of 39 deaths per 1,000. Exposure for 45 years at levels of respirable crystalline silica in the range of the current limits for construction and shipyards result in even higher risk estimates, as presented in Table VII–2.

To further demonstrate significant risk, OSHA compares the risk from currently permissible crystalline silica exposures to risks found across a broad variety of occupations. The Agency has used similar occupational risk comparisons in the significant risk determination for substance-specific standards promulgated since the benzene decision. This approach is supported by 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: ''In determining the priority for establishing standards under this section, 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).

Fatal injury rates for most U.S. industries and occupations may be obtained from data collected by the Bureau of Labor Statistics. Table VII–3 shows annual fatality rates per 1,000 employees for several industries for 2007, as well as projected fatalities per 1,000 employees assuming exposure to workplace hazards for 45 years based on these annual rates (BLS, 2010). While it is difficult to meaningfully compare aggregate industry fatality rates to the risks estimated in the quantitative risk assessment for crystalline silica, which address one specific hazard (inhalation exposure to respirable crystalline silica) and several health outcomes (lung cancer, silicosis, NMRD, renal disease mortality), these rates provide a useful frame of reference for considering risk from inhalation exposure to crystalline silica. For example, OSHA's estimated range of 6–60 excess lung cancer deaths per 1,000 workers from regular occupational exposure to respirable crystalline silica in the range of 0.05—0.1 mg/m³ is roughly comparable to, or higher than, the expected risk of fatal injuries over a working life in high-risk occupations such as mining and construction (*see* Table VII–3). Regular exposures at higher levels, including the current construction and shipyard PELs for respirable crystalline silica, are expected to cause substantially more deaths per 1,000 workers from lung cancer (ranging from 37 to 653 per 1,000) than result from occupational injuries in most private industry. At the proposed PEL of 0.05 mg/m³ respirable crystalline silica, the Agency's estimate of excess lung cancer mortality, from 6 to 26 deaths per 1,000 workers, is still 3- to10-fold or more higher than private industry's average fatal injury rate, given the same employment time, and substantially exceeds those rates found in lower-risk industries such as finance and educational and health services.

TABLE VII–3—FATAL INJURIES PER 1000 EMPLOYEES, BY INDUSTRY OR SECTOR

	Over 1 year	Over 45 years
All Private Industry	0.043	1.9
Mining (General)	0.214	9.6
Construction	0.108	4.8
Manufacturing	0.024	1.1
Wholesale Trade	0.045	2.0
Transportation and Warehousing	0.165	7.4
Financial Activities	0.012	0.5
Educational and Health Services	0.008	0.4

Source: BLS (2010).

Because there is little available information on the incidence of occupational cancer across all industries, risk from crystalline silica exposure cannot be compared with overall risk from other workplace carcinogens. However, OSHA's previous risk assessments provide estimates of risk from exposure to certain carcinogens. These risk assessments, as with the current assessment for crystalline silica, were based on animal or human data of reasonable or high quality and used the best information then available. Table VII–4 shows the Agency's best estimates of cancer risk from 45 years of occupational exposure to several carcinogens, as published in the preambles to final rules promulgated since the benzene decision in 1980. These risks were judged by the Agency to be significant.

TABLE VII–4—SELECTED OSHA RISK ESTIMATES FOR PRIOR AND CURRENT PELS

[Excess Cancers per 1000 workers]

Standard	Risk at prior PEL	Risk at current PEL	**Federal Register** date
Ethylene Oxide	63–109 per 1000	1.2–2.3 per 1000	June 22, 1984.
Asbestos	64 per 1000	6.7 per 1000	June 20, 1986.
Benzene	95 per 1000	10 per 1000	September 11, 1987.
Formaldehyde	0.4–6.2 per 1000	0.0056 per 1000	December 4, 1987.
Methylenedianiline	*6–30 per 1000	0.8 per 1000	August 10, 1992.
Cadmium	58–157 per 1000	3–15 per 1000	September 14, 1992.
1,3-Butadiene	11.2–59.4 per 1000	1.3–8.1 per 1000	November 4, 1996.
Methylene Chloride	126 per 1000	3.6 per 1000	January 10, 1997.
Chromium VI	101–351 per 1000	10–45 per 1000	February 28, 2006
Crystalline Silica:			
General Industry PEL	**13–60 per 1000	***6–26 per 1000	N/A
Construction/Shipyard PEL	**27–653 per 1000	***6–26 per 1000	

* no prior standard; reported risk is based on estimated exposures at the time of the rulemaking
** estimated excess lung cancer risks at the current PEL
*** estimated excess lung cancer risks at the proposed new PEL

The estimated excess lung cancer risks associated with respirable crystalline silica at the current general industry PEL, 13–60 deaths per 1,000 workers, are comparable to, and in some cases higher than, the estimated excess cancer risks for many other workplace carcinogens for which OSHA made a determination of significant risk (*see* Table VII–4, ''Selected OSHA Risk Estimates for Prior and Current PELs''). The estimated excess lung cancer risks associated with exposure to the current construction and shipyard PELs are even higher. The estimated risk from lifetime occupational exposure to respirable crystalline silica at the proposed PEL is 6–26 excess lung cancer deaths per 1,000 workers, a range still higher than the risks from exposure to many other carcinogens regulated by OSHA (*see* Table VII–4, ''Selected OSHA Risk Estimates for Prior and Current PELs'').

OSHA's preliminary risk assessment also shows that reduction of the current PELs to the proposed level of 0.05 mg/m^3 will result in substantial reduction in risk, although quantification of that reduction is subject to model uncertainty. Risk models that reflect attenuation of the risk with increasing exposure, such as those relating risk to a log transformation of cumulative exposure, will result in lower estimates of risk reduction compared to linear risk models. Thus, for lung cancer risks, the assessment based on the 10-cohort pooled analysis by Steenland et al. (2001; also Toxichemica, 2004; Steenland 2010) suggests risk will be reduced by about 14 percent from the current general industry PEL and by 28–41 percent from the current construction/shipyard PEL (based on the midpoint of the ranges of estimated risk derived from the three models used for the pooled cohort data). These risk reduction estimates, however, are much lower than those derived from the single cohort studies (Rice et al., 2001; Attfield and Costello, 2004; Hughes et al., 2001; Miller and MacCalman, 2009), which used linear or log-linear relative risk models with untransformed cumulative exposure as the dose metric. These single cohort studies suggest that reducing the current PELs to the proposed PEL will reduce lung cancer risk by more than 50 percent in general industry and by more than 80 percent in construction and shipyards.

For silicosis mortality, OSHA's assessment indicates that risk will be reduced by 36 percent and by 58–68 percent as a result of reducing the current general industry and construction/shipyard PELs, respectively. Non-malignant respiratory disease mortality risks will be reduced by 48 percent and by 77–87 percent from reducing the general industry and construction/shipyard PELs, respectively, to the proposed PEL. There is also a substantial reduction in renal disease mortality risks; an 18-percent reduction associated with reducing the general industry PEL and a 38- to 49-percent reduction associated with reducing the construction/shipyard PEL.

Thus, OSHA believes that the proposed PEL of 0.05 mg/m^3 respirable crystalline silica will substantially reduce the risk of material health impairments associated with exposure to silica. However, even at the proposed PEL, as well as the action level of 0.025 mg/m^3, the risk posed to workers with 45 years of regular exposure to respirable crystalline silica is greater than 1 per 1,000 workers and is still clearly significant.

b. Silicosis Morbidity Risks

OSHA's Preliminary Risk Assessment characterizes the risk of developing lung fibrosis as detected by chest x-ray. For 45 years of exposure at the current general industry PEL, OSHA estimates that the risk of developing lung fibrosis consistent with an ILO category 1+ degree of small opacity profusion ranges from 60 to 773 cases per 1,000. For exposure at the construction and shipyard PELs, the risk approaches unity. The wide range of risk estimates derived from the underlying studies relied on for the risk assessment may reflect differences in the relative toxicity of quartz particles in different workplaces; nevertheless, OSHA believes that each of these risk estimates clearly represent a significant risk of developing fibrotic lesions in the lung. Exposure to the proposed PEL of 0.05 mg/m^3 respirable crystalline silica for 45 years yields an estimated risk of

between 20 and 170 cases per 1,000 for developing fibrotic lesions consistent with an ILO category of 1+. These risk estimates indicate that promulgation of the proposed PEL would result in a reduction in risk by about two-thirds or more, which the Agency believes is a substantial reduction of the risk of developing abnormal chest x-ray findings consistent with silicosis.

One study of coal miners also permitted the agency to evaluate the risk of developing lung fibrosis consistent with an ILO category 2+ degree of profusion of small opacities (Buchanan et al., 2003). This level of profusion has been shown to be associated with a higher prevalence of lung function decrement and an increased rate of early mortality (Ng et al., 1987a; Begin et al., 1998; Moore et al., 1988; Ng et al., 1992a; Infante-Rivard et al., 1991). From this study, OSHA estimates that the risk associated with 45 years of exposure to the current general industry PEL is 301 cases per 1,000 workers, again a clearly significant risk. Exposure to the proposed PEL of 0.05 mg/m^3 respirable crystalline silica for 45 years yields an estimated risk of 55 cases per 1,000 for developing lesions consistent with an ILO category 2+ degree of small opacity profusion. This represents a reduction in risk of over 80 percent, again a clearly substantial reduction of the risk of developing radiologic silicosis consistent with ILO category 2+ degree of small opacity profusion.

As is the case for other health effects addressed in the preliminary risk assessment (*i.e.,* lung cancer, silicosis morbidity defined as ILO 1+ level of profusion), there is some evidence that this risk will vary according to the nature of quartz particles present in different workplaces. In particular, risk may vary depending on whether quartz is freshly fractured during work operations and the co-existence of other minerals and substances that could alter the biological activity of quartz. Using medical and exposure data taken from a cohort of heavy clay workers first studied by Love et al. (1999), Miller and Soutar (2007) compared the silicosis prevalence within the cohort to that predicted by the exposure-response model derived by Buchanan et al. (2003) and used by OSHA to estimate the risk of radiologic silicosis with a classification of ILO 2+. They found that the model predicted about a 4-fold higher prevalence of workers having an abnormal x-ray than was actually seen in the clay cohort (31 cases predicted vs. 8 observed). Unlike the coal miner study, the clay worker cohort included only active workers and not retirees (Love et al., 1999); however, Miller and Soutar believed this could not explain the magnitude of the difference between the model prediction and observed silicosis prevalence in the clay worker cohort. OSHA believes that the result obtained by Miller and Soutar (2007) likely does reflect differences in the toxic potency of quartz particles in different work settings. Nevertheless, even if the risk estimates predicted by the model derived from the coal worker study were reduced substantially, even by more than a factor of 10, the resulting risk estimate would still reflect the presence of a significant risk.

The Preliminary Quantitative Risk Assessment also discusses the question of a threshold exposure level for silicosis. There is little quantitative data available with which to estimate a threshold exposure level for silicosis or any of the other silica-related diseases addressed in the risk assessment. The risk assessment discussed one study that perhaps provides the best information. This is an analysis by Kuempel et al. (2001) who used a rat-based toxicokinetic/toxicodynamic model along with a human lung deposition/clearance model to estimate a minimum lung burden necessary to cause the initial inflammatory events that can lead to lung fibrosis and an indirect genotoxic cause of lung cancer. They estimated that the threshold effect level of lung burden associated with this inflammation (M_{crit}) is the equivalent of exposure to 0.036 mg/m^3 for 45 years; thus, exposures below this level would presumably not lead to an excess lung cancer risk (based on an indirect genotoxic mechanism) nor to silicosis, at least in the ''average individual.'' This might suggest that exposures to a concentration of silica at the proposed action level would not be associated with a risk of silicosis, and possibly not of lung cancer. However, OSHA does not believe that the analysis by Kuemple et al. is definitive with respect to a threshold for silica-related disease. First, since the critical quartz burden is a mean value derived from the model, the authors estimated that a 45-year exposure to a concentration as low as 0.005 mg/m^3, or 5 times below the proposed action level, would result in a lung quartz burden that was equal to the 95-percent lower confidence limit on M_{crit}. Due to the statistical uncertainty in Kuemple et al.'s estimate of critical lung burden, OSHA cannot rule out the existence of a threshold lung burden that is below that resulting from exposure to the proposed action level. In addition, with respect to silica-related lung cancer, if at least some of the risk is from a direct genotoxic mechanism (*see* section II.F of the Health Effects Literature Review), then this threshold value is not relevant to the risk of lung cancer. Supporting evidence comes from Steenland and Deddens (2002), who found that, for the 10-cohort pooled data set, a risk model that incorporated a threshold did fit better than a no-threshold model, but the estimated threshold was very low, 0.010 mg/m^3 (10 μg/m^3). OSHA acknowledges that a threshold exposure level might lie within the range of the proposed action level, as suggested by the work of Kuempel et al. (2001) and that this possibility adds uncertainty to the estimated risks associated with exposure to the action level. However, OSHA believes that available information cannot firmly establish a threshold exposure level for silica-related effects, and there is no empirical evidence that a threshold exists at or above the proposed PEL of 0.05 mg/m^3 for respirable crystalline silica.

VIII. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

A. Introduction and Summary

OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this proposed respirable crystalline silica rule and evaluates regulatory alternatives to the proposed 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 PEA has been placed in OSHA rulemaking docket OSHA–2010–0034. 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 PEA is to:

- Identify the establishments and industries potentially affected by the proposed rule;

- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the proposed rule in terms of reductions in cases of silicosis, lung cancer, other forms of chronic obstructive pulmonary disease, and renal failure;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the proposed rule;
- Assess the economic feasibility of the proposed rule for affected industries; and
- Assess the impact of the proposed rule on small entities through an Initial Regulatory Flexibility Analysis (IRFA), to include an evaluation of significant regulatory alternatives to the proposed rule that OSHA has considered.

The Preliminary Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Assessing the Need for Regulation
Chapter III. Profile of Affected Industries
Chapter IV. Technological Feasibility
Chapter V. Costs of Compliance
Chapter VI. Economic Impacts
Chapter VII. Benefits and Net Benefits
Chapter VIII. Regulatory Alternatives
Chapter IX. Initial Regulatory Flexibility Analysis
Chapter X. Environmental Impacts

Key findings of these chapters are summarized below and in sections VIII.B through VIII.I of this PEA summary.

Profile of Affected Industries

The proposed rule would affect employers and employees in many different industries across the economy. As described in Section VIII.C and reported in Table VIII–3 of this preamble, OSHA estimates that a total of 2.1 million employees in 550,000 establishments and 533,000 firms (entities) are potentially at risk from exposure to respirable crystalline silica. This total includes 1.8 million employees in 477,000 establishments and 486,000 firms in the construction industry and 295,000 employees in 56,000 establishments and 47,000 firms in general industry and maritime.

Technological Feasibility

As described in more detail in Section VIII.D of this preamble and in Chapter IV of the PEA, OSHA assessed, for all affected sectors, the current exposures and the technological feasibility of the proposed PEL of 50 μg/m³ and, for analytic purposes, an alternative PEL of 25 μg/m³.

Tables VIII–6 and VIII–7 in section VIII.D of this preamble summarize all the industry sectors and construction activities studied in the technological feasibility analysis and show how many operations within each can achieve levels of 50 μg/m³ through the implementation of engineering and work practice controls. The table also summarizes the overall feasibility finding for each industry sector or construction activity based on the number of feasible versus infeasible operations. For the general industry sector, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For the construction activities, OSHA has determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls (seven out of 108 operations, *see* Tables VIII–6 and VIII–7), employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

Based on the information presented in the technological feasibility analysis, the Agency believes that 50 μg/m³ is the lowest feasible PEL. An alternative PEL of 25 μg/m³ would not be feasible because the engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to levels below 25 μg/m³ in most operations most of the time. OSHA believes that an alternative PEL of 25 μg/m³ would not be feasible for many industries, and that the use of respiratory protection would be necessary in most operations most of the time to achieve compliance. Additionally, the current methods of sampling analysis create higher errors and lower precision in measurement as concentrations of silica lower than the proposed PEL are analyzed. However, the Agency preliminarily concludes that these sampling and analytical methods are adequate to permit employers to comply with all applicable requirements triggered by the proposed action level and PEL.

Costs of Compliance

As described in more detail in Section VIII.E and reported by industry in Table VIII–8 of this preamble, the total annualized cost of compliance with the proposed standard is estimated to be about $658 million. The major cost elements associated with the revisions to the standard are costs for engineering controls, including controls for abrasive blasting ($344 million); medical surveillance ($79 million); exposure monitoring ($74 million); respiratory protection ($91 million); training ($50 million) and regulated areas or access control ($19 million). Of the total cost, $511 million would be borne by firms in the construction industry and $147 million would be borne by firms in general industry and maritime.

The compliance costs are expressed as annualized costs in order to evaluate economic impacts against annual revenue and annual profits, to be able to compare the economic impact of the rulemaking with other OSHA regulatory actions, and to be able to add and track Federal regulatory compliance costs and economic impacts in a consistent manner. Annualized costs also represent a better measure for assessing the longer-term potential impacts of the rulemaking. The annualized costs were calculated by annualizing the one-time costs over a period of 10 years and applying discount rates of 7 and 3 percent as appropriate.

The estimated costs for the proposed silica standard rule include the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

OSHA's exposure profile represents the Agency's best estimate of current exposures (*i.e.,* baseline exposures). OSHA did not attempt to determine the extent to which current exposures in compliance with the current silica PELs are the result of baseline engineering controls or the result of circumstances leading to low exposures. This information is not needed to estimate the costs of (additional) engineering controls needed to comply with the proposed standard.

Because of the severe health hazards involved, the Agency expects that the estimated 15,446 abrasive blasters in the construction sector and the estimated 4,550 abrasive blasters in the maritime sector are currently wearing respirators in compliance with OSHA's abrasive blasting provisions. Furthermore, for the construction baseline, an estimated 241,269 workers, including abrasive blasters, will need to use respirators to achieve compliance with the proposed

rule, and, based on the NIOSH/BLS respirator use survey (NIOSH/BLS, 2003), an estimated 56 percent of construction employers currently require such respiratory use and have respirator programs that meet OSHA's respirator standard. OSHA has not taken any costs for employers and their workers currently in compliance with the respiratory provisions in the proposed rule.

In addition, under both the general industry and construction baselines, an estimated 50 percent of employers have pre-existing training programs that address silica-related risks (as required under OSHA's hazard communication standard) and partially satisfy the proposed rule's training requirements (for costing purposes, estimated to satisfy 50 percent of the training requirements in the proposed rule). These employers will need fewer resources to achieve full compliance with the proposed rule than those employers without pre-existing training programs that address silica-related risks.

Other than respiratory protection and worker training concerning silica-related risks, OSHA did not assume baseline compliance with any ancillary provisions, even though some employers have reported that they do currently monitor silica exposure and some employers have reported conducting medical surveillance.

Economic Impacts

To assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the new requirements on entities in each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide an assessment of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts.

As described in greater detail in Section VIII.F of this preamble, the costs of compliance with the proposed rulemaking are not large in relation to the corresponding annual financial flows associated with each of the affected industry sectors. The estimated annualized costs of compliance represent about 0.02 percent of annual revenues and about 0.5 percent of annual profits, on average, across all firms in general industry and maritime, and about 0.05 percent of annual revenues and about 1.0 percent of annual profits, on average, across all firms in construction. Compliance costs do not represent more than 0.39 percent of revenues or more than 8.8 percent of profits in any affected industry in general industry or maritime, or more than 0.13 percent of revenues or more than 3 percent of profits in any affected industry in construction.

Based on its analysis of international trade effects, OSHA concluded that most or all costs arising from this proposed silica rule would be passed on in higher prices rather than absorbed in lost profits and that any price increases would result in minimal loss of business to foreign competition.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has preliminarily concluded that compliance with the requirements of the proposed rulemaking would be economically feasible in every affected industry sector.

In addition, OSHA directed Inforum—a not-for-profit corporation with over 40 years of experience in the design and application of macroeconomic models—to run its LIFT (Long-term Interindustry Forecasting Tool) model of the U.S. economy to estimate the industry and aggregate employment effects of the proposed silica rule. Inforum developed estimates of the employment impacts over the ten-year period from 2014–2023 by feeding OSHA's year-by-year and industry-by-industry estimates of the compliance costs of the proposed rule into its LIFT model. The most important Inforum result is that the proposed silica rule would have a negligible—albeit slightly positive—net effect on aggregate U.S. employment.

Based on its analysis of the costs and economic impacts associated with this rulemaking and on Inforum's estimates of associated employment and other macroeconomic impacts, OSHA preliminarily concludes that the effect of the proposed standard on employment, wages, and economic growth for the United States would be negligible.

Benefits, Net Benefits, and Cost-Effectiveness

As described in more detail in Section VIII.G of this preamble, OSHA estimated the benefits, net benefits, and incremental benefits of the proposed silica rule. That section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and benefit parameters. A full explanation of the derivation of the estimates presented there is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of its estimation of the benefits and net benefits of the proposed rule.

OSHA estimated the benefits associated with the proposed PEL of 50 μg/m³ and, for analytical purposes to comply with OMB Circular A–4, with an alternative PEL of 100 μg/m³ for respirable crystalline silica by applying the dose-response relationship developed in the Agency's quantitative risk assessment—summarized in Section VI of this preamble—to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile (presented in Chapter IV of the PEA) for industries with workers exposed to respirable crystalline silica, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile is summarized in Table VIII–5 in Section VIII.C of this preamble.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given current exposure levels (the ''baseline''):

- Fatal cases of lung cancer,
- fatal cases of non-malignant respiratory disease (including silicosis),
- fatal cases of end-stage renal disease, and
- cases of silicosis morbidity.

Table VIII–1 provides a summary of OSHA's best estimate of the costs and benefits of the proposed rule using a discount rate of 3 percent. As shown, the proposed rule is estimated to prevent 688 fatalities and 1,585 silica-related illnesses annually once it is fully effective, and the estimated cost of the rule is $637 million annually. Also as shown in Table VIII–1, the discounted monetized benefits of the proposed rule are estimated to be $5.3 billion annually, and the proposed rule is estimated to generate net benefits of $4.6 billion annually. Table VIII–1 also presents the estimated costs and benefits of the proposed rule using a discount rate of 7 percent. The estimated costs and benefits of the proposed rule, disaggregated by industry sector, were previously presented in Table SI–3 in this preamble.

TABLE VIII–1—ANNUALIZED BENEFITS, COSTS AND NET BENEFITS OF OSHA'S PROPOSED SILICA STANDARD OF 50 μG/M³

Discount rate		3%	7%
Annualized Costs			
Engineering Controls (includes Abrasive Blasting)		$329,994,068	$343,818,700
Respirators		90,573,449	90,918,741
Exposure Assessment		72,504,999	74,421,757
Medical Surveillance		76,233,932	79,069,527
Training		48,779,433	50,266,744
Regulated Area or Access Control		19,243,500	19,396,743
Total Annualized Costs (point estimate)		637,329,380	657,892,211
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancers (midpoint estimate)	162		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	375		
Fatal Renal Disease	151		
Silica-Related Mortality	688	3,203,485,869	2,101,980,475
Silicosis Morbidity	1,585	1,986,214,921	1,363,727,104
Monetized Annual Benefits (midpoint estimate)		5,189,700,790	3,465,707,579
Net Benefits		4,552,371,410	2,807,815,368

Initial Regulatory Flexibility Analysis

OSHA has prepared an Initial Regulatory Flexibility Analysis (IRFA) in accordance with the requirements of the Regulatory Flexibility Act, as amended in 1996. Among the contents of the IRFA are an analysis of the potential impact of the proposed rule on small entities and a description and discussion of significant alternatives to the proposed rule that OSHA has considered. The IRFA is presented in its entirety both in Chapter IX of the PEA and in Section VIII.I of this preamble.

The remainder of this section (Section VIII) of the preamble is organized as follows:

B. The Need for Regulation
C. Profile of Affected Industry
D. Technological Feasibility
E. Costs of Compliance
F. Economic Feasibility Analysis and Regulatory Flexibility Determination
G. Benefits and Net Benefits
H. Regulatory Alternatives
I. Initial Regulatory Flexibility Analysis.

B. Need for Regulation

Employees in work environments addressed by the proposed silica 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 PEA in support of the proposed rule, the risks to employees are excessively large due to the existence of various types of market failure, and existing and alternative methods of overcoming these negative consequences—such as workers' compensation systems, tort liability options, and information dissemination programs—have been shown to provide insufficient worker protection.

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 silica exposure, the proposed mandatory standards represent the best choice for reducing the risks to employees. In addition, rulemaking is necessary in this case in order to replace older existing standards with updated, clear, and consistent health standards.

C. Profile of Affected Industries

1. Introduction

Chapter III of the PEA presents profile data for industries potentially affected by the proposed silica rule. The discussion below summarizes the findings in that chapter. As a first step, OSHA identifies the North American Industrial Classification System (NAICS) industries, both in general industry and maritime and in the construction sector, with potential worker exposure to silica. Next, OSHA provides summary statistics for the affected industries, including the number of affected entities and establishments, the number of at-risk workers, and the average revenue for affected entities and establishments. [3] Finally, OSHA presents silica exposure profiles for at-risk workers. These data are presented by sector and job category. Summary data are also provided for the number of workers in each affected industry who are currently exposed above the proposed silica PEL of 50 μg/m³, as well as above an alternative PEL of 100 μg/m³ for economic analysis purposes.

The methodological basis for the industry and at-risk worker data presented here comes from ERG (2007a, 2007b, 2008a, and 2008b). The actual data presented here comes from the technological feasibility analyses presented in Chapter IV of the PEA and from ERG (2013), which updated ERG's earlier spreadsheets to reflect the most recent industry data available. The technological feasibility analyses identified the job categories with potential worker exposure to silica. ERG (2007a, 2007b) matched the BLS Occupational Employment Survey (OES) occupational titles in NAICS industries with the at-risk job categories and then calculated the percentages of production employment represented by each at-risk job title.[4] These percentages were then used to project the number of employees in the at-risk job categories by NAICS industry. OSHA welcomes additional information and data that might help improve the accuracy and usefulness of the industry profile presented here and in Chapter III of the PEA.

2. Selection of NAICS Industries for Analysis

The technological feasibility analyses presented in Chapter IV of the PEA identify the general industry and maritime sectors and the construction activities potentially affected by the proposed silica standard.

[3] An establishment is a single physical location at which business is conducted or services or industrial operations are performed. An entity is an aggregation of all establishments owned by a parent company within an industry with some annual payroll.

[4] Production employment includes workers in building and grounds maintenance; forestry, fishing, and farming; installation and maintenance; construction; production; and material handling occupations.

a. General Industry and Maritime

Employees engaged in various activities in general industry and maritime routinely encounter crystalline silica as a molding material, as an inert mineral additive, as a refractory material, as a sandblasting abrasive, or as a natural component of the base materials with which they work. Some industries use various forms of silica for multiple purposes. As a result, employers are challenged to limit worker exposure to silica in dozens of job categories throughout the general industry and maritime sectors.

Job categories in general industry and maritime were selected for analysis based on data from the technical industrial hygiene literature, evidence from OSHA Special Emphasis Program (SEP) results, and, in several cases, information from ERG site visit reports. These data sources provided evidence of silica exposures in numerous sectors. While the available data are not entirely comprehensive, OSHA believes that silica exposures in other sectors are quite limited.

The 25 industry subsectors in the overall general industry and maritime sectors that OSHA identified as being potentially affected by the proposed silica standard are as follows:

- Asphalt Paving Products
- Asphalt Roofing Materials
- Industries with Captive Foundries
- Concrete Products
- Cut Stone
- Dental Equipment and Supplies
- Dental Laboratories
- Flat Glass
- Iron Foundries
- Jewelry
- Mineral Processing
- Mineral Wool
- Nonferrous Sand Casting Foundries
- Non-Sand Casting Foundries
- Other Ferrous Sand Casting Foundries
- Other Glass Products
- Paint and Coatings
- Porcelain Enameling
- Pottery
- Railroads
- Ready-Mix Concrete
- Refractories
- Refractory Repair
- Shipyards
- Structural Clay

In some cases, affected industries presented in the technological feasibility analysis have been disaggregated to facilitate the cost and economic impact analysis. In particular, flat glass, mineral wool, and other glass products are subsectors of the glass industry described in Chapter IV of the PEA, and captive foundries,[5] iron foundries, nonferrous sand casting foundries, non-sand cast foundries, and other ferrous sand casting foundries are subsectors of the overall foundries industry presented in Chapter IV of the PEA.

As described in ERG (2008b), OSHA identified the six-digit NAICS codes for these subsectors to develop a list of industries potentially affected by the proposed silica standard. Table VIII–2 presents the sectors listed above with their corresponding six-digit NAICS industries.

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[5] Captive foundries include establishments in other industries with foundry processes incidental to the primary products manufactured. ERG (2008b) provides a discussion of the methodological issues involved in estimating the number of captive foundries and in identifying the industries in which they are found.

Table VIII-2
General Industry and Martime Sectors and Industries Potentially Affected by OSHA's Proposed Silica Rule

Sector	NAICS	Industry
Asphalt Paving Products	324121	Asphalt paving mixture and block mfg
Asphalt Roofing Materials	324122	Asphalt shingle and roofing materials
Captive Foundries	331111	Iron & steel mills
	331112	Electrometallurgical ferroalloy product mfg
	331210	Iron & steel pipes & tubes mfg from purchased steel
	331221	Cold-rolled steel shape mfg
	331222	Steel wire drawing
	331314	Secondary smelting & alloying of aluminum
	331423	Secondary smelting, refining, & alloying of copper
	331492	Other nonferrous metal secondary smelting, refining, & alloying
	332111	Iron & steel forging
	332112	Nonferrous forging
	332115	Crown & closure mfg
	332116	Metal stamping
	332117	Powder metallurgy part mfg
	332211	Cutlery & flatware (except precious) mfg
	332212	Hand & edge tool mfg
	332213	Saw blade & handsaw mfg
	332214	Kitchen utensil, pot, & pan mfg
	332439	Other metal container mfg
	332510	Hardware mfg
	332611	Spring (heavy gauge) mfg
	332612	Spring (light gauge) mfg
	332618	Other fabricated wire product mfg
	332710	Machine shops
	332911	Industrial valve mfg
	332912	Fluid power valve & hose fitting mfg
	332913	Plumbing fixture fitting & trim mfg
	332919	Other metal valve & pipe fitting mfg
	332991	Ball & roller bearing mfg
	332996	Fabricated pipe & pipe fitting mfg
	332997	Industrial pattern mfg
	332998	Enameled iron & metal sanitary ware mfg
	332999	All other miscellaneous fabricated metal product mfg
	333319	Other commercial & service industry machinery mfg
	333411	Air purification equipment mfg
	333412	Industrial & commercial fan & blower mfg
	333414	Heating equipment (except warm air furnaces) mfg
	333511	Industrial mold mfg
	333512	Machine tool (metal cutting types) mfg
	333513	Machine tool (metal forming types) mfg
	333514	Special die & tool, die set, jig, & fixture mfg
	333515	Cutting tool & machine tool accessory mfg
	333516	Rolling mill machinery & equipment mfg
	333518	Other metalworking machinery mfg
	333612	Speed changer, industrial high-speed drive, & gear mfg
	333613	Mechanical power transmission equipment mfg
	333911	Pump & pumping equipment mfg
	333912	Air & gas compressor mfg
	333991	Power-driven handtool mfg
	333992	Welding & soldering equipment mfg
	333993	Packaging machinery mfg
	333994	Industrial process furnace & oven mfg
	333995	Fluid power cylinder & actuator mfg
	333996	Fluid power pump & motor mfg
	333997	Scale & balance (except laboratory) mfg
	333999	All other miscellaneous general-purpose machinery mfg
	334518	Watch, clock, & part mfg
	336111	Automobile mfg
	336112	Light truck & utility vehicle mfg
	336120	Heavy duty truck mfg
	336211	Motor vehicle body mfg
	336212	Truck trailer mfg

Table VIII-2
General Industry and Martime Sectors and Industries Potentially Affected by OSHA's Proposed Silica Rule (Continued)

Sector	NAICS	Industry
	336213	Motor home mfg
	336311	Carburetor, piston, piston ring, & valve mfg
	336312	Gasoline engine & engine parts mfg
	336322	Other motor vehicle electrical & electronic equipment mfg
	336330	Motor vehicle steering & suspension component (except spring) mfg
	336340	Motor vehicle brake system mfg
	336350	Motor vehicle transmission & power train parts mfg
	336370	Motor vehicle metal stamping
	336399	All other motor vehicle parts mfg
	336992	Military armored vehicle, tank, & tank component mfg
	337215	Showcase, partition, shelving, & locker mfg
	339914	Costume jewelry & novelty mfg
Concrete Products	327331	Concrete block & brick mfg
	327332	Concrete pipe mfg
	327390	Other concrete product mfg
	327999	All other miscellaneous nonmetallic mineral product mfg
Cut Stone	327991	Cut stone & stone product mfg
Dental Equipment and Supplies	339114	Dental equipment and supplies, manufacturing
Dental Laboratories	339116	Dental laboratories
	621210	Offices of dentists
Flat Glass	327211	Flat glass mfg
Iron Foundries	331511	Iron foundries
Jewelry	339911	Jewelry (except costume) mfg
	339913	Jewelers' material & lapidary work mfg
	339914	Costume jewelry & novelty mfg
Mineral Processing	327992	Ground or treated mineral and earth manufacturing
Mineral Wool	327993	Mineral wool mfg
Nonferrous Sand Casting Foundries	331524	Aluminum foundries (except die-casting)
	331525	Copper foundries (except die-casting)
	331528	Other nonferrous foundries (except die-casting)
Non-Sand Casting Foundries	331512	Steel investment foundries
	331524	Aluminum foundries (except die-casting)
	331525	Copper foundries (except die-casting)
	331528	Other nonferrous foundries (except die-casting)
Other Ferrous Sand Casting Foundries	331513	Steel foundries (except investment)
Other Glass Products	327212	Other pressed & blown glass & glassware mfg
	327213	Glass container mfg
Paint and Coatings	325510	Paint & coating mfg [e]
Porcelain Enameling	332812	Metal coating and allied services
	332998	Enameled iron & metal sanitary ware mfg
	335211	Electric housewares and household fans
	335221	Household cooking appliance manufactruing
	335222	Household refrigerator and home freezer manufacturing
	332323	Ornamental and architectural metal work
	335224	Household laundry equipment manufacturing
	335228	Other major household appliance manufacturing
	339950	Sign manufacturing
Pottery	327111	Vitreous china plumbing fixture & bathroom accessories mfg
	327112	Vitreous china, fine earthenware, & other pottery product mfg
	327113	Porcelain electrical supply mfg
Railraods	482110	Rail transportation
Ready-Mix Concrete	327320	Ready-mix concrete mfg
Refractories	327124	Clay refractory mfg
	327125	Nonclay refractory mfg
Refractory Repair	423840	Industrial supplies - wholesale
Shipyards	336611	Ship building & repairing
	336612	Boat building
Structural Clay	327121	Brick & structural clay tile mfg
	327122	Ceramic wall & floor tile mfg
	327123	Other structural clay product mfg

Source: ERG, 2013

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b. Construction

The construction sector is an integral part of the nation's economy, accounting for almost 6 percent of total employment. Establishments in this industry are involved in a wide variety of activities, including land development and subdivision, homebuilding, construction of nonresidential buildings and other structures, heavy construction work (including roadways and bridges), and a myriad of special trades such as plumbing, roofing, electrical, excavation, and demolition work.

Construction activities were selected for analysis based on historical data of recorded samples of construction worker exposures from the OSHA Integrated Management Information System (IMIS) and the National Institute for Occupational Safety and Health (NIOSH). In addition, OSHA reviewed the industrial hygiene literature across the full range of construction activities, and focused on dusty operations where silica sand was most likely to be fractured or abraded by work operations. These physical processes have been found to cause the silica exposures that pose the greatest risk of silicosis for workers.

The 12 construction activities, by job category, that OSHA identified as being potentially affected by the proposed silica standard are as follows:

- Abrasive Blasters
- Drywall Finishers
- Heavy Equipment Operators
- Hole Drillers Using Hand-Held Drills
- Jackhammer and Impact Drillers
- Masonry Cutters Using Portable Saws
- Masonry Cutters Using Stationary Saws
- Millers Using Portable or Mobile Machines
- Rock and Concrete Drillers
- Rock-Crushing Machine Operators and Tenders
- Tuckpointers and Grinders
- Underground Construction Workers

As shown in ERG (2008a) and in Chapter IV of the PEA, these construction activities occur in the following construction industries, accompanied by their four-digit NAICS codes: [6] [7]

- 2361 Residential Building Construction
- 2362 Nonresidential Building Construction
- 2371 Utility System Construction
- 2372 Land Subdivision
- 2373 Highway, Street, and Bridge Construction
- 2379 Other Heavy and Civil Engineering Construction
- 2381 Foundation, Structure, and Building Exterior Contractors
- 2382 Building Equipment Contractors
- 2383 Building Finishing Contractors
- 2389 Other Specialty Trade Contractors

Characteristics of Affected Industries

Table VIII–3 provides an overview of the industries and estimated number of workers affected by the proposed rule. Included in Table VIII–3 are summary statistics for each of the affected industries, subtotals for construction and for general industry and maritime, and grand totals for all affected industries combined.

The first five columns in Table VIII–3 identify each industry in which workers are routinely exposed to respirable crystalline silica (preceded by the industry's NAICS code) and the total number of entities, establishments, and employees for that industry. Note that not all entities, establishments, and employees in these affected industries necessarily engage in activities involving silica exposure.

The next three columns in Table VIII–3 show, for each affected industry, OSHA's estimate of the number of affected entities, establishments, and workers—that is, the number of entities and establishments in which workers are actually exposed to silica and the total number of workers exposed to silica. Based on ERG (2007a, 2007b), OSHA's methodology focused on estimation of the number of affected workers. The number of affected establishments was set equal to the total number of establishments in an industry (based on Census data) unless the number of affected establishments would exceed the number of affected employees in the industry. In that case, the number of affected establishments in the industry was set equal to the number of affected employees, and the number of affected entities in the industry was reduced so as to maintain the same ratio of entities to establishments in the industry.[8]

[6] ERG and OSHA used the four-digit NAICS codes for the construction sector both because the BLS's Occupational Employment Statistics survey only provides data at this level of detail and because, unlike the case in general industry and maritime, job categories in the construction sector are task-specific, not industry-specific. Furthermore, as far as economic impacts are concerned, IRS data on profitability are reported only at the four-digit NAICS code level of detail.

[7] In addition, some public employees in state and local governments are exposed to elevated levels of respirable crystalline silica. These exposures are included in the construction sector because they are the result of construction activities.

[8] OSHA determined that removing this assumption would have a negligible impact on total costs and would reduce the cost and economic impact on the average affected establishment or entity.

TABLE VIII–3—CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR SILICA—ALL ENTITIES

NAICS	Industry	Total entities [a]	Total establishments [a]	Total employment [a]	Total affected entities [b]	Total affected establishments [b]	Total affected employment [b]	Total FTE affected employees [b]	Total revenues ($1,000) [c]	Revenues per entity	Revenues per establishment
	Construction										
236100	Residential Building Construction	197,600	198,912	966,198	54,973	55,338	55,338	27,669	$374,724,410	$1,896,379	$1,883,870
236200	Nonresidential Building Construction	43,634	44,702	741,978	43,634	44,702	173,939	34,788	313,592,140	7,186,876	7,015,170
237100	Utility System Construction	20,236	21,232	496,628	20,236	21,232	217,070	96,181	98,129,343	4,849,246	4,621,766
237200	Land Subdivision	12,383	12,469	77,406	6,466	6,511	6,511	3,255	24,449,519	1,974,442	1,960,824
237300	Highway, Street, and Bridge Construction	11,081	11,860	325,182	11,081	11,860	204,899	66,916	96,655,241	8,722,610	8,149,683
237900	Other Heavy and Civil Engineering Construction	5,326	5,561	90,167	5,326	5,561	46,813	18,835	19,456,230	3,653,066	3,498,693
238100	Foundation, Structure, and Building Exterior Contractors	116,836	117,456	1,167,986	116,836	117,456	559,729	111,946	157,513,197	1,348,156	1,341,040
238200	Building Equipment Contractors	179,051	182,368	1,940,281	19,988	20,358	20,358	10,179	267,537,377	1,494,196	1,467,019
238300	Building Finishing Contractors	132,219	133,343	975,335	119,000	120,012	120,012	60,006	112,005,298	847,120	839,979
238900	Other Specialty Trade Contractors	73,922	74,446	557,638	73,922	74,446	274,439	137,219	84,184,953	1,138,835	1,130,819
999000	State and local governments [d]	14,397	N/A	5,762,939	14,397	NA	170,068	85,034	N/A	N/A	N/A
	Subtotals—Construction	806,685	802,349	13,101,738	485,859	477,476	1,849,175	652,029	1,548,247,709	1,954,148	1,929,644
	General Industry and Maritime										
324121	Asphalt paving mixture and block manufacturing	480	1,431	14,471	480	1,431	5,043	.....	8,909,030	18,560,480	6,225,737
324122	Asphalt shingle and roofing materials	121	224	12,631	121	224	4,395	.....	7,168,591	59,244,556	32,002,640
325510	Paint and coating manufacturing [e]	1,093	1,344	46,209	1,093	1,344	3,285	.....	24,113,682	22,061,923	17,941,728
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	31	41	5,854	31	41	2,802	.....	818,725	26,410,479	19,968,899
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	728	731	9,178	728	731	4,394	.....	827,296	1,136,395	1,131,731
327113	Porcelain electrical supply mfg	110	125	6,168	110	125	2,953	.....	951,475	8,649,776	7,611,802
327121	Brick and structural clay mfg	104	204	13,509	104	204	5,132	.....	2,195,641	21,111,931	10,762,945
327122	Ceramic wall and floor tile mfg	180	193	7,094	180	193	2,695	.....	1,217,597	6,764,429	6,308,794
327123	Other structural clay product mfg	45	49	1,603	45	49	609	.....	227,406	5,053,461	4,640,933
327124	Clay refractory manufacturing	108	129	4,475	108	129	1,646	.....	955,377	8,846,082	7,406,022
327125	Nonclay refractory manufacturing	81	105	5,640	81	105	2,075	.....	1,453,869	17,948,999	13,846,371
327211	Flat glass manufacturing	56	83	11,003	56	83	271	.....	3,421,674	61,101,328	41,224,993
327212	Other pressed and blown glass and glassware manufacturing	457	499	20,625	457	499	1,034	.....	3,395,635	7,430,274	6,804,880
327213	Glass container manufacturing	32	72	14,392	32	72	722	.....	4,365,673	136,427,289	60,634,351
327320	Ready-mixed concrete manufacturing	2,470	6,064	107,190	2,470	6,064	43,920	.....	27,904,708	11,297,453	4,601,700
327331	Concrete block and brick mfg	599	951	22,738	599	951	10,962	.....	5,127,518	8,560,131	5,391,712
327332	Concrete pipe mfg	194	385	14,077	194	385	6,787	.....	2,861,038	14,747,620	7,431,268
327390	Other concrete product mfg	1,934	2,281	66,095	1,934	2,281	31,865	.....	10,336,178	5,344,456	4,531,424
327991	Cut stone and stone product manufacturing	1,885	1,943	30,633	1,885	1,943	12,085	.....	3,507,209	1,860,588	1,805,048
327992	Ground or treated mineral and earth manufacturing	171	271	6,629	171	271	5,051	.....	2,205,910	12,900,061	8,139,891
327993	Mineral wool manufacturing	195	321	19,241	195	321	1,090	.....	5,734,226	29,406,287	17,863,633
327999	All other misc. nonmetallic mineral product mfg	350	465	10,028	350	465	4,835	.....	2,538,560	7,253,028	5,459,268
331111	Iron and steel mills	686	805	108,592	523	614	614	.....	53,496,748	77,983,597	66,455,587
331112	Electrometallurgical ferroalloy product manufacturing	22	22	2,198	12	12	12	.....	1,027,769	46,716,774	46,716,774
331210	Iron and steel pipe and tube manufacturing from purchased steel.	186	240	21,543	94	122	122	.....	7,014,894	37,714,484	29,228,725
331221	Rolled steel shape manufacturing	150	170	10,857	54	61	61	.....	4,494,254	29,961,696	26,436,790
331222	Steel wire drawing	232	288	14,669	67	83	83	.....	3,496,143	15,069,584	12,139,387
331314	Secondary smelting and alloying of aluminum	119	150	7,381	33	42	42	.....	4,139,263	34,783,724	27,595,088
331423	Secondary smelting, refining, and alloying of copper	29	31	1,278	7	7	7	.....	765,196	26,386,082	24,683,755
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	195	217	9,383	48	53	53	.....	3,012,985	15,451,203	13,884,721
331511	Iron foundries	457	527	59,209	457	527	22,111	.....	9,753,093	21,341,560	18,506,818
331512	Steel investment foundries	115	132	16,429	115	132	5,934	.....	2,290,472	19,917,147	17,352,060
331513	Steel foundries (except investment)	208	222	17,722	208	222	6,618	.....	3,640,441	17,502,121	16,398,383
331524	Aluminum foundries (except die-casting)	441	466	26,565	441	466	9,633	.....	3,614,233	8,195,541	7,755,866
331525	Copper foundries (except die-casting)	251	256	6,120	251	256	2,219	.....	747,437	2,977,835	2,919,674
331528	Other nonferrous foundries (except die-casting)	119	124	4,710	119	124	1,708	.....	821,327	6,901,910	6,623,607
332111	Iron and steel forging	358	398	26,596	135	150	150	.....	5,702,872	15,929,811	14,328,825
332112	Nonferrous forging	67	77	8,814	43	50	50	.....	2,080,000	31,044,783	27,012,993
332115	Crown and closure manufacturing	50	59	3,243	15	18	18	.....	905,206	18,104,119	15,342,473
332116	Metal stamping	1,556	1,641	64,724	347	366	366	.....	10,418,233	6,695,523	6,348,710
332117	Powder metallurgy part manufacturing	111	129	8,362	41	47	47	.....	1,178,698	10,618,900	9,137,193
332211	Cutlery and flatware (except precious) manufacturing	138	141	5,779	32	33	33	.....	1,198,675	8,686,049	8,501,240
332212	Hand and edge tool manufacturing	1,056	1,155	36,622	189	207	207	.....	6,382,593	6,044,123	5,526,055
332213	Saw blade and handsaw manufacturing	127	136	7,304	39	41	41	.....	1,450,781	11,423,474	10,667,509
332214	Kitchen utensil, pot, and pan manufacturing	64	70	3,928	20	22	22	.....	1,226,230	19,159,850	17,517,577
332323	Ornamental and architectural metal work	2,408	2,450	39,947	53	54	54	.....	6,402,565	2,658,873	2,613,292
332439	Other metal container manufacturing	364	401	15,195	78	86	86	.....	2,817,120	7,739,340	7,025,236

332510	Hardware manufacturing	734	828	45,282	227	256	256		9,268,800	12,627,793	11,194,203
332611	Spring (heavy gauge) manufacturing	109	113	4,059	22	23	23		825,444	7,572,882	7,304,815
332612	Spring (light gauge) manufacturing	270	340	15,336	69	87	87		2,618,283	9,697,344	7,700,832
332618	Other fabricated wire product manufacturing	1,103	1,198	36,364	189	205	205		5,770,701	5,231,823	4,816,946
332710	Machine shops	21,135	21,356	266,597	1,490	1,506	1,506		32,643,382	1,544,518	1,528,534
332812	Metal coating and allied services	2,363	2,599	56,978	2,363	2,599	4,695		11,010,624	4,659,595	4,236,485
332911	Industrial valve manufacturing	394	488	38,330	175	216	216		8,446,768	21,438,497	17,308,951
332912	Fluid power valve and hose fitting manufacturing	306	381	35,519	161	201	201		8,044,008	26,287,608	21,112,882
332913	Plumbing fixture fitting and trim manufacturing	126	144	11,513	57	65	65		3,276,413	26,003,281	22,752,871
332919	Other metal valve and pipe fitting manufacturing	240	268	18,112	91	102	102		3,787,626	15,781,773	14,132,931
332991	Ball and roller bearing manufacturing	107	180	27,197	91	154	154		6,198,871	57,933,374	34,438,172
332996	Fabricated pipe and pipe fitting manufacturing	711	765	27,201	143	154	154		4,879,023	6,862,198	6,377,808
332997	Industrial pattern manufacturing	459	461	5,281	30	30	30		486,947	1,060,887	1,056,285
332998	Enameled iron and metal sanitary ware manufacturing	72	76	5,655	72	76	96		1,036,508	14,395,940	13,638,259
332999	All other miscellaneous fabricated metal product manufacturing.	3,043	3,123	72,201	397	408	408		12,944,345	4,253,811	4,144,843
333319	Other commercial and service industry machinery manufacturing.	1,253	1,349	53,012	278	299	299		12,744,730	10,171,373	9,447,539
333411	Air purification equipment manufacturing	303	351	14,883	72	84	84		2,428,159	8,013,727	6,917,833
333412	Industrial and commercial fan and blower manufacturing	142	163	10,506	52	59	59		1,962,040	13,817,181	12,037,053
333414	Heating equipment (except warm air furnaces) manufacturing	377	407	20,577	108	116	116		4,266,536	11,317,071	10,482,888
333511	Industrial mold manufacturing	2,084	2,126	39,917	221	226	226		4,963,915	2,381,917	2,334,861
333512	Machine tool (metal cutting types) manufacturing	514	530	17,220	94	97	97		3,675,264	7,150,320	6,934,461
333513	Machine tool (metal forming types) manufacturing	274	285	8,556	46	48	48		1,398,993	5,105,812	4,908,746
333514	Special die and tool, die set, jig, and fixture manufacturing	3,172	3,232	57,576	319	325	325		7,232,706	2,280,172	2,237,842
333515	Cutting tool and machine tool accessory manufacturing	1,482	1,552	34,922	188	197	197		4,941,932	3,334,637	3,184,235
333516	Rolling mill machinery and equipment manufacturing	70	73	3,020	17	17	17		652,141	9,316,299	8,933,437
333518	Other metalworking machinery manufacturing	362	383	12,470	67	70	70		2,605,582	7,197,740	6,803,086
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	197	226	12,374	61	70	70		2,280,825	11,577,790	10,092,145
333613	Mechanical power transmission equipment manufacturing	196	231	15,645	75	88	88		3,256,010	16,612,294	14,095,280
333911	Pump and pumping equipment manufacturing	413	490	30,764	147	174	174		7,872,517	19,061,785	16,066,362
333912	Air and gas compressor manufacturing	272	318	21,417	104	121	121		6,305,944	23,183,616	19,830,011
333991	Power-driven handtool manufacturing	137	150	8,714	45	49	49		3,115,514	22,740,979	20,770,094
333992	Welding and soldering equipment manufacturing	250	275	15,853	82	90	90		4,257,678	17,030,713	15,482,466
333993	Packaging machinery manufacturing	583	619	21,179	113	120	120		4,294,579	7,366,345	6,937,931
333994	Industrial process furnace and oven manufacturing	312	335	10,720	56	61	61		1,759,938	5,640,828	5,253,548
333995	Fluid power cylinder and actuator manufacturing	269	319	19,887	95	112	112		3,991,832	14,839,523	12,513,579
333996	Fluid power pump and motor manufacturing	146	178	13,631	63	77	77		3,019,188	20,679,367	16,961,728
333997	Scale and balance (except laboratory) manufacturing	95	102	3,748	20	21	21		694,419	7,309,671	6,808,027
333999	All other miscellaneous general purpose machinery manufacturing.	1,630	1,725	52,454	280	296	296		9,791,511	6,007,062	5,676,238
334518	Watch, clock, and part manufacturing	104	106	2,188	12	12	12		491,114	4,722,250	4,633,151
335211	Electric housewares and household fans	99	105	7,425	20	22	22		2,175,398	21,973,717	20,718,076
335221	Household cooking appliance manufacturing	116	125	16,033	43	47	47		4,461,008	38,456,968	35,688,066
335222	Household refrigerator and home freezer manufacturing	18	26	17,121	18	26	50		4,601,594	255,644,105	176,984,380
335224	Household laundry equipment manufacturing	17	23	16,269	17	23	47		4,792,444	281,908,445	208,367,112
335228	Other major household appliance manufacturing	39	45	12,806	32	37	37		4,549,859	116,663,058	101,107,984
336111	Automobile manufacturing	167	181	75,225	167	181	425		87,308,106	522,803,033	482,365,229
336112	Light truck and utility vehicle manufacturing	63	94	103,815	63	94	587		139,827,543	2,219,484,812	1,487,527,055
336120	Heavy duty truck manufacturing	77	95	32,122	77	95	181		17,387,065	225,806,042	183,021,739
336211	Motor vehicle body manufacturing	728	820	47,566	239	269	269		11,581,029	15,908,007	14,123,206
336212	Truck trailer manufacturing	353	394	32,260	163	182	182		6,313,133	17,884,229	16,023,179
336213	Motor home manufacturing	79	91	21,533	79	91	122		5,600,569	70,893,283	61,544,718
336311	Carburetor, piston, piston ring, and valve manufacturing	102	116	10,537	52	60	60		2,327,226	22,815,945	20,062,296
336312	Gasoline engine and engine parts manufacturing	810	876	66,112	345	373	373		30,440,351	37,580,680	34,749,259
336322	Other motor vehicle electrical and electronic equipment manufacturing.	643	697	62,016	323	350	350		22,222,133	34,560,082	31,882,544
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	214	257	39,390	185	223	223		10,244,934	47,873,524	39,863,557
336340	Motor vehicle brake system manufacturing	188	241	33,782	149	191	191		11,675,801	62,105,323	48,447,306
336350	Motor vehicle transmission and power train parts manufacturing.	432	535	83,756	382	473	473		31,710,273	73,403,409	59,271,538
336370	Motor vehicle metal stamping	635	781	110,578	508	624	624		24,461,822	38,522,554	31,321,154
336399	All other motor vehicle parts manufacturing	1,189	1,458	149,251	687	843	843		42,936,991	36,111,851	29,449,239
336611	Ship building and repair	575	635	87,352	575	635	2,798		14,650,189	25,478,589	23,071,163
336612	Boat building	1,066	1,129	54,705	1,066	1,129	1,752		10,062,908	9,439,876	8,913,116
336992	Military armored vehicle, tank, and tank component manufacturing.	47	57	6,899	32	39	39		2,406,966	51,212,047	42,227,477
337215	Showcase, partition, shelving, and locker manufacturing	1,647	1,733	59,080	317	334	334		8,059,533	4,893,462	4,650,625
339114	Dental equipment and supplies manufacturing	740	763	15,550	399	411	411		3,397,252	4,590,881	4,452,493
339116	Dental laboratories	7,028	7,261	47,088	7,028	7,261	33,214		3,852,293	548,135	530,546
339911	Jewelry (except costume) manufacturing	1,760	1,777	25,280	1,760	1,777	7,813		6,160,238	3,500,135	3,466,650
339913	Jewelers' materials and lapidary work manufacturing	261	264	5,199	261	264	1,607		934,387	3,580,028	3,539,346
339914	Costume jewelry and novelty manufacturing	590	590	6,775	590	590	1,088		751,192	1,273,206	1,273,206

TABLE VIII–3—CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR SILICA—ALL ENTITIES—Continued

NAICS	Industry	Total entities [a]	Total establishments [a]	Total employment [a]	Total affected entities [b]	Total affected establishments [b]	Total affected employment [b]	Total FTE affected employees [b]	Total revenues ($1,000) [c]	Revenues per entity	Revenues per establishment
339950	Sign manufacturing	6,291	6,415	89,360	487	496	496	.....	11,299,429	1,796,126	1,761,407
423840	Industrial supplies, wholesalers	7,016	10,742	111,198	250	383	383	.....	19,335,522	2,755,918	1,799,993
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	16,895	.....	N/A	N/A	N/A
621210	Dental offices	119,471	124,553	817,396	7,655	7,980	7,980	.....	88,473,742	740,546	710,330
	Subtotals—General Industry and maritime	219,203	238,942	4,406,990	47,007	56,121	294,886	.....	1,101,555,989	5,025,278	4,610,140
	Totals—All Industries	1,025,888	1,041,291	17,508,728	532,866	533,597	2,144,061	652,029	$2,649,803,698	$2,619,701	$2,544,729

a U.S. Census Bureau, Statistics of U.S. Businesses, 2006.
[b] OSHA estimates of employees potentially exposed to silica and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees.
[c] Estimates based on 2002 receipts and payroll data from U.S. Census Bureau, Statistics of U.S. Businesses, 2002, and payroll data from the U.S. Census Bureau, Statistics of U.S. Businesses, 2006. Receipts are not reported for 2006, but were estimated assuming the ratio of receipts to payroll remained unchanged from 2002 to 2006.
[d] State-plan states only. State and local governments are included under the construction sector because the silica risks for public employees are the result of construction-related activities.
[e] OSHA estimates that only one-third of the entities and establishments in this industry, as reported above, use silica-containing inputs.
Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG, 2013.

As shown in Table VIII–3, OSHA estimates that a total of 533,000 entities (486,000 in construction; 47,000 in general industry and maritime), 534,000 establishments (477,500 in construction; 56,100 in general industry and maritime), and 2.1 million workers (1.8 million in construction; 0.3 million in general industry and maritime) would be affected by the proposed silica rule. Note that only slightly more than 50 percent of the entities and establishments, and about 12 percent of the workers in affected industries, actually engage in activities involving silica exposure.[9]

The ninth column in Table VIII–3, with data only for construction, shows for each affected NAICS construction industry the number of full-time-equivalent (FTE) affected workers that corresponds to the total number of affected construction workers in the previous column.[10] This distinction is necessary because affected construction workers may spend large amounts of time working on tasks with no risk of silica exposure. As shown in Table VIII–3, the 1.8 million affected workers in construction converts to approximately 652,000 FTE affected workers. In contrast, OSHA based its analysis of the affected workers in general industry and maritime on the assumption that they were engaged full time in activities with some silica exposure.

[9] It should be emphasized that these percentages vary significantly depending on the industry sector and, within an industry sector, depending on the NAICS industry. For example, about 14 percent of the workers in construction, but only 7 percent of workers in general industry, actually engage in activities involving silica exposure. As an example within construction, about 63 percent of workers in highway, street, and bridge construction, but only 3 percent of workers in state and local governments, actually engage in activities involving silica exposure.

[10] FTE affected workers becomes a relevant variable in the estimation of control costs in the construction industry. The reason is that, consistent with the costing methodology, control costs depend only on how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. For the derivation of FTEs, see Tables IV–8 and IV–22 and the associated text in ERG (2007a).

The last three columns in Table VIII–3 show combined total revenues for all entities (not just affected entities) in each affected industry, and the average revenue per entity and per establishment in each affected industry. Because OSHA did not have data to distinguish revenues for affected entities and establishments in any industry, average revenue per entity and average revenue per affected entity (as well as average revenue per establishment and average revenue per affected establishment) are estimated to be equal in value.

Silica Exposure Profile of At-Risk Workers

The technological feasibility analyses presented in Chapter IV of the PEA contain data and discussion of worker exposures to silica throughout industry. Exposure profiles, by job category, were developed from individual exposure measurements that were judged to be substantive and to contain sufficient accompanying description to allow interpretation of the circumstance of each measurement. The resulting exposure profiles show the job categories with current overexposures to silica and, thus, the workers for whom silica controls would be implemented under the proposed rule.

Chapter IV of the PEA includes a section with a detailed description of the methods used to develop the exposure profile and to assess the technological feasibility of the proposed standard. That section documents how OSHA selected and used the data to establish the exposure profiles for each operation in the affected industry sectors, and discusses sources of uncertainly including the following:

- Data Selection—OSHA discusses how exposure samples with sample durations of less than 480 minutes (an 8-hour shift) are used in the analysis.
- Use of IMIS data—OSHA discusses the limitations of data from its Integrated Management Information System.
- Use of analogous information—OSHA discusses how information from one industry or operation is used to describe exposures in other industries or operations with similar characteristics.
- Non-Detects—OSHA discusses how exposure data that is identified as ''less than the LOD (limit of detection)'' is used in the analysis.

OSHA seeks comment on the assumptions and data selection criteria the Agency used to develop the exposure profiles shown in Chapter IV of the PEA.

Table VIII–4 summarizes, from the exposure profiles, the total number of workers at risk from silica exposure at any level, and the distribution of 8-hour TWA respirable crystalline silica exposures by job category for general industry and maritime sectors and for construction activities. Exposures are grouped into the following ranges: less than 25 $\mu g/m^3$; $\geq$ 25 $\mu g/m^3$ and $\leq$ 50 $\mu g/m^3$; > 50 $\mu g/m^3$ and $\leq$ 100 $\mu g/m^3$; > 100 $\mu g/m^3$ and $\leq$ 250 $\mu g/m^3$; and greater than 250 $\mu g/m^3$. These frequencies represent the percentages of production employees in each job category and sector currently exposed at levels within the indicated range.

Table VIII–5 presents data by NAICS code—for each affected general, maritime, and construction industry—on the estimated number of workers currently at risk from silica exposure, as well as the estimated number of workers at risk of silica exposure at or above 25 $\mu g/m^3$, above 50 $\mu g/m^3$, and above 100 $\mu g/m^3$. As shown, an estimated 1,026,000 workers (851,000 in construction; 176,000 in general industry and maritime) currently have silica exposures at or above the proposed action level of 25 $\mu g/m^3$; an estimated 770,000 workers (648,000 in construction; 122,000 in general industry and maritime) currently have silica exposures above the proposed PEL of 50 $\mu g/m^3$; and an estimated 501,000 workers (420,000 in construction; 81,000 in general industry and maritime) currently have silica exposures above 100 $\mu g/m^3$—an alternative PEL investigated by OSHA for economic analysis purposes.

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Table VIII-4
Distribution of Silica Exposures by Sector and Job Category or Activity

Sector	Job Category/Activity	Silica Exposure Range <25 µg/m³	25-50 µg/m³	50-100 µg/m³	100-250 µg/m³	>250 µg/m³	Total
Construction							
	Abrasive Blasters	18.6%	11.9%	16.9%	20.3%	32.2%	100.0%
	Drywall Finishers	86.7%	6.7%	6.7%	0.0%	0.0%	100.0%
	Heavy Equipment Operators	79.2%	8.3%	8.3%	4.2%	0.0%	100.0%
	Hole Drillers Using Hand-Held Drills	14.3%	28.6%	35.7%	14.3%	7.1%	100.0%
	Jackhammer and Impact Drillers	18.3%	8.3%	15.6%	24.8%	33.0%	100.0%
	Masonry Cutters Using Portable Saws	24.2%	9.9%	12.1%	38.5%	15.4%	100.0%
	Masonry Cutters Using Stationary Saws	21.4%	25.0%	25.0%	3.6%	25.0%	100.0%
	Millers Using Portable or Mobile Machines	54.3%	20.0%	20.0%	2.9%	2.9%	100.0%
	Rock and Concrete Drillers	35.9%	17.9%	17.9%	17.9%	10.3%	100.0%
	Rock-Crushing Machine Operators and Tenders	0.0%	0.0%	0.0%	20.0%	80.0%	100.0%
	Tuckpointers and Grinders	10.0%	8.5%	11.9%	18.4%	51.2%	100.0%
	Underground Construction Workers	59.3%	18.5%	11.1%	7.4%	3.7%	100.0%
General Industry/Maritime							
Asphalt Paving Products	Front-end loader operator	50.0%	0.0%	50.0%	0.0%	0.0%	100.0%
	Maintenance worker	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Plant operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Asphalt Roofing Materials	Material handler	0.0%	28.6%	42.9%	28.6%	0.0%	100.0%
	Production operator	0.0%	60.0%	20.0%	20.0%	0.0%	100.0%
Captive Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Concrete Products	Abrasive blasting operator	13.3%	6.7%	20.0%	26.7%	33.3%	100.0%
	Finishing operator	45.9%	16.2%	10.8%	16.2%	10.8%	100.0%
	Forming Line operator	83.3%	7.1%	7.1%	2.4%	0.0%	100.0%
	Material handler	41.9%	22.6%	19.4%	9.7%	6.5%	100.0%
	Mixer Operator	46.2%	15.4%	0.0%	30.8%	7.7%	100.0%
	Packaging operator	33.3%	0.0%	33.3%	16.7%	16.7%	100.0%
Cut Stone	Abrasive blasting ops	14.3%	28.6%	14.3%	14.3%	28.6%	100.0%
	Fabricator	16.7%	33.3%	8.3%	25.0%	16.7%	100.0%
	Machine operator	11.8%	17.6%	23.5%	35.3%	11.8%	100.0%
	Sawyer	17.4%	26.1%	39.1%	17.4%	0.0%	100.0%
	Splitter/chipper	17.2%	13.8%	20.7%	48.3%	0.0%	100.0%
Dental Equipment	Production operator	33.3%	0.0%	33.3%	33.3%	0.0%	100.0%
Dental Laboratories	Dental technician	83.9%	12.9%	3.2%	0.0%	0.0%	100.0%
Flat Glass	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Iron Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Jewelry	Jewelry workers	37.5%	18.8%	12.5%	18.8%	12.5%	100.0%
Mineral Processing	Production worker	0.0%	82.4%	11.8%	5.9%	0.0%	100.0%
Mineral Wool	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Nonferrous Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%

Table VIII-4
Distribution of Silica Exposures by Sector and Job Category or Activity
(Continued)

Sector	Job Category/Activity	Silica Exposure Range					Total
		<25 µg/m³	25-50 µg/m³	50-100 µg/m³	100-250 µg/m³	>250 µg/m³	
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Non-Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Other Ferrous Sand Casting Foundries	Abrasive blasting operator	6.6%	24.6%	27.9%	27.9%	13.1%	100.0%
	Cleaning/Finishing operator	15.5%	21.6%	19.2%	21.1%	22.5%	100.0%
	Coremaker	25.5%	32.1%	29.2%	9.4%	3.8%	100.0%
	Furnace operator	37.5%	25.0%	0.0%	12.5%	25.0%	100.0%
	Housekeeping worker	14.3%	14.3%	42.9%	14.3%	14.3%	100.0%
	Knockout operator	10.8%	35.1%	18.9%	24.3%	10.8%	100.0%
	Maintenance operator	16.7%	25.0%	25.0%	12.5%	20.8%	100.0%
	Material handler	28.1%	18.8%	31.3%	21.9%	0.0%	100.0%
	Molder	26.3%	24.3%	28.9%	19.1%	1.3%	100.0%
	Pouring operator	25.0%	25.0%	16.7%	29.2%	4.2%	100.0%
	Sand systems operator	17.2%	15.5%	25.9%	27.6%	13.8%	100.0%
	Shakeout operator	14.4%	25.8%	29.9%	17.5%	12.4%	100.0%
Other Glass Products	Batch operator	50.0%	0.0%	33.3%	0.0%	16.7%	100.0%
	Material handler	0.0%	16.7%	33.3%	33.3%	16.7%	100.0%
Paint and Coatings	Material handler	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Mixer operator	80.0%	0.0%	0.0%	0.0%	20.0%	100.0%
Porcelain Enameling	Enamel preparer	33.3%	33.3%	33.3%	0.0%	0.0%	100.0%
	Porcelain applicator	52.2%	13.0%	21.7%	0.0%	13.0%	100.0%
Pottery	Coatings operator	18.9%	10.8%	16.2%	32.4%	21.6%	100.0%
	Coatings preparer	5.3%	5.3%	31.6%	26.3%	31.6%	100.0%
	Finishing operator	15.4%	34.6%	19.2%	30.8%	0.0%	100.0%
	Forming Line operator	25.6%	40.0%	14.4%	20.0%	0.0%	100.0%
	Material handler	38.1%	19.0%	19.0%	9.5%	14.3%	100.0%
Railroads	Ballast dumper	50.0%	26.9%	7.7%	7.7%	7.7%	100.0%
	Machine operator	21.0%	38.0%	23.0%	11.0%	7.0%	100.0%
Ready mix	Batch operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Maintenance operator	60.0%	20.0%	20.0%	0.0%	0.0%	100.0%
	Material handler	75.0%	0.0%	25.0%	0.0%	0.0%	100.0%
	Quality control technician	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Truck driver	0.0%	0.0%	0.0%	0.0%	100.0%	100.0%
Refractories	Ceramic fiber furnace operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Finishing operator	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
	Forming operator	45.5%	27.3%	13.6%	13.6%	0.0%	100.0%
	Material handler	33.3%	22.2%	22.2%	18.5%	3.7%	100.0%
	Packaging operator	50.0%	41.7%	0.0%	8.3%	0.0%	100.0%
Refractory Repair	Production operator	20.0%	40.0%	20.0%	20.0%	0.0%	100.0%
Shipyards	Abrasive blasters	0.0%	28.6%	14.3%	14.3%	42.9%	100.0%
Structural Clay	Forming line operator/Coatings blender	10.0%	10.0%	50.0%	30.0%	0.0%	100.0%
	Forming line operator/Formers	27.0%	16.2%	16.2%	29.7%	10.8%	100.0%
	Forming Line operator/Pug mill operator	0.0%	14.3%	14.3%	28.6%	42.9%	100.0%
	Grinding operator	21.4%	7.1%	21.4%	28.6%	21.4%	100.0%
	Material handler/Loader operator	42.9%	0.0%	28.6%	28.6%	0.0%	100.0%
	Material handler/post-production	70.3%	16.2%	10.8%	2.7%	0.0%	100.0%
	Material handler/production	30.0%	20.0%	30.0%	15.0%	5.0%	100.0%

Source: Technological feasibility analysis in Chapter IV of the PEA.

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TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (µg/m³))

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
	Construction							
236100	Residential Building Construction	198,912	966,198	55,338	32,260	24,445	14,652	7,502
236200	Nonresidential Building Construction	44,702	741,978	173,939	83,003	63,198	39,632	20,504
237100	Utility System Construction	21,232	496,628	217,070	76,687	53,073	28,667	9,783
237200	Land Subdivision	12,469	77,406	6,511	1,745	1,172	560	186

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
237300	Highway, Street, and Bridge Construction.	11,860	325,182	204,899	58,441	39,273	19,347	7,441
237900	Other Heavy and Civil Engineering Construction.	5,561	90,167	46,813	12,904	8,655	4,221	1,369
238100	Foundation, Structure, and Building Exterior Contractors.	117,456	1,167,986	559,729	396,582	323,119	237,537	134,355
238200	Building Equipment Contractors	182,368	1,940,281	20,358	6,752	4,947	2,876	1,222
238300	Building Finishing Contractors	133,343	975,335	120,012	49,202	37,952	24,662	14,762
238900	Other Specialty Trade Contractors	74,446	557,638	274,439	87,267	60,894	32,871	13,718
999000	State and local governments [d]	NA	5,762,939	170,068	45,847	31,080	15,254	5,161
Subtotals—Construction.		802,349	13,101,738	1,849,175	850,690	647,807	420,278	216,003
	General Industry and Maritime							
324121	Asphalt paving mixture and block manufacturing.	1,431	14,471	5,043	48	48	0	0
324122	Asphalt shingle and roofing materials	224	12,631	4,395	4,395	1,963	935	0
325510	Paint and coating manufacturing	1,344	46,209	3,285	404	404	404	404
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	41	5,854	2,802	2,128	1,319	853	227
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	731	9,178	4,394	3,336	2,068	1,337	356
327113	Porcelain electrical supply mfg	125	6,168	2,953	2,242	1,390	898	239
327121	Brick and structural clay mfg	204	13,509	5,132	3,476	2,663	1,538	461
327122	Ceramic wall and floor tile mfg	193	7,094	2,695	1,826	1,398	808	242
327123	Other structural clay product mfg	49	1,603	609	412	316	182	55
327124	Clay refractory manufacturing	129	4,475	1,646	722	364	191	13
327125	Nonclay refractory manufacturing	105	5,640	2,075	910	459	241	17
327211	Flat glass manufacturing	83	11,003	271	164	154	64	45
327212	Other pressed and blown glass and glassware manufacturing.	499	20,625	1,034	631	593	248	172
327213	Glass container manufacturing	72	14,392	722	440	414	173	120
327320	Ready-mixed concrete manufacturing	6,064	107,190	43,920	32,713	32,110	29,526	29,526
327331	Concrete block and brick mfg	951	22,738	10,962	5,489	3,866	2,329	929
327332	Concrete pipe mfg	385	14,077	6,787	3,398	2,394	1,442	575
327390	Other concrete product mfg	2,281	66,095	31,865	15,957	11,239	6,769	2,700
327991	Cut stone and stone product manufacturing.	1,943	30,633	12,085	10,298	7,441	4,577	1,240
327992	Ground or treated mineral and earth manufacturing.	271	6,629	5,051	5,051	891	297	0
327993	Mineral wool manufacturing	321	19,241	1,090	675	632	268	182
327999	All other misc. nonmetallic mineral product mfg.	465	10,028	4,835	2,421	1,705	1,027	410
331111	Iron and steel mills	805	108,592	614	456	309	167	57
331112	Electrometallurgical ferroalloy product manufacturing.	22	2,198	12	9	6	3	1
331210	Iron and steel pipe and tube manufacturing from purchased steel.	240	21,543	122	90	61	33	11
331221	Rolled steel shape manufacturing	170	10,857	61	46	31	17	6
331222	Steel wire drawing	288	14,669	83	62	42	23	8
331314	Secondary smelting and alloying of aluminum.	150	7,381	42	31	21	11	4
331423	Secondary smelting, refining, and alloying of copper.	31	1,278	7	5	4	2	1
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	217	9,383	53	39	27	14	5
331511	Iron foundries	527	59,209	22,111	16,417	11,140	6,005	2,071
331512	Steel investment foundries	132	16,429	5,934	4,570	3,100	1,671	573
331513	Steel foundries (except investment)	222	17,722	6,618	4,914	3,334	1,797	620
331524	Aluminum foundries (except die-casting)	466	26,565	9,633	7,418	5,032	2,712	931
331525	Copper foundries (except die-casting)	256	6,120	2,219	1,709	1,159	625	214
331528	Other nonferrous foundries (except die-casting).	124	4,710	1,708	1,315	892	481	165
332111	Iron and steel forging	398	26,596	150	112	76	41	14
332112	Nonferrous forging	77	8,814	50	37	25	13	5
332115	Crown and closure manufacturing	59	3,243	18	14	9	5	2
332116	Metal stamping	1,641	64,724	366	272	184	99	34
332117	Powder metallurgy part manufacturing	129	8,362	47	35	24	13	4
332211	Cutlery and flatware (except precious) manufacturing.	141	5,779	33	24	16	9	3
332212	Hand and edge tool manufacturing	1,155	36,622	207	154	104	56	19
332213	Saw blade and handsaw manufacturing	136	7,304	41	31	21	11	4
332214	Kitchen utensil, pot, and pan manufacturing.	70	3,928	22	17	11	6	2

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
332323	Ornamental and architectural metal work.	2,450	39,947	54	26	19	7	7
332439	Other metal container manufacturing	401	15,195	86	64	43	23	8
332510	Hardware manufacturing	828	45,282	256	190	129	69	24
332611	Spring (heavy gauge) manufacturing	113	4,059	23	17	12	6	2
332612	Spring (light gauge) manufacturing	340	15,336	87	64	44	24	8
332618	Other fabricated wire product manufacturing.	1,198	36,364	205	153	104	56	19
332710	Machine shops	21,356	266,597	1,506	1,118	759	409	141
332812	Metal coating and allied services	2,599	56,978	4,695	2,255	1,632	606	606
332911	Industrial valve manufacturing	488	38,330	216	161	109	59	20
332912	Fluid power valve and hose fitting manufacturing.	381	35,519	201	149	101	55	19
332913	Plumbing fixture fitting and trim manufacturing.	144	11,513	65	48	33	18	6
332919	Other metal valve and pipe fitting manufacturing.	268	18,112	102	76	51	28	10
332991	Ball and roller bearing manufacturing	180	27,197	154	114	77	42	14
332996	Fabricated pipe and pipe fitting manufacturing.	765	27,201	154	114	77	42	14
332997	Industrial pattern manufacturing	461	5,281	30	22	15	8	3
332998	Enameled iron and metal sanitary ware manufacturing.	76	5,655	96	56	38	16	11
332999	All other miscellaneous fabricated metal product manufacturing.	3,123	72,201	408	303	205	111	38
333319	Other commercial and service industry machinery manufacturing.	1,349	53,012	299	222	151	81	28
333411	Air purification equipment manufacturing	351	14,883	84	62	42	23	8
333412	Industrial and commercial fan and blower manufacturing.	163	10,506	59	44	30	16	6
333414	Heating equipment (except warm air furnaces) manufacturing.	407	20,577	116	86	59	32	11
333511	Industrial mold manufacturing	2,126	39,917	226	168	114	61	21
333512	Machine tool (metal cutting types) manufacturing.	530	17,220	97	72	49	26	9
333513	Machine tool (metal forming types) manufacturing.	285	8,556	48	36	24	13	5
333514	Special die and tool, die set, jig, and fixture manufacturing.	3,232	57,576	325	241	164	88	30
333515	Cutting tool and machine tool accessory manufacturing.	1,552	34,922	197	146	99	54	18
333516	Rolling mill machinery and equipment manufacturing.	73	3,020	17	13	9	5	2
333518	Other metalworking machinery manufacturing.	383	12,470	70	52	35	19	7
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	226	12,374	70	52	35	19	7
333613	Mechanical power transmission equipment manufacturing.	231	15,645	88	66	44	24	8
333911	Pump and pumping equipment manufacturing.	490	30,764	174	129	88	47	16
333912	Air and gas compressor manufacturing	318	21,417	121	90	61	33	11
333991	Power-driven handtool manufacturing	150	8,714	49	37	25	13	5
333992	Welding and soldering equipment manufacturing.	275	15,853	90	67	45	24	8
333993	Packaging machinery manufacturing	619	21,179	120	89	60	32	11
333994	Industrial process furnace and oven manufacturing.	335	10,720	61	45	31	16	6
333995	Fluid power cylinder and actuator manufacturing.	319	19,887	112	83	57	31	11
333996	Fluid power pump and motor manufacturing.	178	13,631	77	57	39	21	7
333997	Scale and balance (except laboratory) manufacturing.	102	3,748	21	16	11	6	2
333999	All other miscellaneous general purpose machinery manufacturing.	1,725	52,454	296	220	149	80	28
334518	Watch, clock, and part manufacturing	106	2,188	12	9	6	3	1
335211	Electric housewares and household fans.	105	7,425	22	10	8	3	3
335221	Household cooking appliance manufacturing.	125	16,033	47	22	16	6	6
335222	Household refrigerator and home freezer manufacturing.	26	17,121	50	24	17	7	7
335224	Household laundry equipment manufacturing.	23	16,269	47	23	17	6	6
335228	Other major household appliance manufacturing.	45	12,806	37	18	13	5	5
336111	Automobile manufacturing	181	75,225	425	316	214	115	40

TABLE VIII–5—NUMBERS OF WORKERS EXPOSED TO SILICA (BY AFFECTED INDUSTRY AND EXPOSURE LEVEL (μg/m³))—Continued

NAICS	Industry	Number of establishments	Number of employees	Numbers exposed to Silica				
				>=0	>=25	>=50	>=100	>=250
336112	Light truck and utility vehicle manufacturing.	94	103,815	587	436	296	159	55
336120	Heavy duty truck manufacturing	95	32,122	181	135	91	49	17
336211	Motor vehicle body manufacturing	820	47,566	269	200	135	73	25
336212	Truck trailer manufacturing	394	32,260	182	135	92	50	17
336213	Motor home manufacturing	91	21,533	122	90	61	33	11
336311	Carburetor, piston, piston ring, and valve manufacturing.	116	10,537	60	44	30	16	6
336312	Gasoline engine and engine parts manufacturing.	876	66,112	373	277	188	101	35
336322	Other motor vehicle electrical and electronic equipment manufacturing.	697	62,016	350	260	176	95	33
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	257	39,390	223	165	112	60	21
336340	Motor vehicle brake system manufacturing.	241	33,782	191	142	96	52	18
336350	Motor vehicle transmission and power train parts manufacturing.	535	83,756	473	351	238	128	44
336370	Motor vehicle metal stamping	781	110,578	624	464	315	170	58
336399	All other motor vehicle parts manufacturing.	1,458	149,251	843	626	425	229	79
336611	Ship building and repair	635	87,352	2,798	2,798	1,998	1,599	1,199
336612	Boat building	1,129	54,705	1,752	1,752	1,252	1,001	751
336992	Military armored vehicle, tank, and tank component manufacturing.	57	6,899	39	29	20	11	4
337215	Showcase, partition, shelving, and locker manufacturing.	1,733	59,080	334	248	168	91	31
339114	Dental equipment and supplies manufacturing.	763	15,550	411	274	274	137	0
339116	Dental laboratories	7,261	47,088	33,214	5,357	1,071	0	0
339911	Jewelry (except costume) manufacturing.	1,777	25,280	7,813	4,883	3,418	2,442	977
339913	Jewelers' materials and lapidary work manufacturing.	264	5,199	1,607	1,004	703	502	201
339914	Costume jewelry and novelty manufacturing.	590	6,775	1,088	685	479	338	135
339950	Sign manufacturing	6,415	89,360	496	249	172	57	57
423840	Industrial supplies, wholesalers	10,742	111,198	383	306	153	77	0
482110	Rail transportation	NA	NA	16,895	11,248	5,629	2,852	1,233
621210	Dental offices	124,553	817,396	7,980	1,287	257	0	0
Subtotals—General Industry and Maritime.		238,942	4,406,990	294,886	175,801	122,472	80,731	48,956
Totals		1,041,291	17,508,728	2,144,061	1,026,491	770,280	501,009	264,959

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Table III–5 and the technological feasibility analysis presented in Chapter IV of the PEA.

D. Technological Feasibility Analysis of the Proposed Permissible Exposure Limit to Crystalline Silica Exposures

Chapter IV of the Preliminary Economic Analysis (PEA) provides the technological feasibility analysis that guided OSHA's selection of the proposed PEL, consistent with the requirements of the Occupational Safety and Health Act (''OSH Act''), 29 U.S.C. 651 et seq. Section 6(b)(5) of the OSH Act requires that OSHA ''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.'' 29 U.S.C. 655(b)(5) (emphasis added). The Court of Appeals for the D.C. Circuit has clarified the Agency's obligation to demonstrate the technological feasibility of reducing occupational exposure to a hazardous substance:

> 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.

United Steelworkers of America, AFL–CIO–CIC v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980).

Additionally, the D.C. Circuit has 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. . . .'' *American Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 990 (D.C. Cir. 1991).

To demonstrate the limits of feasibility, OSHA's analysis examines the technological feasibility of the proposed PEL of 50 μg/m³, as well as

the technological feasibility of an alternative PEL of 25 μg/m³. In total, OSHA analyzed technological feasibility in 108 operations in general industry, maritime, and construction industries. This analysis addresses two different aspects of technological feasibility: (1) The extent to which engineering controls can reduce and maintain exposures; and (2) the capability of existing sampling and analytical methods to measure silica exposures. The discussion below summarizes the findings in Chapter IV of the PEA (*see* Docket No. OSHA–2010–0034).

Methodology

The technological feasibility analysis relies on information from a wide variety of sources. These sources include published literature, OSHA inspection reports, NIOSH reports and engineering control feasibility studies, and information from other federal agencies, state agencies, labor organizations, industry associations, and other groups. OSHA has limited the analysis to job categories that are associated with substantial direct silica exposure. The technological feasibility analyses group the general industry and maritime workplaces into 23 industry sectors.[11] The Agency has divided each industry sector into specific job categories on the basis of common materials, work processes, equipment, and available exposure control methods. OSHA notes that these job categories are intended to represent job functions; actual job titles and responsibilities might differ depending on the facility.

OSHA has organized the construction industry by grouping workers into 12 general construction activities. The Agency organized construction workers into general activities that create silica exposures rather than organizing them by job titles because construction workers often perform multiple activities and job titles do not always coincide with the sources of exposure. In organizing construction worker activity this way, OSHA was able to create a more accurate exposure profile and apply control methods to workers who perform these activities in any segment of the construction industry.

The exposure profiles include silica exposure data only for workers in the United States. Information on international exposure levels is occasionally referenced for perspective or in discussions of control options. It is important to note that the vast majority of crystalline silica encountered by workers in the United States is in the quartz form, and the terms crystalline silica and quartz are often used interchangeably. Unless specifically indicated otherwise, all silica exposure data, samples, and results discussed in the technological feasibility analysis refer to measurements of personal breathing zone (PBZ) respirable crystalline silica.

In general and maritime industries, the exposure profiles in the technological feasibility analysis consist mainly of full-shift samples, collected over periods of 360 minutes or more. By using full-shift sampling results, OSHA minimizes the number of results that are less than the limit of detection (LOD) and eliminates the ambiguity associated with the LOD for low air volume samples. Thus, results that are reported in the original data source as below the LOD are included without contributing substantial uncertainty regarding their relationship to the proposed PEL. This is particularly important for general industry samples, which on average have lower silica levels than typical results for many tasks in the construction industry.

In general and maritime industries, the exposure level for the period sampled is assumed to have continued over any unsampled portion of the worker's shift. OSHA has preliminarily determined that this sample criterion is valid because workers in these industries are likely to work at the same general task or same repeating set of tasks over most of their shift; thus, unsampled periods generally are likely to be similar to the sampled periods.

In the construction industry, much of the data analyzed for the defined activities consisted of full-shift samples collected over periods of 360 minutes or more. Construction workers are likely to spend a shift working at multiple discrete tasks, independent of occupational titles, and do not normally engage in those discrete tasks for the entire duration of a shift. Therefore, the Agency occasionally included partial-shift samples (periods of less than 360 minutes), but has limited the use of partial-shift samples with results below the LOD, giving preference to data covering a greater part of the workers' shifts.

OSHA believes that the partial-shift samples were collected for the entire duration of the task and that the exposure to silica ended when the task was completed. Therefore, OSHA assumes that the exposure to silica was zero for the remaining unsampled time. OSHA understands that this may not always be the case, and that there may be activities other than the sampled tasks that affect overall worker exposures, but the documentation regarding these factors is insufficient to use in calculating a time-weighted average. It is important to note, however, that the Agency has identified to the best of its ability the construction activities that create significant exposures to respirable crystalline silica.

In cases where exposure information from a specific job category is not available, OSHA has based that portion of the exposure profile on surrogate data from one or more similar job categories in related industries. The surrogate data is selected based on strong similarities of raw materials, equipment, worker activities, and exposure duration between the job categories. When used, OSHA has clearly identified the surrogate data and the relationship between the industries or job categories.

1. Feasibility Determination of Sampling and Analytical Methods

As part of its technological feasibility analysis, OSHA examined the capability of currently available sampling methods and sensitivity[12] and precision of currently available analytical methods to measure respirable crystalline silica (please refer to the ''Feasibility of Measuring Respirable Crystalline Silica Exposures at The Proposed PEL'' section in Chapter IV of the PEA). The Agency understands that several commercially available personal sampling cyclones exist that can be operated at flow rates that conform to the ISO/CEN particle size selection criteria with an acceptable level of bias. Some of these sampling devices are the Dorr-Oliver, Higgens-Dowel, BGI GK 2.69, and the SKC G–3 cyclones. Bias against the ISO/CEN criteria will fall within ±20 percent, and often is within ±10 percent.

Additionally, the Agency preliminarily concludes that all of the mentioned cyclones are capable of allowing a sufficient quantity of quartz to be collected from atmospheric concentrations as low as 25 μg/m³ to exceed the limit of quantification for the OSHA ID–142 analytical method, provided that a sample duration is at least 4 hours. Furthermore, OSHA believes that these devices are also capable of collecting more than the minimum amount of cristobalite at the proposed PEL and action level

[11] Note that OSHA's technological feasibility analysis contains 21 general industry sections. The number is expanded to 23 in this summary because Table VIII.D–1 describes the foundry industry as three different sectors (ferrous, nonferrous, and non-sand casting foundries) to provide a more detailed analysis of exposures.

[12] Note that sensitivity refers to the smallest quantity that can be measured with a specified level of accuracy, expressed either as the limit of detection or limit of quantification.

necessary for quantification with OSHA's method ID–142 for a full shift. One of these cyclones (GK 2.69) can also collect an amount of cristobalite exceeding OSHA's limit of quantification (LOQ) with a 4-hour sample at the proposed PEL and action level.

Regarding analytical methods to measure silica, OSHA investigated the sensitivity and precision of available methods. The Agency preliminarily concludes that the X-Ray Diffraction (XRD) and Infrared Spectroscopy (IR) methods of analysis are both sufficiently sensitive to quantify levels of quartz and cristobalite that would be collected on air samples taken from concentrations at the proposed PEL and action level. Available information shows that poor inter-laboratory agreement and lack of specificity render colorimetric spectrophotometry (another analytical method) inferior to XRD or IR techniques. As such, OSHA is proposing not to permit employers to rely on exposure monitoring results based on analytical methods that use colorimetric methods.

For the OSHA XRD Method ID–142 (revised December 1996), precision is ±23 percent at a working range of 50 to 160 μg crystalline silica, and the SAE (sampling and analytical error) is ±19 percent. The NIOSH and MSHA XRD and IR methods report a similar degree of precision. OSHA's Salt Lake Technical Center (SLTC) evaluated the precision of ID–142 at lower filter loadings and has shown an acceptable level of precision is achieved at filter loadings of approximately 40 μg and 20 μg corresponding to the amounts collected from full-shift sampling at the proposed PEL and action level, respectively. This analysis showed that at filter loadings corresponding to the proposed PEL, the precision and SAE for quartz are ±17 and ±14 percent, respectively. For cristobalite, the precision and SAE are ±19 and ±16 percent, respectively. These results indicate that employers can have confidence in sampling results for the purpose of assessing compliance with the PEL and identifying when additional engineering and work practice controls and/or respiratory protection are needed.

For example, given an SAE for quartz of 0.14 at a filter load of 40 μg, employers can be virtually certain that the PEL is not exceeded where exposures are less than 43 μg/m^3, which represents the lower 95-percent confidence limit (*i.e.,* 50 μg/m^3 minus 50*0.14). At 43 μg/m^3, a full-shift sample that collects 816 L of air will result in a filter load of 35 μg of quartz, or more than twice the LOQ for Method ID–142. Thus, OSHA believes that the method is sufficiently sensitive and precise to allow employers to distinguish between operations that have sufficient dust control to comply with the PEL from those that do not. Finally, OSHA's analysis of PAT data indicates that most laboratories achieve good agreement in results for samples having filter loads just above 40 μg quartz (49–70 μg).

At the proposed action level, the study by SLTC found the precision and SAE of the method for quartz at 20 μg to be ±19 and ±16 percent, respectively. For cristobalite, the precision and SAE at 20 μg were also ±19 and ±16 percent, respectively. OSHA believes that these results show that Method ID–142 can achieve a sufficient degree of precision for the purpose of identifying those operations where routine exposure monitoring should be conducted.

However, OSHA also believes that limitations in the characterization of the precision of the analytical method in this range of filter load preclude the Agency from proposing a PEL of 25 μg/m^3 at this time. First, the measurement error increases by about 4 to 5 percent for a full-shift sample taken at 25 μg/m^3 compared to one taken at 50 μg/m^3, and the error would be expected to increase further as filter loads approach the limit of detection. Second, for an employer to be virtually certain that an exposure to quartz did not exceed 25 μg/m^3 as an exposure limit, the exposure would have to be below 21 μg/m^3 given the SAE of ±16 percent calculated from the SLTC study. For a full-shift sample of 0.816 L of air, only about 17 μg of quartz would be collected at 21 μg/m^3, which is near the LOQ for Method ID–142 and at the maximum acceptable LOD that would be required by the proposed rule. Thus, given a sample result that is below a laboratory's reported LOD, employers might not be able to rule out whether a PEL of 25 μg/m^3 was exceeded.

Finally, there are no available data that describe the total variability seen between laboratories at filter loadings in the range of 20 μg crystalline silica since the lowest filter loading used in PAT samples is about 50 μg. Given these considerations, OSHA believes that a PEL of 50 μg/m^3 is more appropriate in that employers will have more confidence that sampling results are properly informing them where additional dust controls and respiratory protection is needed.

Based on the evaluation of the nationally recognized sampling and analytical methods for measuring respirable crystalline silica presented in the section titled ''Feasibility of Measuring Respirable Crystalline Silica Exposures at The Proposed PEL'' in Chapter IV of the PEA, OSHA preliminarily concludes that it is technologically feasible to reliably measure exposures of workers at the proposed PEL of 50 μg/m^3 and action level of 25 μg/m^3. OSHA notes that the sampling and analytical error is larger at the proposed action level than that for the proposed PEL. In the ''Issues'' section of this preamble (*see* Provisions of the Standards—Exposure Assessment), OSHA solicits comments on whether measurements of exposures at the proposed action level and PEL are sufficiently precise to permit employers to adequately determine when additional exposure monitoring is necessary under the standard, when to provide workers with the required medical surveillance, and when to comply with all other requirements of the proposed standard. OSHA also solicits comments on the appropriateness of specific requirements in the proposed standard for laboratories that perform analyses of respirable crystalline silica samples to reduce the variability between laboratories.

2. Feasibility Determination of Control Technologies

The Agency has conducted a feasibility analysis for each of the identified 23 general industry sectors and 12 construction industry activities that are potentially affected by the proposed silica standard. Additionally, the Agency identified 108 operations within those sectors/activities and developed exposure profiles for each operation, except for two industries, engineered stone products and landscape contracting industries. For these two industries, data satisfying OSHA's criteria for inclusion in the exposure profile were unavailable (refer to the Methodology section in Chapter 4 of the PEA for criteria). However, the Agency obtained sufficient information in both of these industries to make feasibility determinations (*see* Chapter IV Sections C.7 and C.11 of the PEA). Each feasibility analysis contains a description of the applicable operations, the baseline conditions for each operation (including the respirable silica samples collected), additional controls necessary to reduce exposures, and final feasibility determinations for each operation.

3. Feasibility Findings for the Proposed Permissible Exposure Limit of 50 μg/m^3

Tables VIII–6 and VIII–7 summarize all the industry sectors and construction

activities studied in the technological feasibility analysis and show how many operations within each can achieve levels of 50 μg/m³ through the implementation of engineering and work practice controls. The tables also summarize the overall feasibility finding for each industry sector or construction activity based on the number of feasible versus not feasible operations. For the general industry sector, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For the construction activities, OSHA has determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls (seven out of 108 operations, *see* Tables VIII–6 and VIII–7), employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

4. Feasibility Findings for an Alternative Permissible Exposure Limit of 25 μg/m³

Based on the information presented in the technological feasibility analysis, OSHA believes that engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to PELs lower than 50 μg/m³. The Agency believes that a proposed PEL of 25 μg/m³, for example, would not be feasible for many industries, and to use respiratory protection would have to be required in most operations and most of the time to achieve compliance.

However, OSHA has data indicating that an alternative PEL of 25 μg/m³ has already been achieved in several industries (*e.g.* asphalt paving products, dental laboratories, mineral processing, and paint and coatings manufacturing in general industry, and drywall finishers and heavy equipment operators in construction). In these industries, airborne respirable silica concentrations are inherently low because either small amounts of silica containing materials are handled or these materials are not subjected to high energy processes that generate large amounts of respirable dust.

For many of the other industries, OSHA believes that engineering and work practice controls will not be able to reduce and maintain exposures to an alternative PEL of 25 μg/m³ in most operations and most of the time. This is especially the case in industries that use silica containing material in substantial quantities and industries with high energy operations. For example, in general industry, the ferrous foundry industry would not be able to comply with an alternative PEL of 25 μg/m³ without widespread respirator use. In this industry, silica containing sand is transported, used, and recycled in significant quantities to create castings, and as a result, workers can be exposed to high levels of silica in all steps of the production line. Additionally, some high energy operations in foundries create airborne dust that causes high worker exposures to silica. One of these operations is the shakeout process, where operators monitor equipment that separates castings from mold materials by mechanically vibrating or tumbling the casting. The dust generated from this process causes elevated silica exposures for shakeout operators and often contributes to exposures for other workers in a foundry. For small, medium, and large castings, exposure information with engineering controls in place show that exposures below 50 μg/m³ can be consistently achieved, but exposures above an alternative PEL of 25 μg/m³ still occur. With engineering controls in place, exposure data for these operations range from 13 μg/m³ to 53 μg/m³, with many of the reported exposures above 25 μg/m³.

In the construction industry, OSHA estimates that an alternative PEL of 25 μg/m³ would be infeasible in most operations because most of them are high energy operations that produce significant levels of dust, causing workers to have elevated exposures, and available engineering controls would not be able to maintain exposures at or below the alternative PEL most of the time. For example, jackhammering is a high energy operation that creates a large volume of silica containing dust, which disburses rapidly in highly disturbed air. OSHA estimates that the exposure levels of most workers operating jackhammers outdoors will be reduced to less that 100 μg/m³ as an 8-hour TWA, by using either wet methods or LEV paired with a suitable vacuum.

OSHA believes that typically, the majority of jackhammering is performed for less than four hours of a worker's shift, and in these circumstances the Agency estimates that most workers will experience levels below 50 μg/m³. Jackhammer operators who work indoors or with multiple jackhammers will achieve similar results granted that the same engineering controls are used and that fresh air circulation is provided to prevent accumulation of respirable dust in a worker's vicinity. OSHA does not have any data indicating that these control strategies would reduce exposures of most workers to levels of 25 μg/m³ or less.

5. Overall Feasibility Determination

Based on the information presented in the technological feasibility analysis, the Agency believes that 50 μg/m³ is the lowest feasible PEL. An alternative PEL of 25 μg/m³ would not be feasible because the engineering and work practice controls identified to date will not be sufficient to consistently reduce exposures to levels below 25 μg/m³ in most operations most of the time. OSHA believes that an alternative PEL of 25 μg/m³ would not be feasible for many industries, and that the use of respiratory protection would be necessary in most operations most of the time to achieve compliance. Additionally, the current methods of sampling analysis create higher errors and lower precision in measurement as concentrations of silica lower than the proposed PEL are analyzed. However, the Agency preliminarily concludes that these sampling and analytical methods are adequate to permit employers to comply with all applicable requirements triggered by the proposed action level and PEL.

TABLE VIII–6—SUMMARY OF TECHNOLOGICAL FEASIBILITY OF CONTROL TECHNOLOGIES IN GENERAL AND MARITIME INDUSTRIES AFFECTED BY SILICA EXPOSURES

Industry sector	Total number of affected operations	Number of operations for which the proposed PEL is achievable with engineering controls and work practice controls	Number of operations for which the proposed PEL is *NOT* achievable with engineering controls and work practice controls	Overall feasibility finding for industry sector
Asphalt Paving Products	3	3	0	Feasible.
Asphalt Roofing Materials	2	2	0	Feasible.
Concrete Products	6	5	1	Feasible.
Cut Stone	5	5	0	Feasible.
Dental Equipment and Suppliers	1	1	0	Feasible.
Dental Laboratories	1	1	0	Feasible.
Engineered Stone Products	1	1	0	Feasible.
Foundries: Ferrous*	12	12	0	Feasible.
Foundries: Nonferrous*	12	12	0	Feasible.
Foundries: Non-Sand Casting*	11	11	0	Feasible.
Glass	2	2	0	Feasible.
Jewelry	1	1	0	Feasible.
Landscape Contracting	1	1	0	Feasible.
Mineral Processing	1	1	0	Feasible.
Paint and Coatings	2	2	0	Feasible.
Porcelain Enameling	2	2	0	Feasible.
Pottery	5	5	0	Feasible.
Railroads	5	5	0	Feasible.
Ready-Mix Concrete	5	4	1	Feasible.
Refractories	5	5	0	Feasible.
Refractory Repair	1	1	0	Feasible.
Shipyards (Maritime Industry)	2	1	1	Feasible.
Structural Clay	3	3	0	Feasible.
Totals	89	96.6%	3.4%	

*Section 8 of the Technological Feasibility Analysis includes four subsectors of the foundry industry. Each subsector includes its own exposure profile and feasibility analysis in that section. This table lists three of those four subsectors individually based on the difference in casting processes used and subsequent potential for silica exposure. The table does not include captive foundries because the captive foundry operations are incorporated into the larger manufacturing process of the parent foundry.

TABLE VIII–7—SUMMARY OF TECHNOLOGICAL FEASIBILITY OF CONTROL TECHNOLOGIES IN CONSTRUCTION ACTIVITIES AFFECTED BY SILICA EXPOSURES

Construction activity	Total number of affected operations	Number of operations for which the proposed PEL is achievable with engineering controls and work practice controls	Number of operations for which the proposed PEL is *NOT* achievable with engineering controls and work practice controls	Overall feasibility finding for activity
Abrasive Blasters	2	0	2	Not Feasible.
Drywall Finishers	1	1	0	Feasible.
Heavy Equipment Operators	1	1	0	Feasible.
Hole Drillers Using Hand-Held Drills	1	1	0	Feasible.
Jackhammer and Impact Drillers	1	1	0	Feasible.
Masonry Cutters Using Portable Saws	3	3	0	Feasible.
Masonry Cutters Using Stationary Saws	1	1	0	Feasible.
Millers Using Portable and Mobile Machines	3	3	0	Feasible.
Rock and Concrete Drillers	1	1	0	Feasible.
Rock-Crushing Machine Operators and Tenders	1	1	0	Feasible.
Tuckpointers and Grinders	3	1	2	Not Feasible.
Underground Construction Workers	1	1	0	Feasible.
Totals	19	78.9%	21.1%	

E. Costs of Compliance

Chapter V of the PEA in support of the proposed silica rule provides a detailed assessment of the costs to establishments in all affected industry sectors of reducing worker exposures to silica to an eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 50 μg/m³ and of complying with the proposed standard's ancillary requirements. The discussion below summarizes the findings in the PEA cost chapter. OSHA's preliminary cost assessment is based on the Agency's technological feasibility

analysis presented in Chapter IV of the PEA (2013); analyses of the costs of the proposed standard conducted by OSHA's contractor, Eastern Research Group (ERG, 2007a, 2007b, and 2013); and the comments submitted to the docket as part of the SBREFA panel process.

OSHA estimates that the proposed rule will cost $657.9 million per year in 2009 dollars. Costs originally estimated for earlier years were adjusted to 2009 dollars using the appropriate price indices. All costs are annualized using a discount rate of 7 percent. (A sensitivity analysis using discount rates of 3 percent and 0 percent is presented in the discussion of net benefits.) One-time costs are annualized over 10-year annualization period, and capital goods are annualized over the life of the equipment. OSHA has historically annualized one-time costs over at least a 10-year period, which approximately reflects the average life of a business in the United States. (The Agency has chosen a longer annualization period under special circumstances, such as when a rule involves longer and more complex phase-in periods. In general, a longer annualization period, in such cases, will tend to reduce annualized costs slightly.)

The estimated costs for the proposed silica standard rule include the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

Table VIII–8 provides the annualized costs of the proposed rule by cost category for general industry, maritime, and construction. As shown in Table VIII–8, of the total annualized costs of the proposed rule, $132.5 million would be incurred by general industry, $14.2 million by maritime, and $511.2 million by construction.

Table VIII–9 shows the annualized costs of the proposed rule by cost category and by industry for general industry and maritime, and Table VIII–10 shows the annualized costs similarly disaggregated for construction. These tables show that engineering control costs represent 69 percent of the costs of the proposed standard for general industry and maritime and 47 percent of the costs of the proposed standard for construction. Considering other leading cost categories, costs for exposure assessment and respirators represent, respectively, 20 percent and 5 percent of the costs of the proposed standard for general industry and maritime; costs for respirators and medical surveillance represent, respectively, 16 percent and 15 percent of the costs of the proposed standard for construction.

While the costs presented here represent the Agency's best estimate of the costs to industry of complying with the proposed rule under static conditions (that is, using existing technology and the current deployment of workers), OSHA recognizes that the actual costs could be somewhat higher or lower, depending on the Agency's possible overestimation or underestimation of various cost factors. In Chapter VII of the PEA, OSHA provides a sensitivity analysis of its cost estimates by modifying certain critical unit cost factors. Beyond the sensitivity analysis, however, OSHA believes its cost estimates may significantly overstate the actual costs of the proposed rule because, in response to the rule, industry may be able to take two types of actions to reduce compliance costs.

First, in construction, 53 percent of the estimated costs of the proposed rule (all costs except engineering controls) vary directly with the number of workers exposed to silica. However, as shown in Table VIII–3 of this preamble, almost three times as many construction workers would be affected by the proposed rule as would the number of full-time-equivalent construction workers necessary to do the work. This is because most construction workers currently do work involving silica exposure for only a portion of their workday. In response to the proposed rule, many employers are likely to assign work so that fewer construction workers perform tasks involving silica exposure; correspondingly, construction work involving silica exposure will tend to become a full-time job for some construction workers.[13] Were this approach fully implemented in construction, the actual cost of the proposed rule would decline by over 25 percent, or by $180 million annually, to under $480 million annually.[14]

Second, the costs presented here do not take into account the likely development and dissemination of cost-reducing compliance technology in response to the proposed rule.[15] One possible example is the development of safe substitutes for silica sand in abrasive blasting operations, repair and replacement of refractory materials, foundry operations, and the railroad transportation industry. Another is expanded uses of automated processes, which would allow workers to be isolated from the points of operation that involve silica exposure (such as tasks between the furnace and the pouring machine in foundries and at sand transfer stations in structural clay production facilities). Yet another example is the further development and use of bags with valves that seal effectively when filled, thereby preventing product leakage and worker exposure (for example, in mineral processing and concrete products industries). Probably the most pervasive and significant technological advances, however, will likely come from the integration of compliant control technology into production equipment as standard equipment. Such advances would both increase the effectiveness and reduce the costs of silica controls retrofitted to production equipment. Possible examples include local exhaust ventilation (LEV) systems attached to portable tools used by grinders and tuckpointers; enclosed operator cabs equipped with air filtration and air conditioning in industries that mechanically transfer silica or silica-containing materials; and machine-integrated wet dust suppression systems used, for example, in road milling operations. Of course, all the possible technological advances in response to the proposed rule and their effects on costs are difficult to predict.[16]

OSHA has decided at this time not to create a more dynamic and predictive analysis of possible cost-reducing

[13] There are numerous instances of job reassignments and job specialties arising in response to OSHA regulation. For example, asbestos removal and confined space work in construction have become activities performed by well-trained specialized employees, not general laborers (whose only responsibility is to identify the presence of asbestos or a confined space situation and then to notify the appropriate specialist).

[14] OSHA expected that such a structural change in construction work assignments would not have a significant effect on the benefits of the proposed rule. As discussed in Chapter VII of the PEA, the benefits of the proposed rule are relatively insensitive to changes in average occupational tenure or how total silica exposure in an industry is distributed among individual workers.

[15] Evidence of such technological responses to regulation is widespread (see for example Ashford, Ayers, and Stone (1985), OTA (1995), and OSHA's regulatory reviews of existing standards under § 610 of the Regulatory Flexibility Act (''610 lookback reviews'')).

[16] A dramatic example from OSHA's 610 lookback review of its 1984 ethylene oxide (EtO) standard is the use of EtO as a sterilant. OSHA estimated the costs of add-on controls for EtO sterilization, but in response to the standard, improved EtO sterilizers with built-in controls were developed and widely disseminated at about half the cost of the equipment with add-on controls. (See OSHA, 2005.) Lower-cost EtO sterilizers with built-in controls did not exist, and their development had not been predicted by OSHA, at the time the final rule was published in 1984.

technological advances or worker specialization because the technological and economic feasibility of the proposed rule can easily be demonstrated using existing technology and employment patterns. However, OSHA believes that actual costs, if future developments of this type were fully accounted for, would be lower than those estimated here.

OSHA invites comment on this discussion concerning the costs of the proposed rule.

TABLE VIII–8—ANNUALIZED COMPLIANCE COSTS FOR EMPLOYERS IN GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

[2009 dollars]

Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas or access control	Total
General Industry	$88,442,480	$6,914,225	$29,197,633	$2,410,253	$2,952,035	$2,580,728	$132,497,353
Maritime	12,797,027	NA	671,175	646,824	43,865	70,352	14,229,242
Construction	242,579,193	84,004,516	44,552,948	76,012,451	47,270,844	16,745,663	511,165,616
Total	343,818,700	90,918,741	74,421,757	79,069,527	50,266,744	19,396,743	657,892,211

U.S. Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2007a, 2007b, and 2013).

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
324121	Asphalt paving mixture and block manufacturing.	$179,111	$2,784	$8,195	$962	$49,979	$1,038	$242,070
324122	Asphalt shingle and roofing materials	2,194,150	113,924	723,761	39,364	43,563	42,495	3,157,257
325510	Paint and coating manufacturing	0	23,445	70,423	8,179	33,482	8,752	144,281
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	1,128,859	76,502	369,478	26,795	29,006	28,554	1,659,194
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,769,953	119,948	579,309	42,012	45,479	44,770	2,601,471
327113	Porcelain electrical supply mfg	1,189,482	80,610	389,320	28,234	30,564	30,087	1,748,297
327121	Brick and structural clay mfg	6,966,654	154,040	554,322	53,831	51,566	57,636	7,838,050
327122	Ceramic wall and floor tile mfg	3,658,389	80,982	306,500	28,371	27,599	30,266	4,132,107
327123	Other structural clay product mfg	826,511	18,320	72,312	6,417	6,302	6,838	936,699
327124	Clay refractory manufacturing	304,625	21,108	124,390	7,393	17,043	7,878	482,438
327125	Nonclay refractory manufacturing	383,919	26,602	156,769	9,318	21,479	9,929	608,017
327211	Flat glass manufacturing	227,805	8,960	29,108	3,138	2,800	3,344	275,155
327212	Other pressed and blown glass and glassware manufacturing.	902,802	34,398	111,912	12,048	10,708	12,839	1,084,706
327213	Glass container manufacturing	629,986	24,003	78,093	8,374	7,472	8,959	756,888
327320	Ready-mixed concrete manufacturing	7,029,710	1,862,221	5,817,205	652,249	454,630	695,065	16,511,080
327331	Concrete block and brick mfg	2,979,495	224,227	958,517	78,536	113,473	83,692	4,437,939
327332	Concrete pipe mfg	1,844,576	138,817	593,408	48,621	70,250	51,813	2,747,484
327390	Other concrete product mfg	8,660,830	651,785	2,786,227	228,290	329,844	243,276	12,900,251
327991	Cut stone and stone product manufacturing.	5,894,506	431,758	1,835,498	151,392	126,064	161,080	8,600,298
327992	Ground or treated mineral and earth manufacturing.	3,585,439	51,718	867,728	18,134	52,692	19,295	4,595,006
327993	Mineral wool manufacturing	897,980	36,654	122,015	12,852	11,376	13,675	1,094,552
327999	All other misc. nonmetallic mineral product mfg.	1,314,066	98,936	431,012	34,691	50,435	36,911	1,966,052
331111	Iron and steel mills	315,559	17,939	72,403	6,129	5,836	6,691	424,557
331112	Electrometallurgical ferroalloy product manufacturing.	6,375	362	1,463	124	118	135	8,577
331210	Iron and steel pipe and tube manufacturing from purchased steel.	62,639	3,552	14,556	1,239	1,222	1,328	84,537
331221	Rolled steel shape manufacturing	31,618	1,793	7,348	625	617	670	42,672
331222	Steel wire drawing	42,648	2,419	9,911	843	832	904	57,557
331314	Secondary smelting and alloying of aluminum.	21,359	1,213	4,908	419	406	453	28,757
331423	Secondary smelting, refining, and alloying of copper.	3,655	207	857	72	71	78	4,940
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	27,338	1,551	6,407	539	531	580	36,946
331511	Iron foundries	11,372,127	645,546	2,612,775	223,005	216,228	241,133	15,310,815
331512	Steel investment foundries	3,175,862	179,639	739,312	62,324	58,892	67,110	4,283,138
331513	Steel foundries (except investment)	3,403,790	193,194	794,973	67,027	65,679	72,174	4,596,837
331524	Aluminum foundries (except die-casting).	5,155,172	291,571	1,220,879	101,588	97,006	108,935	6,975,150
331525	Copper foundries (except die-casting)	1,187,578	67,272	309,403	23,668	23,448	25,095	1,636,463

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
331528	Other nonferrous foundries (except die-casting).	914,028	51,701	212,778	17,937	16,949	19,314	1,232,708
332111	Iron and steel forging	77,324	4,393	19,505	1,538	1,555	1,640	105,955
332112	Nonferrous forging	25,529	1,451	6,440	508	513	541	34,982
332115	Crown and closure manufacturing	9,381	532	2,236	186	186	199	12,720
332116	Metal stamping	188,102	10,676	45,595	3,734	3,736	3,988	255,832
332117	Powder metallurgy part manufacturing	24,250	1,375	5,727	481	479	514	32,828
332211	Cutlery and flatware (except precious) manufacturing.	16,763	952	4,229	333	337	355	22,970
332212	Hand and edge tool manufacturing	106,344	6,041	26,356	2,110	2,118	2,255	145,223
332213	Saw blade and handsaw manufacturing.	21,272	1,209	5,090	418	411	451	28,851
332214	Kitchen utensil, pot, and pan manufacturing.	11,442	650	2,886	228	230	243	15,678
332323	Ornamental and architectural metal work.	28,010	1,089	4,808	383	572	406	35,267
332439	Other metal container manufacturing	44,028	2,502	11,106	876	885	934	60,330
332510	Hardware manufacturing	131,574	7,476	33,190	2,617	2,646	2,790	180,292
332611	Spring (heavy gauge) manufacturing	11,792	670	2,974	235	237	250	16,158
332612	Spring (light gauge) manufacturing	44,511	2,529	11,228	885	895	944	60,992
332618	Other fabricated wire product manufacturing.	105,686	6,005	26,659	2,102	2,125	2,241	144,819
332710	Machine shops	774,529	44,074	211,043	15,533	16,157	16,423	1,077,759
332812	Metal coating and allied services	2,431,996	94,689	395,206	33,145	48,563	35,337	3,038,935
332911	Industrial valve manufacturing	111,334	6,316	25,894	2,197	2,159	2,361	150,261
332912	Fluid power valve and hose fitting manufacturing.	103,246	5,863	24,854	2,040	2,021	2,189	140,213
332913	Plumbing fixture fitting and trim manufacturing.	33,484	1,901	8,060	661	655	710	45,472
332919	Other metal valve and pipe fitting manufacturing.	52,542	2,984	12,648	1,038	1,028	1,114	71,354
332991	Ball and roller bearing manufacturing	79,038	4,488	19,027	1,561	1,547	1,676	107,338
332996	Fabricated pipe and pipe fitting manufacturing.	78,951	4,483	19,006	1,560	1,545	1,674	107,219
332997	Industrial pattern manufacturing	15,383	874	3,703	304	301	326	20,891
332998	Enameled iron and metal sanitary ware manufacturing.	46,581	2,225	9,304	774	969	831	60,684
332999	All other miscellaneous fabricated metal product manufacturing.	209,692	11,915	53,603	4,181	4,256	4,446	288,093
333319	Other commercial and service industry machinery manufacturing.	154,006	8,741	37,161	3,053	3,046	3,266	209,273
333411	Air purification equipment manufacturing.	43,190	2,453	10,037	847	823	916	58,265
333412	Industrial and commercial fan and blower manufacturing.	30,549	1,735	7,099	599	582	648	41,212
333414	Heating equipment (except warm air furnaces) manufacturing.	59,860	3,399	13,911	1,174	1,141	1,269	80,754
333511	Industrial mold manufacturing	116,034	6,597	30,348	2,317	2,375	2,460	160,131
333512	Machine tool (metal cutting types) manufacturing.	49,965	2,839	12,313	988	985	1,059	68,151
333513	Machine tool (metal forming types) manufacturing.	24,850	1,411	6,157	495	500	527	33,940
333514	Special die and tool, die set, jig, and fixture manufacturing.	167,204	9,513	44,922	3,346	3,458	3,545	231,988
333515	Cutting tool and machine tool accessory manufacturing.	101,385	5,764	26,517	2,025	2,075	2,150	139,916
333516	Rolling mill machinery and equipment manufacturing.	8,897	506	2,327	178	182	189	12,279
333518	Other metalworking machinery manufacturing.	36,232	2,060	9,476	724	742	768	50,002
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	35,962	2,043	8,308	702	674	763	48,452
333613	Mechanical power transmission equipment manufacturing.	45,422	2,581	10,493	886	852	963	61,197
333911	Pump and pumping equipment manufacturing.	89,460	5,077	21,139	1,767	1,746	1,897	121,086
333912	Air and gas compressor manufacturing	62,241	3,534	14,975	1,230	1,219	1,320	84,518
333991	Power-driven handtool manufacturing	25,377	1,441	6,105	501	497	538	34,459
333992	Welding and soldering equipment manufacturing.	46,136	2,622	10,882	904	879	978	62,401
333993	Packaging machinery manufacturing	61,479	3,491	15,004	1,219	1,218	1,304	83,714
333994	Industrial process furnace and oven manufacturing.	31,154	1,768	7,694	620	626	661	42,523
333995	Fluid power cylinder and actuator manufacturing.	57,771	3,280	13,532	1,137	1,113	1,225	78,057
333996	Fluid power pump and motor manufacturing.	39,598	2,247	9,296	782	772	840	53,535

TABLE VIII–9—ANNUALIZED COMPLIANCE COSTS FOR ALL GENERAL INDUSTRY AND MARITIME ESTABLISHMENTS AFFECTED BY THE PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas	Total
333997	Scale and balance (except laboratory) manufacturing.	10,853	616	2,688	216	218	230	14,822
333999	All other miscellaneous general purpose machinery manufacturing.	152,444	8,657	36,677	3,012	2,985	3,232	207,006
334518	Watch, clock, and part manufacturing	6,389	363	1,596	127	129	135	8,740
335211	Electric housewares and household fans.	11,336	437	1,641	149	203	163	13,928
335221	Household cooking appliance manufacturing.	24,478	944	3,543	321	438	352	30,077
335222	Household refrigerator and home freezer manufacturing.	26,139	1,009	3,784	343	468	376	32,118
335224	Household laundry equipment manufacturing.	24,839	958	3,596	326	444	357	30,521
335228	Other major household appliance manufacturing.	19,551	754	2,830	256	350	281	24,023
336111	Automobile manufacturing	218,635	12,444	49,525	4,203	3,914	4,636	293,357
336112	Light truck and utility vehicle manufacturing.	301,676	17,170	68,335	5,799	5,400	6,397	404,778
336120	Heavy duty truck manufacturing	93,229	5,303	21,179	1,800	1,692	1,977	125,181
336211	Motor vehicle body manufacturing	138,218	7,849	32,738	2,722	2,674	2,931	187,131
336212	Truck trailer manufacturing	93,781	5,325	21,786	1,841	1,791	1,989	126,512
336213	Motor home manufacturing	62,548	3,557	14,284	1,212	1,147	1,326	84,073
336311	Carburetor, piston, piston ring, and valve manufacturing.	30,612	1,739	7,044	598	576	649	41,219
336312	Gasoline engine and engine parts manufacturing.	192,076	10,910	44,198	3,753	3,616	4,073	258,625
336322	Other motor vehicle electrical and electronic equipment manufacturing.	180,164	10,233	41,457	3,520	3,392	3,820	242,586
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	114,457	6,504	26,216	2,228	2,128	2,427	153,960
336340	Motor vehicle brake system manufacturing.	98,118	5,573	22,578	1,917	1,847	2,080	132,114
336350	Motor vehicle transmission and power train parts manufacturing.	243,348	13,832	55,796	4,730	4,510	5,160	327,377
336370	Motor vehicle metal stamping	321,190	18,237	73,408	6,282	6,057	6,810	431,985
336399	All other motor vehicle parts manufacturing.	433,579	24,628	99,769	8,472	8,162	9,194	583,803
336611	Ship building and repair	7,868,944	NA	412,708	397,735	26,973	43,259	8,749,619
336612	Boat building	4,928,083	NA	258,467	249,089	16,892	27,092	5,479,624
336992	Military armored vehicle, tank, and tank component manufacturing.	20,097	1,142	4,786	394	383	426	27,227
337215	Showcase, partition, shelving, and locker manufacturing.	171,563	9,741	41,962	3,405	3,412	3,638	233,720
339114	Dental equipment and supplies manufacturing.	272,308	15,901	48,135	5,524	4,157	5,930	351,955
339116	Dental laboratories	103,876	62,183	892,167	21,602	335,984	23,193	1,439,004
339911	Jewelry (except costume) manufacturing.	260,378	198,421	876,676	69,472	81,414	73,992	1,560,353
339913	Jewelers' materials and lapidary work manufacturing.	53,545	40,804	180,284	14,287	16,742	15,216	320,878
339914	Costume jewelry and novelty manufacturing.	54,734	27,779	122,885	9,726	11,337	10,359	236,821
339950	Sign manufacturing	227,905	9,972	44,660	3,491	5,173	3,718	294,919
423840	Industrial supplies, wholesalers	97,304	8,910	60,422	3,149	4,199	3,315	177,299
482110	Rail transportation	0	327,176	1,738,398	110,229	154,412	121,858	2,452,073
621210	Dental offices	24,957	14,985	251,046	5,286	87,408	5,572	389,256
	Total	101,239,507	6,914,225	29,868,808	3,057,076	2,995,900	2,651,079	146,726,595

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–10—ANNUALIZED COMPLIANCE COSTS FOR CONSTRUCTION EMPLOYERS AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas and access control	Total
236100	Residential Building Construction	$14,610,121	$2,356,507	$1,949,685	$2,031,866	$1,515,047	$825,654	$23,288,881
236200	Nonresidential Building Construction	16,597,147	7,339,394	4,153,899	6,202,842	4,349,517	1,022,115	39,664,913
237100	Utility System Construction	30,877,799	2,808,570	4,458,900	2,386,139	5,245,721	941,034	46,718,162
237200	Land Subdivision	676,046	59,606	128,183	51,327	173,183	22,443	1,110,789
237300	Highway, Street, and Bridge Construction.	16,771,688	2,654,815	3,538,146	2,245,164	4,960,966	637,082	30,807,861

TABLE VIII–10—ANNUALIZED COMPLIANCE COSTS FOR CONSTRUCTION EMPLOYERS AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure assessment	Medical surveillance	Training	Regulated areas and access control	Total
237900	Other Heavy and Civil Engineering Construction.	4,247,372	430,127	825,247	367,517	1,162,105	131,843	7,164,210
238100	Foundation, Structure, and Building Exterior Contractors.	66,484,670	59,427,878	17,345,127	50,179,152	14,435,854	8,034,530	215,907,211
238200	Building Equipment Contractors	3,165,237	366,310	394,270	316,655	526,555	133,113	4,902,138
238300	Building Finishing Contractors	34,628,392	2,874,918	2,623,763	5,950,757	3,156,004	1,025,405	50,259,239
238900	Other Specialty Trade Contractors	43,159,424	4,044,680	5,878,597	4,854,336	7,251,924	2,815,017	68,003,978
999000	State and Local Governments [c]	11,361,299	1,641,712	3,257,131	1,426,696	4,493,968	1,157,427	23,338,234
	Total—Construction	242,579,193	84,004,516	44,552,948	76,012,451	47,270,844	16,745,663	511,165,616

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

1. Unit Costs, Other Cost Parameters, and Methodological Assumptions by Major Provision

Below, OSHA summarizes its methodology for estimating unit and total costs for the major provisions required under the proposed silica standard. For a full presentation of the cost analysis, see Chapter V of the PEA and ERG (2007a, 2007b, 2011, 2013). OSHA invites comment on all aspects of its preliminary cost analysis.

a. Engineering Controls

Engineering controls include such measures as local exhaust ventilation, equipment hoods and enclosures, dust suppressants, spray booths and other forms of wet methods, high efficient particulate air (HEPA) vacuums, and control rooms.

Following ERG's (2011) methodology, OSHA estimated silica control costs on a per-worker basis, allowing the costs to be related directly to the estimates of the number of overexposed workers. OSHA then multiplied the estimated control cost per worker by the numbers of overexposed workers for both the proposed PEL of 50 μg/m³ and the alternative PEL of 100 μg/m³, introduced for economic analysis purposes. The numbers of workers needing controls (*i.e.,* workers overexposed) are based on the exposure profiles for at-risk occupations developed in the technological feasibility analysis in Chapter IV of the PEA and estimates of the number of workers employed in these occupations developed in the industry profile in Chapter III of the PEA. This worker-based method is necessary because, even though the Agency has data on the number of firms in each affected industry, on the occupations and industrial activities with worker exposure to silica, on exposure profiles of at-risk occupations, and on the costs of controlling silica exposure for specific industrial activities, OSHA does not have a way to match up these data at the firm level. Nor does OSHA have facility-specific data on worker exposure to silica or even facility-specific data on the level of activity involving worker exposure to silica. Thus, OSHA could not directly estimate per-affected-facility costs, but instead, first had to estimate aggregate compliance costs and then calculate the average per-affected-facility costs by dividing aggregate costs by the number of affected facilities.

In general, OSHA viewed the extent to which exposure controls are already in place to be reflected in the distribution of overexposures among the affected workers. Thus, for example, if 50 percent of workers in a given occupation are found to be overexposed relative to the proposed silica PEL, OSHA judged this equivalent to 50 percent of facilities lacking the relevant exposure controls. The remaining 50 percent of facilities are expected either to have installed the relevant controls or to engage in activities that do not require that the exposure controls be in place. OSHA recognizes that some facilities might have the relevant controls in place but are still unable, for whatever reason, to achieve the PEL under consideration. ERG's review of the industrial hygiene literature and other source materials (as noted in ERG, 2007b), however, suggest that the large majority of overexposed workers lack relevant controls. Thus, OSHA has generally assumed that overexposures occur due to the absence of suitable controls. This assumption results in an overestimate of costs since, in some cases, employers may merely need to upgrade or better maintain existing controls or to improve work practices rather than to install and maintain new controls.

There are two situations in which the proportionality assumption may oversimplify the estimation of the costs of the needed controls. First, some facilities may have the relevant controls in place but are still unable, for whatever reason, to achieve the PEL under consideration for all employees. ERG's review of the industrial hygiene literature and other source materials (as noted in ERG, 2007b, pg. 3–4), however, suggest that the large majority of overexposed workers lack relevant controls. Thus, OSHA has generally assumed that overexposures occur due to the absence of suitable controls. This assumption could, in some cases, result in an overestimate of costs where employers merely need to upgrade or better maintain existing controls or to improve work practices rather than to install and maintain new controls. Second, there may be situations where facilities do not have the relevant controls in place but nevertheless have only a fraction of all affected employees above the PEL. If, in such situations, an employer would have to install all the controls necessary to meet the PEL, OSHA may have underestimated the control costs. However, OSHA believes that, in general, employers could come into compliance by such methods as checking the work practices of the employee who is above the PEL or installing smaller amounts of LEV at costs that would be more or less proportional to the costs for all employees. Nevertheless there may be situations in which a complete set of controls would be necessary if even one employee in a work area is above the PEL. OSHA welcomes comment on the extent to which this approach may yield underestimates or overestimates of costs.

At many workstations, employers must improve ventilation to reduce silica exposures. Ventilation improvements will take a variety of

forms at different workstations and in different facilities and industries. The cost of ventilation enhancements generally reflects the expense of ductwork and other equipment for the immediate workstation or individual location and, potentially, the cost of incremental capacity system-wide enhancements and increased operation costs for the heating, ventilation, and air conditioning (HVAC) system for the facility.

For a number of occupations, the technological feasibility analysis indicates that, in addition to ventilation, the use of wet methods, improved housekeeping practices, and enclosure of process equipment are needed to reduce silica exposures. The degree of incremental housekeeping depends upon how dusty the operations are and the applicability of HEPA vacuums or other equipment to the dust problem. The incremental costs for most such occupations arise due to the labor required for these additional housekeeping efforts. Because additional labor for housekeeping will be required on virtually every work shift by most of the affected occupations, the costs of housekeeping are substantial. Employers also need to purchase HEPA vacuums and must incur the ongoing costs of HEPA vacuum filters. To reduce silica exposures by enclosure of process equipment, such as in the use of conveyors near production workers in mineral processing, covers can be particularly effective where silica-containing materials are transferred (and notable quantities of dust become airborne), or, as another example, where dust is generated, such as in sawing or grinding operations.

For construction, ERG (2007a) defined silica dust control measures for each representative job as specified in Table 1 of the proposed rule. Generally, these controls involve either a dust collection system or a water-spray approach (wet method) to capture and suppress the release of respirable silica dust. Wet-method controls require a water source (*e.g.,* tank) and hoses. The size of the tank varies with the nature of the job and ranges from a small hand-pressurized tank to a large tank for earth drilling operations. Depending on the tool, dust collection methods entail vacuum equipment, including a vacuum unit and hoses, and either a dust shroud or an extractor. For example, concrete grinding operations using hand-held tools require dust shroud adapters for each tool and a vacuum. The capacity of the vacuum depends on the type and size of tool being used. Some equipment, such as concrete floor grinders, comes with a dust collection system and a port for a vacuum hose. The estimates of control costs for those jobs using dust collection methods assume that an HEPA filter will be required.

For each job, ERG estimated the annual cost of the appropriate controls and translated this cost to a daily charge. The unit costs for control equipment were based on price information collected from manufacturers and vendors. In some cases, control equipment costs were based on data on equipment rental charges.

As noted above, included among the engineering controls in OSHA's cost model are housekeeping and dust-suppression controls in general industry. For the maritime industry and for construction, abrasive blasting operations are expected to require the use of wet methods to control silica dust.

Tables V–3, V–4, V–21, V–22, and V–31 in Chapter V of the PEA and Tables V–A–1 and V–A–2 in Appendix V–A provide details on the unit costs, other unit parameters, and methodological assumptions applied by OSHA to estimate engineering control costs.

b. Respiratory Protection

OSHA's cost estimates assume that implementation of the recommended silica controls prevents workers in general industry and maritime from being exposed over the PEL in most cases. Specifically, based on its technological feasibility analysis, OSHA expects that the technical controls are adequate to keep silica exposures at or below the PEL for an alternative PEL of 100 μg/m^3 (introduced for economic analysis purposes).[17] For the proposed 50 μg/m^3 PEL, OSHA's feasibility analysis suggests that the controls that employers use, either because of technical limitations or imperfect implementation, might not be adequate in all cases to ensure that worker exposures in all affected job categories are at or below 50 μg/m^3. For this preliminary cost analysis, OSHA estimates that ten percent of the at-risk workers in general industry would require respirators, at least occasionally, after the implementation of engineering controls to achieve compliance with the proposed PEL of 50 μg/m^3. For workers in maritime, the only activity with silica exposures above the proposed PEL of 50 μg/m^3 is abrasive blasting, and maritime workers engaged in abrasive blasting are already required to use respirators under the existing OSHA ventilation standard (29 CFR 1910.94(a)). Therefore, OSHA has estimated no additional costs for maritime workers to use respirators as a result of the proposed silica rule.

For construction, employers whose workers receive exposures above the PEL are assumed to adopt the appropriate task-specific engineering controls and, where required, respirators prescribed in Table 1 and under paragraph (g)(1) in the proposed standard. Respirator costs in the construction industry have been adjusted to take into account OSHA's estimate (consistent with the findings from the NIOSH Respiratory Survey, 2003) that 56 percent of establishments in the construction industry are already using respirators that would be in compliance with the proposed silica rule.

ERG (2013) used respirator cost information from a 2003 OSHA respirator study to estimate the annual cost of $570 (in 2009 dollars) for a half-mask, non-powered, air-purifying respirator and $638 per year (in 2009 dollars) for a full-face non-powered air-purifying respirator (ERG, 2003). These unit costs reflect the annualized cost of respirator use, including accessories (*e.g.,* filters), training, fit testing, and cleaning.

In addition to bearing the costs associated with the provision of respirators, employers will incur a cost burden to establish respirator programs. OSHA projects that this expense will involve an initial 8 hours for establishments with 500 or more employees and 4 hours for all other firms. After the first year, OSHA estimates that 20 percent of establishments would revise their respirator program every year, with the largest establishments (500 or more employees) expending 4 hours for program revision, and all other employers expending two hours for program revision. Consistent with the findings from the NIOSH Respiratory Survey (2003), OSHA estimates that 56 percent of establishments in the construction industry that would require respirators to achieve compliance with the proposed PEL already have a respirator program.[18] OSHA further estimates that 50 percent of firms in general industry and all maritime firms that would require

[17] As a result, OSHA expects that establishments in general industry do not currently use respirators to comply with the current OSHA PEL for quartz of approximately 100 μg/m^3.

[18] OSHA's derivation of the 56 percent current compliance rate in construction, in the context of the proposed silica rule, is described in Chapter V in the PEA.

respirators to achieve compliance already have a respirator program.

c. Exposure Assessment

Most establishments wishing to perform exposure monitoring will require the assistance of an outside consulting industrial hygienist (IH) to obtain accurate results. While some firms might already employ or train qualified staff, ERG (2007b) judged that the testing protocols are fairly challenging and that few firms have sufficiently skilled staff to eliminate the need for outside consultants.

Table V–8 in the PEA shows the unit costs and associated assumptions used to estimate exposure assessment costs. Unit costs for exposure sampling include direct sampling costs, the costs of productivity losses, and recordkeeping costs, and, depending on establishment size, range from $225 to $412 per sample in general industry and maritime and from $228 to $415 per sample in construction.

For costing purposes, based on ERG (2007b), OSHA estimated that there are four workers per work area. OSHA interpreted the initial exposure assessment as requiring first-year testing of at least one worker in each distinct job classification and work area who is, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level. This may result in overestimated exposure assessment costs in construction because OSHA anticipates that many employers, aware that their operations currently expose their workers to silica levels above the PEL, will simply choose to comply with Table 1 and avoid the costs of conducting exposure assessments.

For periodic monitoring, the proposed standard provides employers an option of assessing employee exposures either under a fixed schedule (paragraph (d)(3)(i)) or a performance-based schedule (paragraph (d)(3)(ii)). Under the fixed schedule, the proposed standard requires semi-annual sampling for exposures at or above the action level and quarterly sampling for exposures above the 50 μg/m^3 PEL. Monitoring must be continued until the employer can demonstrate that exposures are no longer at or above the action level. OSHA used the fixed schedule option under the frequency-of-monitoring requirements to estimate, for costing purposes, that exposure monitoring will be conducted (a) twice a year where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, and (b) four times a year where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL.

As required under paragraph (d)(4) of the proposed rule, whenever there is a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures at or above the action level or when the employer has any reason to suspect that a change may result in new or additional exposures at or above the action level, the employer must conduct additional monitoring. Based on ERG (2007a, 2007b), OSHA estimated that approximately 15 percent of workers whose initial exposure or subsequent monitoring was at or above the action level would undertake additional monitoring.

A more detailed description of unit costs, other unit parameters, and methodological assumptions for exposure assessments is presented in Chapter V of the PEA.

d. Medical Surveillance

Paragraph (h) of the proposed standard requires an initial health screening and then triennial periodic screenings for workers exposed above the proposed PEL of 50 μg/m^3 for 30 days or more per year. ERG (2013) assembled information on representative unit costs for initial and periodic medical surveillance. Separate costs were estimated for current employees and for new hires as a function of the employment size (*i.e.,* 1–19, 20–499, or 500+ employees) of affected establishments. Table V–10 in the PEA presents ERG's unit cost data and modeling assumptions used by OSHA to estimate medical surveillance costs.

In accordance with the paragraph (h)(2) of the proposed rule, the initial (baseline) medical examination would consist of (1) a medical and work history, (2) a physical examination with special emphasis on the respiratory system, (3) a chest X-ray that is interpreted according to guidelines of the International Labour Organization, (4) a pulmonary function test that meets certain criteria and is administered by spirometry technician with current certification from a NIOSH-approved spirometry course, (5) testing for latent tuberculosis (TB) infection, and (6) any other tests deemed appropriate by the physician or licensed health care professional (PLHCP).

As shown in Table V–10 in the PEA, the estimated unit cost of the initial health screening for current employees in general industry and maritime ranges from approximately $378 to $397 and includes direct medical costs, the opportunity cost of worker time (*i.e.,* lost work time, evaluated at the worker's 2009 hourly wage, including fringe benefits) for offsite travel and for the initial health screening itself, and recordkeeping costs. The variation in the unit cost of the initial health screening is due entirely to differences in the percentage of workers expected to travel offsite for the health screening. In OSHA's experience, the larger the establishment the more likely it is that the selected PLHCP would provide the health screening services at the establishment's worksite. OSHA estimates that 20 percent of establishments with fewer than 20 employees, 75 percent of establishments with 20–499 employees, and 100 percent of establishments with 500 or more employees would have the initial health screening for current employees conducted onsite.

The unit cost components of the initial health screening for new hires in general industry and maritime are identical to those for existing employees with the exception that the percentage of workers expected to travel offsite for the health screening would be somewhat larger (due to fewer workers being screened annually, in the case of new hires, and therefore yielding fewer economies of onsite screening). OSHA estimates that 10 percent of establishments with fewer than 20 employees, 50 percent of establishments with 20–499 employees, and 90 percent of establishments with 500 or more employees would have the initial health screening for new hires conducted onsite. As shown in Chapter V in the PEA, the estimated unit cost of the initial health screening for new hires in general industry and maritime ranges from approximately $380 to $399.

The unit costs of medical surveillance in construction were derived using identical methods. As shown in Table V–39 of the PEA, the estimated unit costs of the initial health screening for current employees in construction range from approximately $389 to $425; the estimated unit costs of the initial health screening for new hires in construction range from approximately $394 to $429.

In accordance with paragraph (h)(3) of the proposed rule, the periodic medical examination (every third year after the initial health screening) would consist of (1) a medical and work history review and update, (2) a physical examination with special emphasis on the respiratory system, (3) a chest X-ray that meets certain standards of the International Labour Organization, (4) a pulmonary function test that meets certain criteria and is administered by a spirometry technician with current certification

from a NIOSH-approved spirometry course, (5) testing for latent TB infection, if recommended by the PLHCP, and (6) any other tests deemed appropriate by the PLHCP.

The estimated unit cost of periodic health screening also includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. As shown in Table V–10 in the PEA, these triennial unit costs in general industry and maritime vary from $378 to $397. For construction, as shown in Table V–39 in the PEA, the triennial unit costs for periodic health screening vary from roughly $389 to $425. The variation in the unit cost (with or without the chest X-ray and pulmonary function test) is due entirely to differences in the percentage of workers expected to travel offsite for the periodic health screening. OSHA estimated that the share of workers traveling offsite, as a function of establishment size, would be the same for the periodic health screening as for the initial health screening for existing employees.

ERG (2013) estimated a turnover rate of 27.2 percent in general industry and maritime and 64.0 percent in construction, based on estimates of the separations rate (layoffs, quits, and retirements) provided by the Bureau of Labor Statistics (BLS, 2007). However, not all new hires would require initial medical testing. As specified in paragraph (h)(2) of the proposed rule, employees who had received a qualifying medical examination within the previous twelve months would be exempt from the initial medical examination. OSHA estimates that 25 percent of new hires in general industry and maritime and 60 percent of new hires in construction would be exempt from the initial medical examination.

Although OSHA believes that some affected establishments in general industry, maritime, and construction currently provide some medical testing to their silica-exposed employees, the Agency doubts that many provide the comprehensive health screening required under the proposed rule. Therefore for costing purposes for the proposed rule, OSHA has assumed no current compliance with the proposed health screening requirements. OSHA requests information from interested parties on the current levels and the comprehensiveness of health screening in general industry, maritime, and construction.

Finally, OSHA estimated the unit cost of a medical examination by a pulmonary specialist for those employees found to have signs or symptoms of silica-related disease or are otherwise referred by the PLHCP. OSHA estimates that a medical examination by a pulmonary specialist costs approximately $307 for workers in general industry and maritime and $333 for workers in construction. This cost includes direct medical costs, the opportunity cost of worker time, and recordkeeping costs. In all cases, OSHA anticipates that the worker will travel offsite to receive the medical examination by a pulmonary specialist.

See Chapter V in the PEA for a full discussion of OSHA's analysis of medical surveillance costs under the proposed standard.

e. Information and Training

As specified in paragraph (i) of the proposed rule and 29 CFR 1910.1200, training is required for all employees in jobs where there is potential exposure to respirable crystalline silica. In addition, new hires would require training before starting work. As previously noted, ERG (2013) provided an estimate of the new-hire rate in general industry and maritime, based on the BLS-estimated separations rate of 27.2 percent in manufacturing, and an estimate of the new-hire rate in construction, based on the BLS-estimated separations rate in construction of 64.0 percent.

OSHA estimated separate costs for initial training of current employees and for training new hires. Given that new-hire training might need to be performed frequently during the year, OSHA estimated a smaller class size for new hires. OSHA anticipates that training, in accordance with the requirements of the proposed rule, will be conducted by in-house safety or supervisory staff with the use of training modules or videos and will last, on average, one hour. ERG (2007b) judged that establishments could purchase sufficient training materials at an average cost of $2 per worker, encompassing the cost of handouts, video presentations, and training manuals and exercises. ERG (2013) included in the cost estimates for training the value of worker and trainer time as measured by 2009 hourly wage rates (to include fringe benefits). ERG also developed estimates of average class sizes as a function of establishment size. For initial training, ERG estimated an average class size of 5 workers for establishments with fewer than 20 employees, 10 workers for establishments with 20 to 499 employees, and 20 workers for establishments with 500 or more employees. For new hire training, ERG estimated an average class size of 2 workers for establishments with fewer than 20 employees, 5 workers for establishments with 20 to 499 employees, and 10 workers for establishments with 500 or more employees.

The unit costs of training are presented in Tables V–14 (for general industry/maritime) and V–43 (for construction) in the PEA. Based on ERG's work, OSHA estimated the annualized cost (annualized over 10 years) of initial training per current employee at between $3.02 and $3.57 and the annual cost of new-hire training at between $22.50 and $32.72 per employee in general industry and maritime, depending on establishment size. For construction, OSHA estimated the annualized cost of initial training per employee at between $3.68 and $4.37 and the annual cost of new hire training at between $27.46 and $40.39 per employee, depending on establishment size.

OSHA recognizes that many affected establishments currently provide training on the hazards of respirable crystalline silica in the workplace. Consistent with some estimates developed by ERG (2007a and 2007b), OSHA estimates that 50 percent of affected establishments already provide such training. However, some of the training specified in the proposed rule requires that workers be familiar with the training and medical surveillance provisions in the rule. OSHA expects that these training requirements in the proposed rule are not currently being provided. Therefore, for costing purposes for the proposed rule, OSHA has estimated that 50 percent of affected establishments currently provide their workers, and would provide new hires, with training that would comply with approximately 50 percent of the training requirements. In other words, OSHA estimates that those 50 percent of establishments currently providing training on workplace silica hazards would provide an additional 30 minutes of training to comply with the proposed rule; the remaining 50 percent of establishments would provide 60 minutes of training to comply with the proposed rule. OSHA also recognizes that many new hires may have been previously employed in the same industry, and in some cases by the same establishment, so that they might have already received (partial) silica training. However, for purposes of cost estimation, OSHA estimates that all new hires will receive the full silica training from the new employer. OSHA requests comments from interested parties on the reasonableness of these assumptions.

f. Regulated Areas and Access Control

Paragraph (e)(1) of the proposed standard requires that wherever an

employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) or an access control plan in accordance with paragraph (e)(3). For costing purposes, OSHA estimated that employers in general industry and maritime would typically prefer and choose option (e)(2) and would therefore establish regulated areas when an employee's exposure to airborne concentrations of silica exceeds, or can reasonably be expected to exceed, the PEL. OSHA believes that general industry and maritime employers will prefer this option as it is expected to be the most practical alternative in fixed worksites. Requirements in the proposed rule for a regulated area include demarcating the boundaries of the regulated area (as separate from the rest of the workplace), limiting access to the regulated area, providing an appropriate respirator to each employee entering the regulated area, and providing protective clothing as needed in the regulated area.

Based on ERG (2007b), OSHA derived unit cost estimates for establishing and maintaining regulated areas to comply with these requirements and estimated that one area would be necessary for every eight workers in general industry and maritime exposed above the PEL. Unit costs include planning time (estimated at eight hours of supervisor time annually); material costs for signs and boundary markers (annualized at $63.64 in 2009 dollars); and costs of $500 annually for two disposable respirators per day to be used by authorized persons (other than those who regularly work in the regulated area) who might need to enter the area in the course of their job duties. In addition, for costing purposes, OSHA estimates that, in response to the protective work clothing requirements in regulated areas, ten percent of employees in regulated areas would wear disposable protective clothing daily, estimated at $5.50 per suit, for an annual clothing cost of $1,100 per regulated area. Tables V–16 in the PEA shows the cost assumptions and unit costs applied in OSHA's cost model for regulated areas in general industry and maritime. Overall, OSHA estimates that each regulated area would, on average, cost employers $1,732 annually in general industry and maritime.

For construction, OSHA estimated that some employers would select the (e)(2) option concerning regulated areas while other employers would prefer the (e)(3) option concerning written access control plans whenever an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Based on the respirator specifications developed by ERG (2007a) and shown in Table V–34 in the PEA, ERG derived the full-time-equivalent number of workers engaged in construction tasks where respirators are required and estimated the costs of establishing a regulated area for these workers.

Under the second option for written access control plans, the employer must include the following elements in the plan: competent person provisions; notification and demarcation procedures; multi-employer workplace procedures; provisions for limiting access; provisions for supplying respirators; and protective clothing procedures. OSHA anticipates that employers will incur costs for labor, materials, respiratory protection, and protective clothing to comply with the proposed access control plan requirements.

Table V–45 in the PEA shows the unit costs and assumptions for developing costs for regulated areas and for access control plans in construction. ERG estimated separate development and implementation costs. ERG judged that developing either a regulated area or an access control plan would take approximately 4 hours of a supervisor's time. The time allowed to set up a regulated area or an access control plan is intended to allow for the communication of access restrictions and locations at multi-employer worksites. ERG estimated a cost of $116 per job based on job frequency and the costs for hazard tape and warning signs (which are reusable). ERG estimated a labor cost of $27 per job for implementing a written access control plan (covering the time expended for revision of the access control plan for individual jobs and communication of the plan). In addition, OSHA estimated that there would be annual disposable clothing costs of $333 per crew for employers who implement either regulated areas or the access control plan option. In addition, OSHA estimated that there would be annual respirator costs of $60 per crew for employers who implement either option.

ERG aggregated costs by estimating an average crew size of four in construction and an average job length of ten days. ERG judged that employers would choose to establish regulated areas in 75 percent of the instances where either regulated areas or an access control plan is required, and that written access control plans would be established for the remaining 25 percent.

See Chapter V in the PEA for a full discussion of OSHA's analysis of costs for regulated areas and written access control plans under the proposed standard.

F. Economic Feasibility Analysis and Regulatory Flexibility Determination

Chapter VI of the PEA presents OSHA's analysis of the economic impacts of its proposed silica rule on affected employers in general industry, maritime, and construction. The discussion below summarizes the findings in that chapter.

As a first step, the Agency explains its approach for achieving the two major objectives of its economic impact analysis: (1) To establish whether the proposed rule is economically feasible for all affected industries, and (2) to determine if the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. Next, this approach is applied to industries with affected employers in general industry and maritime and then to industries with affected employers in construction. Finally, OSHA directed Inforum—a not-for-profit corporation (based at the University of Maryland) specializing in the design and application of macroeconomic models of the United States (and other countries)—to estimate the industry and aggregate employment effects of the proposed silica rule. The Agency invites comment on any aspect of the methods and data presented here or in Chapter VI of the PEA.

1. Analytic Approach

a. Economic Feasibility

The Court of Appeals for the D.C. Circuit has long held that OSHA standards are economically feasible so long as their costs do not threaten the existence of, or cause massive economic dislocations within, a particular industry or alter the competitive structure of that industry. *American Iron and Steel Institute.* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991); *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1265 (D.C. Cir. 1980); *Industrial Union Department* v. *Hodgson,* 499 F.2d 467, 478 (D.C. Cir. 1974).

In practice, the economic burden of an OSHA standard on an industry—and whether the standard is economically feasible for that industry—depends on the magnitude of compliance costs incurred by establishments in that industry and the extent to which they

are able to pass those costs on to their customers. That, in turn, depends, to a significant degree, on the price elasticity of demand for the products sold by establishments in that industry.

The price elasticity of demand refers to the relationship between the price charged for a product and the demand for that product: the more elastic the relationship, the less an establishment's compliance costs can be passed through to customers in the form of a price increase and the more it has to absorb compliance costs in the form of reduced profits. When demand is inelastic, establishments can recover most of the costs of compliance by raising the prices they charge; under this scenario, profit rates are largely unchanged and the industry remains largely unaffected. Any impacts are primarily on those customers using the relevant product. On the other hand, when demand is elastic, establishments cannot recover all compliance costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean reductions both in the quantity of goods and services produced and in total profits, though the profit rate may remain unchanged. In general, ''[w]hen an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *American Dental Association* v. *Secretary of Labor* (984 F.2d 823, 829 (7th Cir. 1993)).

The court's summary is in accord with microeconomic theory. In the long run, firms can remain in business only if their profits are adequate to provide a return on investment that ensures that investment in the industry will continue. Over time, because of rising real incomes and productivity increases, firms in most industries are able to ensure an adequate profit. As technology and costs change, however, the long-run demand for some products naturally increases and the long-run demand for other products naturally decreases. In the face of additional compliance costs (or other external costs), firms that otherwise have a profitable line of business may have to increase prices to stay viable. Increases in prices typically result in reduced quantity demanded, but rarely eliminate all demand for the product. Whether this decrease in the total production of goods and services results in smaller output for each establishment within the industry or the closure of some plants within the industry, or a combination of the two, is dependent on the cost and profit structure of individual firms within the industry.

If demand is perfectly inelastic (*i.e.,* the price elasticity of demand is zero), then the impact of compliance costs that are 1 percent of revenues for each firm in the industry would result in a 1 percent increase in the price of the product, with no decline in quantity demanded. Such a situation represents an extreme case, but might be observed in situations in which there were few if any substitutes for the product in question, or if the products of the affected sector account for only a very small portion of the revenue or income of its customers.

If the demand is perfectly elastic (*i.e.,* the price elasticity of demand is infinitely large), then no increase in price is possible and before-tax profits would be reduced by an amount equal to the costs of compliance (net of any cost savings—such as reduced workers' compensation insurance premiums—resulting from the proposed standard) if the industry attempted to maintain production at the same level as previously. Under this scenario, if the costs of compliance are such a large percentage of profits that some or all plants in the industry could no longer operate in the industry with hope of an adequate return on investment, then some or all of the firms in the industry would close. This scenario is highly unlikely to occur, however, because it can only arise when there are other products—unaffected by the proposed rule—that are, in the eyes of their customers, perfect substitutes for the products the affected establishments make.

A common intermediate case would be a price elasticity of demand of one (in absolute terms). In this situation, if the costs of compliance amount to 1 percent of revenues, then production would decline by 1 percent and prices would rise by 1 percent. As a result, industry revenues would remain the same, with somewhat lower production, but with similar profit rates (in most situations where the marginal costs of production net of regulatory costs would fall as well). Customers would, however, receive less of the product for their (same) expenditures, and firms would have lower total profits; this, as the court described in *American Dental Association* v. *Secretary of Labor,* is the more typical case.

A decline in output as a result of an increase in price may occur in a variety of ways: individual establishments could each reduce their levels of production; some marginal plants could close; or, in the case of an expanding industry, new entry may be delayed until demand equals supply. In many cases it will be a combination of all three kinds of reductions in output. Which possibility is most likely depends on the form that the costs of the regulation take. If the costs are variable costs (*i.e.,* costs that vary with the level of production at a facility), then economic theory suggests that any reductions in output will take the form of reductions in output at each affected facility, with few if any plant closures. If, on the other hand, the costs of a regulation primarily take the form of fixed costs (*i.e.,* costs that do not vary with the level of production at a facility), then reductions in output are more likely to take the form of plant closures or delays in new entry.

Most of the costs of this regulation, as estimated in Chapter V of the PEA, are variable costs. Almost all of the major costs of program elements, such as medical surveillance and training, will vary in proportion to the number of employees (which is a rough proxy for the amount of production). Exposure monitoring costs will vary with the number of employees, but do have some economies of scale to the extent that a larger firm need only conduct representative sampling rather than sample every employee. The costs of engineering controls in construction also vary by level of production because almost all necessary equipment can readily be rented and the productivity costs of using some of these controls vary proportionally to the level of production. Finally, the costs of operating engineering controls in general industry (the majority of the annualized costs of engineering controls in general industry) vary by the number of hours the establishment works, and thus vary by the level of production and are not fixed costs in the strictest sense.

This leaves two kinds of costs that are, in some sense, fixed costs—capital costs of engineering controls in general industry and certain initial costs that new entries to the industry will not have to bear.

Capital costs of engineering controls in general industry due to this standard are relatively small as compared to the total costs, representing less than 8 percent of total annualized costs and approximately $362 per year per affected establishment in general industry.

Some initial costs are fixed in the sense that they will only be borne by firms in the industry today—these include initial costs for general training not currently required and initial costs of medical surveillance. Both of these costs will disappear after the initial year of the standard and thus would be

difficult to pass on. These costs, however, represent less than 4 percent of total costs and less than $55 per affected establishment.

As a result of these considerations, OSHA expects that it is somewhat more likely that reductions in industry output will be met by reductions in output at each affected facility rather than as a result of plant closures. However, closures of some marginal plants or poorly performing facilities are always possible.

To determine whether a rule is economically feasible, OSHA begins with two screening tests to consider minimum threshold effects of the rule under two extreme cases: (1) all costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero), and (2) all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In the former case, the immediate impact of the rule would be observed in increased industry revenues. While there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Retrospective studies of previous OSHA regulations have shown that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure,[19] particularly since most industries have at least some ability to raise prices to reflect increased costs and, as shown in the PEA, normal price variations for products typically exceed three percent a year. Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis.

In the latter case, the immediate impact of the rule would be observed in reduced industry profits. OSHA uses the ratio of annualized costs to annual profits as a second check on economic feasibility. Again, while there is no hard and fast rule, in the absence of evidence to the contrary, OSHA has historically considered a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. In the context of economic feasibility, the Agency believes this threshold level to be fairly modest, given that—as shown in the PEA—normal year-to-year variations in profit rates in an industry can exceed 40 percent or more. OSHA's choice of a threshold level of ten percent of annual profits is low enough that even if, in a hypothetical worst case, all compliance costs were upfront costs, then upfront costs would still equal seventy-one percent of profits and thus would be affordable from profits without resort to credit markets. If the threshold level were *first-year* costs of ten percent of annual profits, firms could even more easily expect to cover first-year costs at the threshold level out of current profits without having to access capital markets and otherwise being threatened with short-term insolvency.

In general, because it is usually the case that firms would able to pass on some or all of the costs of the proposed rule, OSHA will tend to give much more weight to the ratio of industry costs to industry revenues than to the ratio of industry costs to industry profits. However, if costs exceed either the threshold percentage of revenue or the threshold percentage of profits for an industry, or if there is other evidence of a threat to the viability of an industry because of the standard, OSHA will examine the effect of the rule on that industry more closely. Such an examination would include market factors specific to the industry, such as normal variations in prices and profits, international trade and foreign competition, and any special circumstances, such as close domestic substitutes of equal cost, which might make the industry particularly vulnerable to a regulatory cost increase.

The preceding discussion focused on the economic viability of the affected industries in their entirety. However, even if OSHA found that a proposed standard did not threaten the survival of affected industries, there is still the question of whether the industries' competitive structure would be significantly altered. For this reason, OSHA also examines the differential costs by size of firm.

b. Regulatory Flexibility Screening Analysis

The Regulatory Flexibility Act (RFA), Pub. L. No. 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601), requires Federal agencies to consider the economic impact that a proposed rulemaking will have on small entities. The RFA states that whenever a Federal agency is required to publish general notice of proposed rulemaking for any proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA). 5 U.S.C. 603(a). Pursuant to section 605(b), in lieu of an IRFA, the head of an agency may certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. A certification must be supported by a factual basis. If the head of an agency makes a certification, the agency shall publish such certification in the **Federal Register** at the time of publication of general notice of proposed rulemaking or at the time of publication of the final rule. 5 U.S.C. 605(b).

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. These screening tests are similar in concept to those OSHA developed above to identify minimum threshold effects for purposes of demonstrating economic feasibility.

There are, however, two differences. First, for each affected industry, the screening tests are applied, not to all establishments, but to small entities (defined as ''small business concerns'' by SBA) and also to very small entities (defined by OSHA as entities with fewer than 20 employees). Second, although OSHA's regulatory flexibility screening test for revenues also uses a minimum threshold level of annualized costs equal to one percent of annual revenues, OSHA has established a minimum threshold level of annualized costs equal to five percent of annual profits for the average small entity or very small entity. The Agency has chosen a lower minimum threshold level for the profitability screening analysis and has applied its screening tests to both small entities and very small entities in order to ensure that certification will be made, and an IRFA will not be prepared, only if OSHA can be highly confident that a proposed rule will not have a significant economic impact on a substantial number of small entities in any affected industry.

2. Impacts in General Industry and Maritime

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed rule's projected costs of compliance would threaten the economic viability of affected industries, OSHA first compared, for each affected industry, annualized compliance costs to annual revenues and profits per (average)

[19] See OSHA's Web page, *http://www.osha.gov/dea/lookback.html#Completed,* for a link to all completed OSHA lookback reviews.

affected establishment. The results for all affected establishments in all affected industries in general industry and maritime are presented in Table VIII–11, using annualized costs per establishment for the proposed 50 μg/m^3 PEL. Shown in the table for each affected industry are total annualized costs, the total number of affected establishments, annualized costs per affected establishment, annual revenues per establishment, the profit rate, annual profits per establishment, annualized compliance costs as a percentage of annual revenues, and annualized compliance costs as a percentage of annual profits.

The annualized costs per affected establishment for each affected industry were calculated by distributing the industry-level (incremental) annualized compliance costs among all affected establishments in the industry, where costs were annualized using a 7 percent discount rate. The annualized cost of the proposed rule for the average establishment in all of general industry and maritime is estimated at $2,571 in 2009 dollars. It is clear from Table VIII–11 that the estimates of the annualized costs per affected establishment in general industry and maritime vary widely from industry to industry. These estimates range from $40,468 for NAICS 327111 (Vitreous china plumbing fixtures and bathroom accessories manufacturing) and $38,422 for NAICS 327121 (Brick and structural clay manufacturing) to $107 for NAICS 325510 (Paint and coating manufacturing) and $49 for NAICS 621210 (Dental offices).

Table VIII–11 also shows that, within the general industry and maritime sectors, there are no industries in which the annualized costs of the proposed rule exceed 1 percent of annual revenues or 10 percent of annual profits. NAICS 327123 (Other structural clay product manufacturing) has both the highest cost impact as a percentage of revenues, of 0.39 percent, and the highest cost impact as a percentage of profits, of 8.78 percent. Based on these results, even if the costs of the proposed rule were 50 percent higher than OSHA has estimated, the highest cost impact as a percentage of revenues in any affected industry in general industry or maritime would be less than 0.6 percent. Furthermore, the costs of the proposed rule would have to be more than 150 percent higher than OSHA has estimated for the cost impact as a percentage of revenues to equal 1 percent in any affected industry. For all affected establishments in general industry and maritime, the estimated annualized cost of the proposed rule is, on average, equal to 0.02 percent of annual revenue and 0.5 percent of annual profit.

TABLE VIII–11—SCREENING ANALYSIS FOR ESTABLISHMENTS IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$242,070	1,431	$169	$6,617,887	7.50	$496,420	0.00	0.03
324122	Asphalt shingle and roofing materials	3,157,257	224	14,095	34,018,437	7.50	2,551,788	0.04	0.55
325510	Paint and coating manufacturing	144,281	1,344	107	19,071,850	5.38	1,026,902	0.00	0.01
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	1,659,194	41	40,468	21,226,709	4.41	937,141	0.19	4.32
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	2,601,471	731	3,559	1,203,017	4.41	53,112	0.30	6.70
327113	Porcelain electrical supply mfg	1,748,297	125	13,986	8,091,258	4.41	357,222	0.17	3.92
327121	Brick and structural clay mfg	7,838,050	204	38,422	11,440,887	4.41	505,105	0.34	7.61
327122	Ceramic wall and floor tile mfg	4,132,107	193	21,410	6,706,175	4.41	296,072	0.32	7.23
327123	Other structural clay product mfg	936,699	49	19,116	4,933,258	4.41	217,799	0.39	8.78
327124	Clay refractory manufacturing	482,438	129	3,740	7,872,516	4.41	347,565	0.05	1.08
327125	Nonclay refractory manufacturing	608,017	105	5,791	14,718,533	4.41	649,810	0.04	0.89
327211	Flat glass manufacturing	275,155	83	3,315	43,821,692	3.42	1,499,102	0.01	0.22
327212	Other pressed and blown glass and glassware manufacturing.	1,084,706	499	2,174	7,233,509	3.42	247,452	0.03	0.88
327213	Glass container manufacturing	756,888	72	10,512	64,453,615	3.42	2,204,903	0.02	0.48
327320	Ready-mixed concrete manufacturing	16,511,080	6,064	2,723	4,891,554	6.64	324,706	0.06	0.84
327331	Concrete block and brick mfg	4,437,939	951	4,667	5,731,328	6.64	380,451	0.08	1.23
327332	Concrete pipe mfg	2,747,484	385	7,136	7,899,352	6.64	524,366	0.09	1.36
327390	Other concrete product mfg	12,900,251	2,281	5,656	4,816,851	6.64	319,747	0.12	1.77
327991	Cut stone and stone product manufacturing	8,600,298	1,943	4,426	1,918,745	5.49	105,320	0.23	4.20
327992	Ground or treated mineral and earth manufacturing	4,595,006	271	16,956	8,652,610	5.49	474,944	0.20	3.57
327993	Mineral wool manufacturing	1,094,552	321	3,410	18,988,835	5.49	1,042,303	0.02	0.33
327999	All other misc. nonmetallic mineral product mfg	1,966,052	465	4,228	5,803,139	5.49	318,536	0.07	1.33
331111	Iron and steel mills	424,557	614	692	70,641,523	4.49	3,173,209	0.00	0.02
331112	Electrometallurgical ferroalloy product manufacturing	8,577	12	692	49,659,392	4.49	2,230,694	0.00	0.03
331210	Iron and steel pipe and tube manufacturing from purchased steel.	84,537	122	694	31,069,797	4.49	1,395,652	0.00	0.05
331221	Rolled steel shape manufacturing	42,672	61	694	28,102,003	4.49	1,262,339	0.00	0.05
331222	Steel wire drawing	57,557	83	694	12,904,028	4.49	579,647	0.01	0.12
331314	Secondary smelting and alloying of aluminum	28,757	42	692	29,333,260	4.46	1,309,709	0.00	0.05
331423	Secondary smelting, refining, and alloying of copper	4,940	7	695	26,238,546	4.42	1,158,438	0.00	0.06
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	36,946	53	695	14,759,299	4.42	651,626	0.00	0.11
331511	Iron foundries	15,310,815	527	29,053	19,672,534	4.11	809,290	0.15	3.59
331512	Steel investment foundries	4,283,138	132	32,448	18,445,040	4.11	758,794	0.18	4.28
331513	Steel foundries (except investment)	4,596,837	222	20,706	17,431,292	4.11	717,090	0.12	2.89
331524	Aluminum foundries (except die-casting)	6,975,150	466	14,968	8,244,396	4.11	339,159	0.18	4.41
331525	Copper foundries (except die-casting)	1,636,463	256	6,392	3,103,580	4.11	127,675	0.21	5.01
331528	Other nonferrous foundries (except die-casting)	1,232,708	124	9,941	7,040,818	4.11	289,646	0.14	3.43
332111	Iron and steel forging	105,955	150	705	15,231,376	4.71	716,646	0.00	0.10
332112	Nonferrous forging	34,982	50	705	28,714,500	4.71	1,351,035	0.00	0.05
332115	Crown and closure manufacturing	12,720	18	697	16,308,872	4.71	767,343	0.00	0.09
332116	Metal stamping	255,832	366	700	6,748,606	4.71	317,526	0.01	0.22
332117	Powder metallurgy part manufacturing	32,828	47	696	9,712,731	4.71	456,990	0.01	0.15
332211	Cutlery and flatware (except precious) manufacturing	22,970	33	705	9,036,720	5.22	472,045	0.01	0.15
332212	Hand and edge tool manufacturing	145,223	207	702	5,874,133	5.22	306,843	0.01	0.23
332213	Saw blade and handsaw manufacturing	28,851	41	698	11,339,439	5.22	592,331	0.01	0.12
332214	Kitchen utensil, pot, and pan manufacturing	15,678	22	705	18,620,983	5.22	972,693	0.00	0.07
332323	Ornamental and architectural metal work	35,267	54	654	2,777,899	4.70	130,669	0.02	0.50
332439	Other metal container manufacturing	60,330	86	705	7,467,745	3.58	267,613	0.01	0.26
332510	Hardware manufacturing	180,292	256	705	11,899,309	5.22	621,577	0.01	0.11
332611	Spring (heavy gauge) manufacturing	16,158	23	705	7,764,934	5.22	405,612	0.01	0.17
332612	Spring (light gauge) manufacturing	60,992	87	705	8,185,896	5.22	427,602	0.01	0.16
332618	Other fabricated wire product manufacturing	144,819	205	705	5,120,358	5.22	267,469	0.01	0.26
332710	Machine shops	1,077,759	1,506	716	1,624,814	5.80	94,209	0.04	0.76
332812	Metal coating and allied services	3,038,935	2,599	1,169	4,503,334	4.85	218,618	0.03	0.53
332911	Industrial valve manufacturing	150,261	216	694	18,399,215	6.81	1,252,418	0.00	0.06

TABLE VIII–11—SCREENING ANALYSIS FOR ESTABLISHMENTS IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
332912	Fluid power valve and hose fitting manufacturing	140,213	201	698	22,442,750	6.81	1,527,658	0.00	0.05
332913	Plumbing fixture fitting and trim manufacturing	45,472	65	698	24,186,039	6.81	1,646,322	0.00	0.04
332919	Other metal valve and pipe fitting manufacturing	71,354	102	698	15,023,143	6.81	1,022,612	0.00	0.07
332991	Ball and roller bearing manufacturing	107,338	154	698	36,607,380	6.81	2,491,832	0.00	0.03
332996	Fabricated pipe and pipe fitting manufacturing	107,219	154	698	6,779,536	6.81	461,477	0.01	0.15
332997	Industrial pattern manufacturing	20,891	30	698	1,122,819	6.81	76,429	0.06	0.91
332998	Enameled iron and metal sanitary ware manufacturing.	60,684	76	798	14,497,312	6.81	986,819	0.01	0.08
332999	All other miscellaneous fabricated metal product manufacturing.	288,093	408	707	4,405,921	6.81	299,907	0.02	0.24
333319	Other commercial and service industry machinery manufacturing.	209,273	299	699	10,042,625	4.86	487,919	0.01	0.14
333411	Air purification equipment manufacturing	58,265	84	694	7,353,577	4.55	334,804	0.01	0.21
333412	Industrial and commercial fan and blower manufacturing.	41,212	59	694	12,795,249	4.55	582,559	0.01	0.12
333414	Heating equipment (except warm air furnaces) manufacturing.	80,754	116	694	11,143,189	4.55	507,342	0.01	0.14
333511	Industrial mold manufacturing	160,131	226	710	2,481,931	5.29	131,278	0.03	0.54
333512	Machine tool (metal cutting types) manufacturing	68,151	97	702	7,371,252	5.29	389,890	0.01	0.18
333513	Machine tool (metal forming types) manufacturing	33,940	48	702	5,217,940	5.29	275,994	0.01	0.25
333514	Special die and tool, die set, jig, and fixture manufacturing.	231,988	325	714	2,378,801	5.29	125,823	0.03	0.57
333515	Cutting tool and machine tool accessory manufacturing.	139,916	197	710	3,384,805	5.29	179,034	0.02	0.40
333516	Rolling mill machinery and equipment manufacturing	12,279	17	710	9,496,141	5.29	502,283	0.01	0.14
333518	Other metalworking machinery manufacturing	50,002	70	710	7,231,602	5.29	382,504	0.01	0.19
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	48,452	70	693	10,727,834	2.63	281,813	0.01	0.25
333613	Mechanical power transmission equipment manufacturing.	61,197	88	693	14,983,120	2.63	393,597	0.00	0.18
333911	Pump and pumping equipment manufacturing	121,086	174	696	17,078,357	4.58	781,566	0.00	0.09
333912	Air and gas compressor manufacturing	84,518	121	698	21,079,073	4.58	964,653	0.00	0.07
333991	Power-driven handtool manufacturing	34,459	49	698	22,078,371	4.58	1,010,384	0.00	0.07
333992	Welding and soldering equipment manufacturing	62,401	90	696	16,457,683	4.58	753,162	0.00	0.09
333993	Packaging machinery manufacturing	83,714	120	700	7,374,940	4.58	337,503	0.01	0.21
333994	Industrial process furnace and oven manufacturing	42,523	61	702	5,584,460	4.58	255,565	0.01	0.27
333995	Fluid power cylinder and actuator manufacturing	78,057	112	695	13,301,790	4.58	608,737	0.01	0.11
333996	Fluid power pump and motor manufacturing	53,535	77	695	18,030,122	4.58	825,122	0.00	0.08
333997	Scale and balance (except laboratory) manufacturing	14,822	21	702	7,236,854	4.58	331,184	0.01	0.21
333999	All other miscellaneous general purpose machinery manufacturing.	207,006	296	698	6,033,776	4.58	276,127	0.01	0.25
334518	Watch, clock, and part manufacturing	8,740	12	703	4,924,986	5.94	292,667	0.01	0.24
335211	Electric housewares and household fans	13,928	22	643	22,023,076	4.21	927,874	0.00	0.07
335221	Household cooking appliance manufacturing	30,077	47	643	37,936,003	4.21	1,598,316	0.00	0.04
335222	Household refrigerator and home freezer manufacturing.	32,118	26	1,235	188,132,355	4.21	7,926,376	0.00	0.02
335224	Household laundry equipment manufacturing	30,521	23	1,327	221,491,837	4.21	9,331,875	0.00	0.01
335228	Other major household appliance manufacturing	24,023	37	643	107,476,620	4.21	4,528,196	0.00	0.01
336111	Automobile manufacturing	293,357	181	1,621	512,748,675	2.04	10,462,470	0.00	0.02
336112	Light truck and utility vehicle manufacturing	404,778	94	4,306	1,581,224,101	2.04	32,264,364	0.00	0.01
336120	Heavy duty truck manufacturing	125,181	95	1,318	194,549,998	2.04	3,969,729	0.00	0.03
336211	Motor vehicle body manufacturing	187,131	269	696	15,012,805	2.04	306,331	0.00	0.23
336212	Truck trailer manufacturing	126,512	182	694	17,032,455	2.04	347,542	0.00	0.20
336213	Motor home manufacturing	84,073	91	924	65,421,325	2.04	1,334,901	0.00	0.07
336311	Carburetor, piston, piston ring, and valve manufacturing.	41,219	60	693	21,325,990	2.04	435,150	0.00	0.16
336312	Gasoline engine and engine parts manufacturing	258,625	373	693	36,938,061	2.04	753,709	0.00	0.09

336322	Other motor vehicle electrical and electronic equipment manufacturing.	242,586	350	693	33,890,776	2.04	691,530	0.00	0.10
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	153,960	223	692	42,374,501	2.04	864,638	0.00	0.08
336340	Motor vehicle brake system manufacturing	132,114	191	693	51,498,927	2.04	1,050,819	0.00	0.07
336350	Motor vehicle transmission and power train parts manufacturing.	327,377	473	692	63,004,961	2.04	1,285,596	0.00	0.05
336370	Motor vehicle metal stamping	431,985	624	692	33,294,026	2.04	679,354	0.00	0.10
336399	All other motor vehicle parts manufacturing	583,803	843	693	31,304,202	2.04	638,752	0.00	0.11
336611	Ship building and repair	8,749,619	635	13,779	24,524,381	5.86	1,437,564	0.06	0.96
336612	Boat building	5,479,624	1,129	4,854	9,474,540	5.86	555,376	0.05	0.87
336992	Military armored vehicle, tank, and tank component manufacturing.	27,227	39	697	44,887,321	6.31	2,832,073	0.00	0.02
337215	Showcase, partition, shelving, and locker manufacturing.	233,720	334	701	4,943,560	4.54	224,593	0.01	0.31
339114	Dental equipment and supplies manufacturing	351,955	411	856	4,732,949	10.77	509,695	0.02	0.17
339116	Dental laboratories	1,439,004	7,261	198	563,964	10.77	60,734	0.04	0.33
339911	Jewelry (except costume) manufacturing	1,560,353	1,777	878	3,685,009	5.80	213,566	0.02	0.41
339913	Jewelers' materials and lapidary work manufacturing	320,878	264	1,215	3,762,284	5.80	218,045	0.03	0.56
339914	Costume jewelry and novelty manufacturing	236,821	590	401	1,353,403	5.80	78,437	0.03	0.51
339950	Sign manufacturing	294,919	496	594	1,872,356	5.80	108,513	0.03	0.55
423840	Industrial supplies, wholesalers	177,299	383	463	1,913,371	3.44	65,736	0.02	0.70
482110	Rail transportation	2,452,073	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	389,256	7,980	49	755,073	7.34	55,429	0.01	0.09
	Total	146,726,595	56,121	2,571					

[a] Profit rates were calculated by ERG (2013) as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

b. Normal Year-to-Year Variations in Prices and Profit Rates

The United States has a dynamic and constantly changing economy in which an annual percentage increase in industry revenues or prices of one percent or more are common. Examples of year-to-year changes in an industry that could cause such an increase in revenues or prices include increases in fuel, material, real estate, or other costs; tax increases; and shifts in demand.

To demonstrate the normal year-to-year variation in prices for all the manufacturers in general industry and maritime affected by the proposed rule, OSHA developed in the PEA year-to-year producer price indices and year-to-year percentage changes in producer prices, by industry, for the years 1998–2009. For the combined affected manufacturing industries in general industry and maritime over the 12-year period, the average change in producer prices was 3.8 percent a year. For the three industries in general industry and maritime with the largest estimated potential annual cost impact as a percentage of revenue (of approximately 0.35 percent, on average), the average annual changes in producer prices in these industries over the 12-year period averaged 3.5 percent.

Based on these data, it is clear that the potential price impacts of the proposed rule in general industry and maritime are all well within normal year-to-year variations in prices in those industries. Thus, OSHA preliminarily concludes that the potential price impacts of the proposed would not threaten the economic viability of any industries in general industry and maritime.

Changes in profit rates are also subject to the dynamics of the U.S. economy. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers in general industry and maritime affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000–2006. For the combined affected manufacturing industries in general industry and maritime over the 7-year period, the average change in profit rates was 38.9 percent a year. For the 7 industries in general industry and maritime with the largest estimated potential annual cost impacts as a percentage of profit—ranging from 4 percent to 9 percent—the average annual changes in profit rates in these industries over the 7-year period averaged 35 percent.

Nevertheless, a longer-term reduction in profit rates in excess of 10 percent a year could be problematic for some affected industries and might conceivably, under sufficiently adverse circumstances, threaten an industry's economic viability. In OSHA's view, however, affected industries would generally be able to pass on most or all of the costs of the proposed rule in the form of higher prices rather than to bear the costs of the proposed rule in reduced profits. After all, it defies common sense to suggest that the demanded quantities of brick and structural clay, vitreous china, ceramic wall and floor tile, other structural clay products (such as clay sewer pipe), and the various other products manufactured by affected industries would significantly contract in response to a 0.4 percent (or lower) price increase for these products. It is of course possible that such price changes will result in some reduction in output, and the reduction in output might be met through the closure of a small percentage of the plants in the industry. However, the only realistic circumstance such that an entire industry would be significantly affected by small potential price increases would be the availability in the market of a very close or perfect substitute product not subject to OSHA regulation. The classic example, in theory, would be foreign competition. Below, OSHA examines the threat of foreign competition for affected U.S. establishments in general industry and maritime.

c. International Trade Effects

The magnitude and strength of foreign competition is a critical factor in determining the ability of firms in the U.S. to pass on (part or all of) the costs of the proposed rule. If firms are unable to do so, they would likely absorb the costs of the proposed rule out of profits, possibly resulting in the business failure of individual firms or even, if the cost impacts are sufficiently large and pervasive, causing significant dislocations within an affected industry.

In the PEA, OSHA examined how likely such an outcome is. The analysis there included a review of trade theory and empirical evidence and the estimation of impacts. Throughout, the Agency drew on ERG (2007c), which was prepared specifically to help analyze the international trade impacts of OSHA's proposed silica rule. A summary of the PEA results is presented below.

ERG (2007c) focused its analysis on eight of the industries likely to be most affected by the proposed silica rule and for which import and export data were available. ERG combined econometric estimates of the elasticity of substitution between foreign and domestic products, Annual Survey of Manufactures data, and assumptions concerning the values for key parameters to estimate the effect of a range of hypothetical price increases on total domestic production. In particular, ERG estimated the domestic production that would be replaced by imported products and the decrease in exported products that would result from a 1 percent increase in prices—under the assumption that firms would attempt to pass on all of a 1 percent increase in costs arising from the proposed rule. The sum of the increase in imports and decrease in exports represents the total loss to industry attributable to the rule. These projected losses are presented as a percentage of baseline domestic production to provide some context for evaluating the relative size of these impacts.

The effect of a 1 percent increase in the price of a domestic product is derived from the baseline level of U.S. domestic production and the baseline level of imports. The baseline ratio of import values to domestic production for the eight affected industries ranges from 0.04 for iron foundries to 0.547 for ceramic wall and floor tile manufacturing—that is, baseline import values range from 4 percent to more than 50 percent of domestic production in these eight industries. ERG's estimates of the percentage reduction in U.S. production for the eight affected industries due to increased domestic imports (arising from a 1 percent increase in the price of domestic products) range from 0.013 percent for iron foundries to 0.237 percent for cut stone and stone product manufacturing.

ERG also estimated baseline ratio of U.S. exports to consumption in the rest of the world for the sample of eight affected industries. The ratios range from 0.001 for other concrete manufacturing to 0.035 percent for nonclay refractory manufacturing. The estimated percentage reductions in U.S. production due to reduced U.S. exports (arising from a 1 percent increase in the price of domestic products) range from 0.014 percent for ceramic wall and floor tile manufacturing to 0.201 percent for nonclay refractory manufacturing.

The total percentage change in U.S. production for the eight affected industries is the sum of the loss of

increased imports and the loss of exports. The total percentage reduction in U.S. production arising from a 1 percent increase in the price of domestic products range from a low of 0.085 percent for other concrete product manufacturing to a high of 0.299 percent for porcelain electrical supply manufacturing.

These estimates suggest that the proposed rule would have only modest international trade effects. It was previously hypothesized that if price increases resulted in a substantial loss of revenue to foreign competition, then the increased costs of the proposed rule would have to come out of profits. That possibility has been contradicted by the results reported in this section. The maximum loss to foreign competition in any affected industry due to a 1 percent price increase was estimated at approximately 0.3 percent of industry revenue. Because, as reported earlier in this section, the maximum cost impact of the proposed rule for any affected industry would be 0.39 percent of revenue, this means that the maximum loss to foreign competition in any affected industry as a result of the proposed rule would be 0.12 percent of industry revenue—which, even for the most affected industry, would hardly qualify as a substantial loss to foreign competition. This analysis cannot tell us whether the resulting change in revenues will lead to a small decline in the number of establishments in the industry or slightly less revenue for each establishment. However it can reasonably be concluded that revenue changes of this magnitude will not lead to the elimination of industries or significantly alter their competitive structure.

Based on the Agency's preceding analysis of economic impacts on revenues, profits, and international trade, OSHA preliminarily concludes that the annualized costs of the proposed rule are below the threshold level that could threaten the economic viability of any industry in general industry or maritime. OSHA further notes that while there would be additional costs (not attributable to the proposed rule) for some employers in general industry and maritime to come into compliance with the *current* silica standard, these costs would not affect the Agency's preliminary determination of the economic feasibility of the proposed rule.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected industries in their entirety and found that the proposed standard did not threaten the survival of these industries. Now OSHA wishes to demonstrate that the competitive structure of these industries would not be significantly altered.

To address this issue, OSHA examined the annualized costs per affected small entity and per very small entity for each affected industry in general industry and maritime. Again, OSHA used a minimum threshold level of annualized costs equal to one percent of annual revenues—and, secondarily, annualized costs equal to ten percent of annual profits—below which the Agency has concluded that the costs are unlikely to threaten the survival of small entities or very small entities or, consequently, to alter the competitive structure of the affected industries.

As shown in Table VIII–12 and Table VIII–13, the annualized cost of the proposed rule is estimated to be $2,103 for the average small entity in general industry and maritime and $616 for the average very small entity in general industry and maritime. These tables also show that there are no industries in general industry and maritime in which the annualized costs of the proposed rule for small entities or very small entities exceed one percent of annual revenues. NAICS 327111 (Vitreous china plumbing fixtures & bathroom accessories manufacturing) has the highest potential cost impact as a percentage of revenues, of 0.61 percent, for small entities, and NAICS 327112 (Vitreous china, fine earthenware, & other pottery product manufacturing) has the highest potential cost impact as a percentage of revenues, of 0.75 percent, for very small entities. Small entities in two industries in general industry and maritime—NAICS 327111 and NAICS 327123 (Other structural clay product mfg.)—have annualized costs in excess of 10 percent of annual profits (13.91 percent and 10.63 percent, respectively). NAICS 327112 is the only industry in general industry and maritime in which the annualized costs of the proposed rule for very small entities exceed ten percent of annual profits (16.92 percent).

In general, cost impacts for affected small entities or very small entities will tend to be somewhat higher, on average, than the cost impacts for the average business in those affected industries. That is to be expected. After all, smaller businesses typically suffer from diseconomies of scale in many aspects of their business, leading to less revenue per dollar of cost and higher unit costs. Small businesses are able to overcome these obstacles by providing specialized products and services, offering local service and better service, or otherwise creating a market niche for themselves. The higher cost impacts for smaller businesses estimated for this rule generally fall within the range observed in other OSHA regulations and, as verified by OSHA's lookback reviews, have not been of such a magnitude to lead to their economic failure.

TABLE VIII–12—SCREENING ANALYSIS FOR SMALL ENTITIES IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected small entities	Annualized cost per affected entity	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$140,305	431	$326	$10,428,583	7.50	$782,268	0.00	0.04
324122	Asphalt shingle and roofing materials	872,614	106	8,232	14,067,491	7.50	1,055,229	0.06	0.78
325510	Paint and coating manufacturing	71,718	1,042	69	6,392,803	5.38	344,213	0.00	0.02
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	231,845	25	9,274	1,509,677	4.41	66,651	0.61	13.91
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,854,472	717	2,586	693,637	4.41	30,623	0.37	8.45
327113	Porcelain electrical supply mfg	1,004,480	97	10,355	4,574,464	4.41	201,959	0.23	5.13
327121	Brick and structural clay mfg	3,062,272	93	32,928	9,265,846	4.41	409,079	0.36	8.05
327122	Ceramic wall and floor tile mfg	2,189,278	173	12,655	3,236,635	4.41	142,895	0.39	8.86
327123	Other structural clay product mfg	510,811	42	12,162	2,592,114	4.41	114,440	0.47	10.63
327124	Clay refractory manufacturing	212,965	96	2,218	6,026,297	4.41	266,056	0.04	0.83
327125	Nonclay refractory manufacturing	211,512	68	3,110	7,346,739	4.41	324,352	0.04	0.96
327211	Flat glass manufacturing	275,155	56	4,913	64,950,007	3.42	2,221,884	0.01	0.22
327212	Other pressed and blown glass and glassware manufacturing.	243,132	228	1,068	935,353	3.42	31,998	0.11	3.34
327213	Glass container manufacturing	57,797	24	2,408	10,181,980	3.42	348,317	0.02	0.69
327320	Ready-mixed concrete manufacturing	10,490,561	2,401	4,369	7,245,974	6.64	480,994	0.06	0.91
327331	Concrete block and brick mfg	2,862,910	567	5,049	6,318,185	6.64	419,407	0.08	1.20
327332	Concrete pipe mfg	1,441,766	181	7,966	7,852,099	6.64	521,229	0.10	1.53
327390	Other concrete product mfg	8,826,516	1,876	4,705	3,521,965	6.64	233,791	0.13	2.01
327991	Cut stone and stone product manufacturing	8,028,431	1,874	4,284	1,730,741	5.49	95,001	0.25	4.51
327992	Ground or treated mineral and earth manufacturing	2,108,649	132	15,975	6,288,188	5.49	345,160	0.25	4.63
327993	Mineral wool manufacturing	291,145	175	1,664	6,181,590	5.49	339,309	0.03	0.49
327999	All other misc. nonmetallic mineral product mfg	1,130,230	326	3,467	4,299,551	5.49	236,004	0.08	1.47
331111	Iron and steel mills	424,557	523	812	82,895,665	4.49	3,723,664	0.00	0.02
331112	Electrometallurgical ferroalloy product manufacturing	4,987	7	692	24,121,503	4.49	1,083,535	0.00	0.06
331210	Iron and steel pipe and tube manufacturing from purchased steel.	84,537	94	896	40,090,061	4.49	1,800,841	0.00	0.05
331221	Rolled steel shape manufacturing	42,672	54	787	31,848,937	4.49	1,430,651	0.00	0.05
331222	Steel wire drawing	57,557	67	862	16,018,794	4.49	719,562	0.01	0.12
331314	Secondary smelting and alloying of aluminum	15,277	20	777	18,496,524	4.46	825,857	0.00	0.09
331423	Secondary smelting, refining, and alloying of copper	4,206	6	722	20,561,614	4.42	907,800	0.00	0.08
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	18,357	25	741	9,513,728	4.42	420,033	0.01	0.18
331511	Iron foundries	5,312,382	408	13,021	5,865,357	4.11	241,290	0.22	5.40
331512	Steel investment foundries	1,705,373	101	16,885	8,489,826	4.11	349,255	0.20	4.83
331513	Steel foundries (except investment)	2,521,998	192	13,135	11,977,647	4.11	492,738	0.11	2.67
331524	Aluminum foundries (except die-casting)	4,316,135	412	10,476	4,039,244	4.11	166,167	0.26	6.30
331525	Copper foundries (except die-casting)	1,596,288	246	6,489	2,847,376	4.11	117,136	0.23	5.54
331528	Other nonferrous foundries (except die-casting)	620,344	112	5,539	2,640,180	4.11	108,612	0.21	5.10
332111	Iron and steel forging	47,376	63	756	8,310,925	4.71	391,034	0.01	0.19
332112	Nonferrous forging	13,056	17	760	21,892,338	4.71	1,030,048	0.00	0.07
332115	Crown and closure manufacturing	5,080	7	732	6,697,995	4.71	315,145	0.01	0.23
332116	Metal stamping	212,110	279	759	5,360,428	4.71	252,211	0.01	0.30
332117	Powder metallurgy part manufacturing	17,537	23	762	6,328,522	4.71	297,761	0.01	0.26
332211	Cutlery and flatware (except precious) manufacturing	10,419	14	738	2,852,835	5.22	149,022	0.03	0.50
332212	Hand and edge tool manufacturing	87,599	113	772	3,399,782	5.22	177,592	0.02	0.43
332213	Saw blade and handsaw manufacturing	9,221	12	752	5,385,465	5.22	281,317	0.01	0.27
332214	Kitchen utensil, pot, and pan manufacturing	10,475	13	798	10,355,293	5.22	540,923	0.01	0.15
332323	Ornamental and architectural metal work	28,608	42	673	2,069,492	4.70	97,346	0.03	0.69
332439	Other metal container manufacturing	43,857	56	784	5,260,693	3.58	188,521	0.01	0.42
332510	Hardware manufacturing	78,538	104	756	4,442,699	5.22	232,070	0.02	0.33
332611	Spring (heavy gauge) manufacturing	14,071	19	754	6,621,896	5.22	345,904	0.01	0.22
332612	Spring (light gauge) manufacturing	36,826	44	834	4,500,760	5.22	235,103	0.02	0.35
332618	Other fabricated wire product manufacturing	113,603	148	765	3,440,489	5.22	179,719	0.02	0.43
332710	Machine shops	1,032,483	1,399	738	1,464,380	5.80	84,907	0.05	0.87
332812	Metal coating and allied services	2,492,357	2,301	1,083	2,904,851	4.85	141,018	0.04	0.77
332911	Industrial valve manufacturing	53,520	71	752	5,841,019	6.81	397,593	0.01	0.19
332912	Fluid power valve and hose fitting manufacturing	41,712	55	757	6,486,405	6.81	441,524	0.01	0.17

332913	Plumbing fixture fitting and trim manufacturing	19,037	25	752	9,183,477	6.81	625,111	0.01	0.12
332919	Other metal valve and pipe fitting manufacturing	30,618	40	764	9,432,914	6.81	642,090	0.01	0.12
332991	Ball and roller bearing manufacturing	13,624	18	741	5,892,239	6.81	401,079	0.01	0.18
332996	Fabricated pipe and pipe fitting manufacturing	74,633	99	754	4,377,576	6.81	297,978	0.02	0.25
332997	Industrial pattern manufacturing	20,767	28	736	1,127,301	6.81	76,734	0.07	0.96
332998	Enameled iron and metal sanitary ware manufacturing.	13,779	22	630	3,195,173	6.81	217,493	0.02	0.29
332999	All other miscellaneous fabricated metal product manufacturing.	230,825	311	742	2,904,500	6.81	197,707	0.03	0.38
333319	Other commercial and service industry machinery manufacturing.	123,816	165	750	4,960,861	4.86	241,023	0.02	0.31
333411	Air purification equipment manufacturing	27,021	36	748	4,449,669	4.55	202,591	0.02	0.37
333412	Industrial and commercial fan and blower manufacturing.	27,149	34	791	7,928,953	4.55	361,000	0.01	0.22
333414	Heating equipment (except warm air furnaces) manufacturing.	45,308	61	741	5,667,272	4.55	258,027	0.01	0.29
333511	Industrial mold manufacturing	143,216	193	743	2,121,298	5.29	112,203	0.04	0.66
333512	Machine tool (metal cutting types) manufacturing	44,845	60	746	4,136,962	5.29	218,818	0.02	0.34
333513	Machine tool (metal forming types) manufacturing	30,365	40	758	4,358,035	5.29	230,511	0.02	0.33
333514	Special die and tool, die set, jig, and fixture manufacturing.	203,742	274	743	2,083,166	5.29	110,186	0.04	0.67
333515	Cutting tool and machine tool accessory manufacturing.	104,313	140	746	2,082,357	5.29	110,143	0.04	0.68
333516	Rolling mill machinery and equipment manufacturing	9,604	13	744	8,330,543	5.29	440,630	0.01	0.17
333518	Other metalworking machinery manufacturing	38,359	50	765	5,680,062	5.29	300,438	0.01	0.25
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	25,087	32	777	6,028,137	2.63	158,355	0.01	0.49
333613	Mechanical power transmission equipment manufacturing.	26,182	35	754	9,094,798	2.63	238,915	0.01	0.32
333911	Pump and pumping equipment manufacturing	41,360	54	762	6,220,799	4.58	284,686	0.01	0.27
333912	Air and gas compressor manufacturing	23,948	32	758	6,290,845	4.58	287,891	0.01	0.26
333991	Power-driven handtool manufacturing	9,867	13	732	3,816,319	4.58	174,648	0.02	0.42
333992	Welding and soldering equipment manufacturing	23,144	31	745	5,635,771	4.58	257,913	0.01	0.29
333993	Packaging machinery manufacturing	54,872	74	742	4,240,165	4.58	194,045	0.02	0.38
333994	Industrial process furnace and oven manufacturing	34,418	45	757	4,470,378	4.58	204,580	0.02	0.37
333995	Fluid power cylinder and actuator manufacturing	32,249	43	756	5,830,077	4.58	266,805	0.01	0.28
333996	Fluid power pump and motor manufacturing	15,258	20	772	4,401,836	4.58	201,444	0.02	0.38
333997	Scale and balance (except laboratory) manufacturing	12,129	16	764	4,987,858	4.58	228,262	0.02	0.33
333999	All other miscellaneous general purpose machinery manufacturing.	123,384	166	745	3,262,128	4.58	149,287	0.02	0.50
334518	Watch, clock, and part manufacturing	6,646	9	732	2,878,581	5.94	171,059	0.03	0.43
335211	Electric housewares and household fans	3,326	5	643	6,088,365	4.21	256,514	0.01	0.25
335221	Household cooking appliance manufacturing	6,521	10	649	10,460,359	4.21	440,715	0.01	0.15
335222	Household refrigerator and home freezer manufacturing.	32,118	18	1,784	271,746,735	4.21	11,449,210	0.00	0.02
335224	Household laundry equipment manufacturing	30,521	17	1,795	299,665,426	4.21	12,625,478	0.00	0.01
335228	Other major household appliance manufacturing	1,917	3	671	8,269,046	4.21	348,391	0.01	0.19
336111	Automobile manufacturing	293,357	167	1,757	555,733,594	2.04	11,339,563	0.00	0.02
336112	Light truck and utility vehicle manufacturing	404,778	63	6,425	2,359,286,755	2.04	48,140,479	0.00	0.01
336120	Heavy duty truck manufacturing	125,181	77	1,626	240,029,218	2.04	4,897,718	0.00	0.03
336211	Motor vehicle body manufacturing	187,131	239	784	16,910,028	2.04	345,044	0.00	0.23
336212	Truck trailer manufacturing	54,137	72	748	9,018,164	2.04	184,013	0.01	0.41
336213	Motor home manufacturing	84,073	79	1,064	75,358,742	2.04	1,537,671	0.00	0.07
336311	Carburetor, piston, piston ring, and valve manufacturing.	10,269	14	748	2,242,044	2.04	45,748	0.03	1.64
336312	Gasoline engine and engine parts manufacturing	65,767	94	703	4,245,230	2.04	86,623	0.02	0.81
336322	Other motor vehicle electrical and electronic equipment manufacturing.	71,423	101	706	6,746,386	2.04	137,658	0.01	0.51
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	25,492	36	708	7,742,773	2.04	157,989	0.01	0.45
336340	Motor vehicle brake system manufacturing	32,886	46	710	6,554,128	2.04	133,735	0.01	0.53
336350	Motor vehicle transmission and power train parts manufacturing.	46,869	66	710	6,058,947	2.04	123,631	0.01	0.57
336370	Motor vehicle metal stamping	159,156	201	792	11,477,248	2.04	234,190	0.01	0.34
336399	All other motor vehicle parts manufacturing	169,401	235	721	6,985,145	2.04	142,530	0.01	0.51
336611	Ship building and repair	8,749,619	575	15,217	27,083,446	5.86	1,587,570	0.06	0.96

TABLE VIII–12—SCREENING ANALYSIS FOR SMALL ENTITIES IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected small entities	Annualized cost per affected entity	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
336612	Boat building	2,612,088	814	3,209	5,304,212	5.86	310,921	0.06	1.03
336992	Military armored vehicle, tank, and tank component manufacturing.	27,227	32	845	54,437,815	6.31	3,434,642	0.00	0.02
337215	Showcase, partition, shelving, and locker manufacturing.	176,800	235	751	3,637,716	4.54	165,266	0.02	0.45
339114	Dental equipment and supplies manufacturing	261,393	292	895	2,619,222	10.77	282,066	0.03	0.32
339116	Dental laboratories	1,397,271	7,011	199	532,828	10.77	57,381	0.04	0.35
339911	Jewelry (except costume) manufacturing	1,392,054	1,751	795	2,615,940	5.80	151,608	0.03	0.52
339913	Jewelers' materials and lapidary work manufacturing	257,285	258	997	2,775,717	5.80	160,868	0.04	0.62
339914	Costume jewelry and novelty manufacturing	242,158	588	412	971,681	5.80	56,314	0.04	0.73
339950	Sign manufacturing	264,810	428	618	1,642,826	5.80	95,211	0.04	0.65
423840	Industrial supplies, wholesalers	143,614	226	636	5,001,467	3.44	171,830	0.01	0.37
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	370,174	7,423	50	663,948	7.34	48,739	0.01	0.10
	Total	86,520,059	41,136	2,103					

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–13—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Number of affected entities with <20 employees	Annualized costs per affected entities	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
324121	Asphalt paving mixture and block manufacturing	$27,770	260	$107	$4,335,678	7.50	$325,227	0.00	0.03
324122	Asphalt shingle and roofing materials	85,253	57	1,496	4,013,780	7.50	301,081	0.04	0.50
325510	Paint and coating manufacturing	18,910	324	58	1,871,296	5.38	100,758	0.00	0.06
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	26,606	19	1,400	327,368	4.41	14,453	0.43	9.69
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	747,902	645	1,160	155,258	4.41	6,855	0.75	16.92
327113	Porcelain electrical supply mfg	79,824	57	1,400	601,316	4.41	26,548	0.23	5.28
327121	Brick and structural clay mfg	76,696	31	2,474	715,098	4.41	31,571	0.35	7.84
327122	Ceramic wall and floor tile mfg	382,871	136	2,815	807,291	4.41	35,641	0.35	7.90
327123	Other structural clay product mfg	67,176	25	2,687	782,505	4.41	34,547	0.34	7.78
327124	Clay refractory manufacturing	29,861	55	543	1,521,469	4.41	67,172	0.04	0.81
327125	Nonclay refractory manufacturing	34,061	40	852	1,506,151	4.41	66,495	0.06	1.28
327211	Flat glass manufacturing	4,450	4	1,075	905,562	3.42	30,978	0.12	3.47
327212	Other pressed and blown glass and glassware manufacturing.	87,895	79	1,107	370,782	3.42	12,684	0.30	8.73
327213	Glass container manufacturing	4,798	4	1,107	2,690,032	3.42	92,024	0.04	1.20
327320	Ready-mixed concrete manufacturing	1,897,131	1,429	1,328	1,922,659	6.64	127,628	0.07	1.04
327331	Concrete block and brick mfg	544,975	339	1,608	1,995,833	6.64	132,485	0.08	1.21
327332	Concrete pipe mfg	116,670	67	1,741	2,375,117	6.64	157,662	0.07	1.10
327390	Other concrete product mfg	1,885,496	1,326	1,422	974,563	6.64	64,692	0.15	2.20
327991	Cut stone and stone product manufacturing	2,753,051	1,471	1,872	946,566	5.49	51,957	0.20	3.60
327992	Ground or treated mineral and earth manufacturing	389,745	78	4,997	1,635,092	5.49	89,751	0.31	5.57
327993	Mineral wool manufacturing	48,575	46	1,061	1,398,274	5.49	76,752	0.08	1.38
327999	All other misc. nonmetallic mineral product mfg	311,859	235	1,327	1,457,181	5.49	79,985	0.09	1.66
331111	Iron and steel mills	9,342	12	777	4,177,841	4.49	187,668	0.02	0.41
331112	Electrometallurgical ferroalloy product manufacturing	0	0	N/A	1,202,610	4.49	54,021	N/A	N/A
331210	Iron and steel pipe and tube manufacturing from purchased steel.	1,706	2	774	2,113,379	4.49	94,933	0.04	0.82
331221	Rolled steel shape manufacturing	1,612	2	774	2,108,498	4.49	94,713	0.04	0.82

331222	Steel wire drawing	2,939	4	774	835,444	4.49	37,528	0.09	2.06
331314	Secondary smelting and alloying of aluminum	1,254	2	774	2,039,338	4.46	91,055	0.04	0.85
331423	Secondary smelting, refining, and alloying of copper	0	0	N/A	2,729,146	4.42	120,492	N/A	N/A
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	2,897	4	774	1,546,332	4.42	68,271	0.05	1.13
331511	Iron foundries	330,543	201	1,644	1,031,210	4.11	42,422	0.16	3.88
331512	Steel investment foundries	47,902	27	1,774	1,831,394	4.11	75,340	0.10	2.35
331513	Steel foundries (except investment)	162,670	102	1,595	1,577,667	4.11	64,902	0.10	2.46
331524	Aluminum foundries (except die-casting)	503,027	235	2,141	874,058	4.11	35,957	0.24	5.95
331525	Copper foundries (except die-casting)	370,110	164	2,257	814,575	4.11	33,510	0.28	6.73
331528	Other nonferrous foundries (except die-casting)	162,043	77	2,104	837,457	4.11	34,451	0.25	6.11
332111	Iron and steel forging	4,089	5	774	1,175,666	4.71	55,316	0.07	1.40
332112	Nonferrous forging	784	1	774	1,431,874	4.71	67,371	0.05	1.15
332115	Crown and closure manufacturing	992	1	774	1,715,882	4.71	80,733	0.05	0.96
332116	Metal stamping	27,154	35	775	1,146,408	4.71	53,939	0.07	1.44
332117	Powder metallurgy part manufacturing	2,072	3	774	1,580,975	4.71	74,386	0.05	1.04
332211	Cutlery and flatware (except precious) manufacturing	2,217	3	774	391,981	5.22	20,476	0.20	3.78
332212	Hand and edge tool manufacturing	19,535	25	774	770,858	5.22	40,267	0.10	1.92
332213	Saw blade and handsaw manufacturing	2,296	3	774	975,698	5.22	50,967	0.08	1.52
332214	Kitchen utensil, pot, and pan manufacturing	0	0	N/A	826,410	5.22	43,169	N/A	N/A
332323	Ornamental and architectural metal work	9,527	14	694	695,970	4.70	32,737	0.10	2.12
332439	Other metal container manufacturing	5,279	7	788	1,027,511	3.58	36,822	0.08	2.14
332510	Hardware manufacturing	11,863	15	777	776,986	5.22	40,587	0.10	1.92
332611	Spring (heavy gauge) manufacturing	1,927	2	786	1,774,584	5.22	92,698	0.04	0.85
332612	Spring (light gauge) manufacturing	4,960	6	774	1,085,302	5.22	56,692	0.07	1.36
332618	Other fabricated wire product manufacturing	19,946	26	774	778,870	5.22	40,685	0.10	1.90
332710	Machine shops	416,115	537	774	649,804	5.80	37,677	0.12	2.06
332812	Metal coating and allied services	613,903	885	694	602,598	4.85	29,254	0.12	2.37
332911	Industrial valve manufacturing	5,886	8	774	1,294,943	6.81	88,146	0.06	0.88
332912	Fluid power valve and hose fitting manufacturing	4,491	6	774	1,350,501	6.81	91,927	0.06	0.84
332913	Plumbing fixture fitting and trim manufacturing	1,505	2	774	811,318	6.81	55,226	0.10	1.40
332919	Other metal valve and pipe fitting manufacturing	2,710	3	781	2,164,960	6.81	147,367	0.04	0.53
332991	Ball and roller bearing manufacturing	1,132	1	774	1,808,246	6.81	123,086	0.04	0.63
332996	Fabricated pipe and pipe fitting manufacturing	12,453	16	774	1,237,265	6.81	84,220	0.06	0.92
332997	Industrial pattern manufacturing	8,917	12	774	503,294	6.81	34,259	0.15	2.26
332998	Enameled iron and metal sanitary ware manufacturing.	3,287	5	690	725,491	6.81	49,384	0.10	1.40
332999	All other miscellaneous fabricated metal product manufacturing.	55,981	72	774	933,734	6.81	63,558	0.08	1.22
333319	Other commercial and service industry machinery manufacturing.	19,776	26	774	1,127,993	4.86	54,803	0.07	1.41
333411	Air purification equipment manufacturing	4,745	6	774	1,152,661	4.55	52,480	0.07	1.47
333412	Industrial and commercial fan and blower manufacturing.	1,675	2	774	1,454,305	4.55	66,214	0.05	1.17
333414	Heating equipment (except warm air furnaces) manufacturing.	6,087	8	777	901,560	4.55	41,047	0.09	1.89
333511	Industrial mold manufacturing	43,738	56	774	716,506	5.29	37,898	0.11	2.04
333512	Machine tool (metal cutting types) manufacturing	8,756	11	776	911,891	5.29	48,233	0.09	1.61
333513	Machine tool (metal forming types) manufacturing	4,666	6	774	1,308,768	5.29	69,225	0.06	1.12
333514	Special die and tool, die set, jig, and fixture manufacturing.	65,867	85	774	816,990	5.29	43,213	0.09	1.79
333515	Cutting tool and machine tool accessory manufacturing.	31,406	41	775	771,162	5.29	40,789	0.10	1.90
333516	Rolling mill machinery and equipment manufacturing	1,361	2	774	2,243,812	5.29	118,683	0.03	0.65
333518	Other metalworking machinery manufacturing	6,766	9	774	965,694	5.29	51,079	0.08	1.51
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	3,318	4	774	1,393,898	2.63	36,617	0.06	2.11
333613	Mechanical power transmission equipment manufacturing.	3,114	4	774	2,113,156	2.63	55,511	0.04	1.39
333911	Pump and pumping equipment manufacturing	7,209	9	774	1,343,868	4.58	61,500	0.06	1.26
333912	Air and gas compressor manufacturing	4,228	5	774	1,644,664	4.58	75,266	0.05	1.03
333991	Power-driven handtool manufacturing	2,212	3	774	2,158,268	4.58	98,770	0.04	0.78
333992	Welding and soldering equipment manufacturing	3,835	5	774	1,331,521	4.58	60,935	0.06	1.27
333993	Packaging machinery manufacturing	9,742	13	774	809,474	4.58	37,044	0.10	2.09
333994	Industrial process furnace and oven manufacturing	5,631	7	774	1,324,790	4.58	60,627	0.06	1.28
333995	Fluid power cylinder and actuator manufacturing	3,955	5	774	916,613	4.58	41,947	0.08	1.84

TABLE VIII–13—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN GENERAL INDUSTRY AND MARITIME AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Number of affected entities with <20 employees	Annualized costs per affected entities	Revenues per entity	Profit rate [a] (percent)	Profits per entity	Costs as a percentage of revenues	Costs as a percentage of profits
333996	Fluid power pump and motor manufacturing	2,670	3	774	1,417,549	4.58	64,872	0.05	1.19
333997	Scale and balance (except laboratory) manufacturing	1,947	3	774	1,527,651	4.58	69,911	0.05	1.11
333999	All other miscellaneous general purpose machinery manufacturing.	32,637	42	774	871,700	4.58	39,892	0.09	1.94
334518	Watch, clock, and part manufacturing	1,322	2	774	586,350	5.94	34,844	0.13	2.22
335211	Electric housewares and household fans	0	0	N/A	847,408	4.21	35,703	N/A	N/A
335221	Household cooking appliance manufacturing	722	1	698	2,228,319	4.21	93,883	0.03	0.74
335222	Household refrigerator and home freezer manufacturing.	0	0	N/A	4,917,513	4.21	207,184	N/A	N/A
335224	Household laundry equipment manufacturing	0	0	N/A	1,767,776	4.21	74,480	N/A	N/A
335228	Other major household appliance manufacturing	0	0	N/A	1,706,991	4.21	71,919	N/A	N/A
336111	Automobile manufacturing	2,147	3	774	1,507,110	2.04	30,752	0.05	2.52
336112	Light truck and utility vehicle manufacturing	795	1	774	1,089,801	2.04	22,237	0.07	3.48
336120	Heavy duty truck manufacturing	943	1	774	4,371,350	2.04	89,196	0.02	0.87
336211	Motor vehicle body manufacturing	12,371	16	774	1,720,545	2.04	35,107	0.04	2.20
336212	Truck trailer manufacturing	5,147	7	774	2,706,375	2.04	55,223	0.03	1.40
336213	Motor home manufacturing	1,193	2	774	2,184,388	2.04	44,572	0.04	1.74
336311	Carburetor, piston, piston ring, and valve manufacturing.	1,329	2	774	870,496	2.04	17,762	0.09	4.36
336312	Gasoline engine and engine parts manufacturing	11,683	15	774	867,703	2.04	17,705	0.09	4.37
336322	Other motor vehicle electrical and electronic equipment manufacturing.	8,618	11	774	1,383,831	2.04	28,237	0.06	2.74
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	2,876	4	774	1,543,436	2.04	31,493	0.05	2.46
336340	Motor vehicle brake system manufacturing	2,386	3	774	1,378,684	2.04	28,132	0.06	2.75
336350	Motor vehicle transmission and power train parts manufacturing.	6,390	8	774	864,746	2.04	17,645	0.09	4.38
336370	Motor vehicle metal stamping	5,759	7	778	1,519,875	2.04	31,013	0.05	2.51
336399	All other motor vehicle parts manufacturing	16,021	21	774	1,369,097	2.04	27,936	0.06	2.77
336611	Ship building and repair	212,021	65	3,252	770,896	5.86	45,188	0.42	7.20
336612	Boat building	391,950	121	3,247	1,101,324	5.86	64,557	0.29	5.03
336992	Military armored vehicle, tank, and tank component manufacturing.	0	0	N/A	1,145,870	6.31	72,296	N/A	N/A
337215	Showcase, partition, shelving, and locker manufacturing.	28,216	36	774	866,964	4.54	39,387	0.09	1.96
339114	Dental equipment and supplies manufacturing	79,876	87	922	657,192	10.77	70,773	0.14	1.30
339116	Dental laboratories	1,040,112	6,664	156	326,740	10.77	35,187	0.05	0.44
339911	Jewelry (except costume) manufacturing	533,353	1,532	348	673,857	5.80	39,054	0.05	0.89
339913	Jewelers' materials and lapidary work manufacturing	86,465	218	397	919,422	5.80	53,285	0.04	0.74
339914	Costume jewelry and novelty manufacturing	100,556	368	274	454,292	5.80	26,329	0.06	1.04
339950	Sign manufacturing	89,586	140	639	521,518	5.80	30,225	0.12	2.12
423840	Industrial supplies, wholesalers	50,612	95	531	2,432,392	3.44	83,567	0.02	0.64
482110	Rail transportation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
621210	Dental offices	320,986	6,506	49	562,983	7.34	41,328	0.01	0.12
	Total	15,745,425	25,544	616					

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

As a point of clarification, OSHA would like to draw attention to industries with captive foundries. There are three industries with captive foundries whose annualized costs for very small entities approach five percent of annual profits: NAICS 336311 (Carburetor, piston ring, and valve manufacturing); NAICS 336312 (Gasoline engine and engine parts manufacturing); and NAICS 336350 (Motor vehicle transmission and power train parts manufacturing). For very small entities in all three of these industries, the annualized costs as a percentage of annual profits are approximately 4.4 percent. OSHA believes, however, that very small entities in industries with captive foundries are unlikely to actually have captive foundries and that the captive foundries allocated to very small entities in fact belong in larger entities. This would have the result that the costs as percentage of profits for these larger entities would be lower than the 4.4 percent reported above. Instead, OSHA assumed that the affected employees would be distributed among entities of different size according to each entity size class's share of total employment. In other words, if 15 percent of employees in an industry worked in very small entities (those with fewer than 20 employees), then OSHA assumed that 15 percent of affected employees in the industry would work in very small entities. However, in reality, OSHA anticipates that in industries with captive foundries, none of the entities with fewer than 20 employees have captive foundries or, if they do, that the impacts are much smaller than estimated here. OSHA invites comment about whether and to what extent very small entities have captive foundries (in industries with captive foundries).

Regardless of whether the cost estimates have been inflated for very small entities in the three industries with captive foundries listed above, there are two reasons why OSHA is confident that the competitive structure of these industries would not be threatened by adverse competitive conditions for very small entities. First, as shown in Appendix VI–B of the PEA, very small entities in NAICS 336311, NAICS 336312, and NAICS 336350 account for 3 percent, 2 percent, and 3 percent, respectively, of the total number of establishments in the industry. Although it is possible that some of these very small entities could exit the industry in response to the proposed rule, courts interpreting the OSH Act have historically taken the view that losing at most 3 percent of the establishments in an industry would alter the competitive structure of that industry. Second, very small entities in industries with captive foundries, when confronted with higher foundry costs as a result of the proposed rule, have the option of dropping foundry activities, purchasing foundry products and services from businesses directly in the foundry industry, and focusing on the main goods and services produced in the industry. This, after all, is precisely what the rest of the establishments in these industries do.

e. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold level cannot be exceeded for affected small entities or very small entities in any affected industry.

Table VIII–12 and Table VIII–13 show that, in general industry and maritime, the annualized costs of the proposed rule do not exceed one percent of annual revenues for small entities or for very small entities in any industry. These tables also show that the annualized costs of the proposed rule exceed five percent of annual profits for small entities in 10 industries and for very small entities in 13 industries. OSHA is therefore unable to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Section VIII.I of this preamble.

3. Impacts in Construction

a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed rule's projected costs of compliance would threaten the economic viability of affected construction industries, OSHA used the same data sources and methodological approach that were used earlier in this chapter for general industry and maritime. OSHA first compared, for each affected construction industry, annualized compliance costs to annual revenues and profits per (average) affected establishment. The results for all affected establishments in all affected construction industries are presented in Table VIII–14, using annualized costs per establishment for the proposed 50 $\mu g/m^3$ PEL. The annualized cost of the proposed rule for the average establishment in construction, encompassing all construction industries, is estimated at $1,022 in 2009 dollars. It is clear from Table VIII–14 that the estimates of the annualized costs per affected establishment in the 10 construction industries vary widely. These estimates range from $2,598 for NAICS 237300 (Highway, street, and bridge construction) and $2,200 for NAICS 237100 (Utility system construction) to $241 for NAICS 238200 (Building finishing contractors) and $171 for NAICS 237200 (Land subdivision).

Table VIII–14 shows that in no construction industry do the annualized costs of the proposed rule exceed one percent of annual revenues or ten percent of annual profits. NAICS 238100 (Foundation, structure, and building exterior contractors) has both the highest cost impact as a percentage of revenues, of 0.13 percent, and the highest cost impact as a percentage of profits, of 2.97 percent. Based on these results, even if the costs of the proposed rule were 50 percent higher than OSHA has estimated, the highest cost impact as a percentage of revenues in any affected construction industry would be less than 0.2 percent. Furthermore, the costs of the proposed rule would have to be more than 650 percent higher than OSHA has estimated for the cost impact as a percentage of revenues to equal 1 percent in any affected construction industry. For all affected establishments in construction, the estimated annualized cost of the proposed rule is, on average, equal to 0.05 percent of annual revenue and 1.0 percent of annual profit.

Therefore, even though the annualized costs of the proposed rule incurred by the construction industry as a whole are almost four times the combined annualized costs incurred by general industry and maritime, OSHA preliminarily concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the economic viability of any of the construction industries. OSHA further notes that while there would be

additional costs (not attributable to the proposed rule) for some employers in construction industries to come into compliance with the *current* silica standard, these costs would not affect the Agency's preliminary determination of the economic feasibility of the proposed rule.

Below, OSHA provides additional information to further support the Agency's conclusion that the proposed rule would not threaten the economic viability of any construction industry.

TABLE VIII–14—SCREENING ANALYSIS FOR ESTABLISHMENTS IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected establishments	Annualized costs per affected establishment	Revenues per establishment	Profit rate [a] (percent)	Profits per establishment	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$23,288,881	55,338	$421	$2,002,532	4.87	$97,456	0.02	0.43
236200	Nonresidential Building Construction.	39,664,913	44,702	887	7,457,045	4.87	362,908	0.01	0.24
237100	Utility System Construction.	46,718,162	21,232	2,200	4,912,884	5.36	263,227	0.04	0.84
237200	Land Subdivision	1,110,789	6,511	171	2,084,334	11.04	230,214	0.01	0.07
237300	Highway, Street, and Bridge Construction.	30,807,861	11,860	2,598	8,663,019	5.36	464,156	0.03	0.56
237900	Other Heavy and Civil Engineering Construction.	7,164,210	5,561	1,288	3,719,070	5.36	199,264	0.03	0.65
238100	Foundation, Structure, and Building Exterior Contractors.	215,907,211	117,456	1,838	1,425,510	4.34	61,832	0.13	2.97
238200	Building Equipment Contractors.	4,902,138	20,358	241	1,559,425	4.34	67,640	0.02	0.36
238300	Building Finishing Contractors.	50,259,239	120,012	419	892,888	4.34	38,729	0.05	1.08
238900	Other Specialty Trade Contractors.	68,003,978	74,446	913	1,202,048	4.48	53,826	0.08	1.70
999000	State and local governments [d].	23,338,234	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	511,165,616	477,476	1,022	.....	.....	.....	.....	.....

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

b. Normal Year-to-Year Variations in Profit Rates

As previously noted, the United States has a dynamic and constantly changing economy in which large year-to-year changes in industry profit rates are commonplace. A recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession.

To demonstrate the normal year-to-year variation in profit rates for all the manufacturers in construction affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2000—2006. For the combined affected manufacturing industries in general industry and maritime over the 7-year period, the average change in profit rates was 15.4 percent a year.

What these data indicate is that, even if, theoretically, the annualized costs of the proposed rule for the most significantly affected construction industries were completely absorbed in reduced annual profits, the magnitude of reduced annual profit rates are well within normal year-to-year variations in profit rates in those industries and do not threaten their economic viability. Of course, a permanent loss of profits would present a greater problem than a temporary loss, but it is unlikely that all costs of the proposed rule would be absorbed in lost profits. Given that, as discussed in Chapter VI of the PEA, the overall price elasticity of demand for the outputs of the construction industry is fairly low and that almost all of the costs estimated in Chapter V of the PEA are variable costs, there is a reasonable chance that most firms will see small declines in output rather than that any but the most extremely marginal firms would close.

Considering the costs of the proposed rule relative to the size of construction activity in the United States, OSHA preliminarily concludes that the price and profit impacts of the proposed rule on construction industries would, in practice, be quite limited. Based on ERG (2007a), on an annual basis, the cost of the proposed rule would be equal to approximately 2 percent of the value of affected, silica-generating construction activity, and silica-generating construction activity accounts for approximately 4.8 percent of all construction spending in the U.S. Thus, the annualized cost of the proposed rule would be equal to approximately 0.1 percent of the value of annual construction activity in the U.S. On top of that, construction activity in the U.S. is not subject to any meaningful foreign competition, and any foreign firms performing construction activities in the United States would be subject to OSHA regulations.

c. Impacts by Type of Construction Demand

The demand for construction services originates in three independent sectors: residential building construction, nonresidential building construction, and nonbuilding construction.

Residential Building Construction: Residential housing demand is derived from the household demand for housing services. These services are provided by the stock of single and multi-unit residential housing units. Residential housing construction represents changes to the housing stock and includes construction of new units and

modifications, renovations, and repairs to existing units. A number of studies have examined the price sensitivity of the demand for housing services. Depending on the data source and estimation methodologies, these studies have estimated the demand for housing services at price elasticity values ranging from –0.40 to –1.0, with the smaller (in absolute value) less elastic values estimated for short-run periods. In the long run, it is reasonable to expect the demand for the stock of housing to reflect similar levels of price sensitivity. Since housing investments include changes in the existing stock (renovations, depreciation, etc.) as well as new construction, it is likely that the price elasticity of demand for new residential construction will be lower than that for residential construction as a whole.

OSHA judges that many of the silica-generating construction activities affected by the proposed rule are not widely used in single-family construction. This assessment is consistent with the cost estimates that show relatively low impacts for residential building contractors. Multi-family residential construction might have more substantial impacts, but, based on census data, this type of construction represents a relatively small share of net investment in residential buildings.

Nonresidential Building Construction: Nonresidential building construction consists of industrial, commercial, and other nonresidential structures. As such, construction demand is derived from the demand for the output of the industries that use the buildings. For example, the demand for commercial office space is derived from the demand for the output produced by the users of the office space. The price elasticity of demand for this construction category will depend, among other things, on the price elasticity of demand for the final products produced, the importance of the costs of construction in the total cost of the final product, and the elasticity of substitution of other inputs that could substitute for nonresidential building construction. ERG (2007c) found no studies that attempted to quantify these relationships. But given the costs of the proposed rule relative to the size of construction spending in the United States, the resultant price or revenue effects are likely to be so small as to be barely detectable.

Nonbuilding Construction: Nonbuilding construction includes roads, bridges, and other infrastructure projects. Utility construction (power lines, sewers, water mains, etc.) and a variety of other construction types are also included. A large share of this construction (63.8 percent) is publicly financed (ERG, 2007a). For this reason, a large percentage of the decisions regarding the appropriate level of such investments is not made in a private market setting. The relationship between the costs and price of such investments and the level of demand might depend more on political considerations than the factors that determine the demand for privately produced goods and services.

While a number of studies have examined the factors that determine the demand for publicly financed construction projects, these studies have focused on the ability to finance such projects (*e.g.,* tax receipts) and socio-demographic factors (*e.g.,* population growth) to the exclusion of cost or price factors. In the absence of budgetary constraints, OSHA believes, therefore, that the price elasticity of demand for public investment is probably quite low. On the other hand, budget-imposed limits might constrain public construction spending. If the dollar value of public investments were fixed, a price elasticity of demand of 1 (in absolute terms) would be implied. Any percentage increase in construction costs would be offset with an equal percentage reduction in investment (measured in physical units), keeping public construction expenditures constant.

Public utility construction comprises the remainder of nonbuilding construction. This type of construction is subject to the same derived-demand considerations discussed for nonresidential building construction, and for the same reasons, OSHA expects the price and profit impacts to be quite small.

d. Economic Feasibility Screening Analysis: Small and Very Small Businesses

The preceding discussion focused on the economic viability of the affected construction industries in their entirety and found that the proposed standard did not threaten the survival of these construction industries. Now OSHA wishes to demonstrate that the competitive structure of these industries would not be significantly altered.

To address this issue, OSHA examined the annualized costs per affected small and very small entity for each affected construction industry. Table VIII–15 and Table VIII–16 show that in no construction industries do the annualized costs of the proposed rule exceed one percent of annual revenues or ten percent of annual profits either for small entities or for very small entities. Therefore, OSHA preliminarily concludes, based on its screening analysis, that the annualized costs as a percentage of annual revenues and as a percentage of annual profits are below the threshold level that could threaten the competitive structure of any of the construction industries.

TABLE VIII–15—SCREENING ANALYSIS FOR SMALL ENTITIES IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected small entities	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$18,527,934	44,212	$419	$1,303,262	4.87	$67,420	0.03	0.62
236200	Nonresidential Building Construction.	24,443,185	42,536	575	4,117,755	4.87	200,396	0.01	0.29
237100	Utility System Construction.	30,733,201	20,069	1,531	3,248,053	5.36	174,027	0.05	0.88
237200	Land Subdivision	546,331	3,036	180	1,215,688	11.04	134,272	0.01	0.13
237300	Highway, Street, and Bridge Construction.	13,756,992	10,350	1,329	3,851,971	5.36	206,385	0.03	0.64
237900	Other Heavy and Civil Engineering Construction.	5,427,484	5,260	1,032	2,585,858	5.36	138,548	0.04	0.74
238100	Foundation, Structure, and Building Exterior Contractors.	152,160,159	115,345	1,319	991,258	4.34	42,996	0.13	3.07

TABLE VIII–15—SCREENING ANALYSIS FOR SMALL ENTITIES IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD—Continued

NAICS	Industry	Total annualized costs	Affected small entities	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
238200	Building Equipment Contractors.	3,399,252	13,933	244	1,092,405	4.34	47,383	0.02	0.51
238300	Building Finishing Contractors.	36,777,673	87,362	421	737,930	4.34	32,008	0.06	1.32
238900	Other Specialty Trade Contractors.	53,432,213	73,291	729	1,006,640	4.48	45,076	0.07	1.62
999000	State and local governments [d].	2,995,955	13,482	222	N/A	N/A	N/A	N/A	N/A
	Total	342,200,381	428,876	798	.....	.....	.....	.....	.....

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–16—SCREENING ANALYSIS FOR VERY SMALL ENTITIES (FEWER THAN 20 EMPLOYEES) IN CONSTRUCTION AFFECTED BY OSHA'S PROPOSED SILICA STANDARD

NAICS	Industry	Total annualized costs	Affected entities with <20 employees	Annualized costs per affected entities	Revenues per entities	Profit rate [a] (percent)	Profits per entities	Costs as a percentage of revenues	Costs as a percentage of profits
236100	Residential Building Construction.	$13,837,293	32,042	$432	$922,275	4.87	$44,884	0.05	0.96
236200	Nonresidential Building Construction.	10,777,269	35,746	301	1,902,892	4.87	92,607	0.02	0.33
237100	Utility System Construction.	8,578,771	16,113	532	991,776	5.36	53,138	0.05	1.00
237200	Land Subdivision	546,331	3,036	180	1,215,688	11.04	134,272	0.01	0.13
237300	Highway, Street, and Bridge Construction.	4,518,038	8,080	559	1,649,324	5.36	88,369	0.03	0.63
237900	Other Heavy and Civil Engineering Construction.	1,650,007	4,436	372	834,051	5.36	44,688	0.04	0.83
238100	Foundation, Structure, and Building Exterior Contractors.	81,822,550	105,227	778	596,296	4.34	25,864	0.13	3.01
238200	Building Equipment Contractors.	1,839,588	7,283	253	579,724	4.34	25,146	0.04	1.00
238300	Building Finishing Contractors.	21,884,973	50,749	431	429,154	4.34	18,615	0.10	2.32
238900	Other Specialty Trade Contractors.	30,936,078	68,075	454	600,658	4.48	26,897	0.08	1.69
999000	State and local governments [d].	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Total	176,390,899	330,786	533	.....	.....	.....	.....	.....

[a] Profit rates were calculated by ERG, 2013, as the average of profit rates for 2000 through 2006, based on balance sheet data reported in the Internal Revenue Service's *Corporation Source Book* (IRS, 2007).
Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on ERG (2013).

e. Differential Impacts on Small Entities and Very Small Entities

Below, OSHA provides some additional information about differential compliance costs for small and very small entities that might influence the magnitude of differential impacts for these smaller businesses.

The distribution of impacts by size of business is affected by the characteristics of the compliance measures. For silica controls in construction, the dust control measures consist primarily of equipment modifications and additions made to individual tools, rather than large, discrete investments, such as might be applied in a manufacturing setting. As a result, compliance advantages for large firms through economies of scale are limited. It is possible that some large construction firms might derive purchasing power by buying dust control measures in bulk. Given the simplicity of many control measures, however, such as the use of wet methods on machines already manufactured to accommodate them, such differential purchasing power appears to be of limited consequence.

The greater capital resources of large firms will give them some advantage in making the relatively large investments for some control measures. For example, cab enclosures on heavy construction equipment or foam-based dust control systems on rock crushers might be particularly expensive for some small entities with an unusual number of heavy equipment pieces. Nevertheless, where differential investment capabilities might exist, small construction firms might also have the capability to achieve compliance with lower-cost measures, such as by modifying work practices. In the case of rock crushing, for example, simple water spray systems can be arranged without large-scale investments in the best commercially available systems.

In the program area, large firms might have a slight advantage in the delivery of training or in arranging for health screenings. Given the likelihood that small firms can, under most circumstances, call upon independent

training specialists at competitive prices, and the widespread availability of medical services for health screenings, the advantage for large firms is, again, expected to be fairly modest.

f. Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed silica rule will not have a significant economic impact on a substantial number of small entities, the Agency has developed screening tests to consider minimum threshold effects of the proposed rule on small entities. The minimum threshold effects for this purpose are annualized costs equal to one percent of annual revenues and annualized costs equal to five percent of annual profits applied to each affected industry. OSHA has applied these screening tests both to small entities and to very small entities. For purposes of certification, the threshold levels cannot be exceeded for affected small or very small entities in any affected industry.

Table VIII–15 and Table VIII–16 show that in no construction industries do the annualized costs of the proposed rule exceed one percent of annual revenues or five percent of annual profits either for small entities or for very small entities. However, as previously noted in this section, OSHA is unable to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities in general industry and maritime and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Section VIII.I of this preamble.

4. Employment Impacts on the U.S. Economy

In October 2011, OSHA directed Inforum—a not-for-profit Maryland corporation (based at the University of Maryland)—to run its macroeconomic model to estimate the employment impacts of the costs of the proposed silica rule.[20] The specific model of the U.S. economy that Inforum used—called the LIFT model—is particularly suitable for this work because it combines the industry detail of a pure input-output model (which shows, in matrix form, how the output of each industry serves as inputs in other industries) with macroeconomic modeling of demand, investment, and other macroeconomic parameters.[21] The Inforum model can thus both trace changes in particular industries through their effect on other industries and also examine the effects of these changes on aggregate demand, imports, exports, and investment, and in turn determine net changes to GDP, employment, prices, etc.

In order to estimate the possible macroeconomic impacts of the proposed rule, Inforum had to run its model twice: once to establish a baseline and then again with changes in industry expenditures to reflect the year-by-year costs of the proposed silica rule as estimated by OSHA in its Preliminary Economic Analysis (PEA).[22] The difference in employment, GDP, etc. between the two runs of the model revealed the estimated economic impacts of the proposed rule.[23]

OSHA selected 2014 as the starting year for running the Inforum model under the assumption that that would be the earliest that a final silica rule could take effect. Inforum ran the model through the year 2023 and reported its annual and cumulative results for the ten-year period 2014–2023. The most important Inforum result is that the proposed silica rule cumulatively generates an additional 8,625 job-years over the period 2014–2023, or an additional 862.5 job-years annually, on average, over the period (Inforum, 2011).[24]

For a fuller discussion of the employment and other macroeconomic impacts of the silica rule, see Inforum (2011) and Chapter VI of the PEA for the proposed rule.

G. Benefits and Net Benefits

In this section, OSHA presents a summary of the estimated benefits, net benefits, and incremental benefits of the proposed silica rule. This section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and benefit parameters. A full explanation of the derivation of the estimates presented here is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of its estimation of the benefits and net benefits of the proposed rule.

1. Estimation of the Number of Silica-Related Diseases Avoided

OSHA estimated the benefits associated with the proposed PEL of 50 μg/m^3 and, for economic analysis purposes, with an alternative PEL of 100 μg/m^3 for respirable crystalline silica by applying the dose-response relationship developed in the Agency's quantitative risk assessment (QRA)—summarized in Section VI of this preamble—to exposures at or below the current PELs. OSHA determined exposures at or below the current PELs by first developing an exposure profile (presented in Chapter IV of the PEA) for industries with workers exposed to respirable crystalline silica, using OSHA inspection and site-visit data, and then applying this exposure profile to the total current worker population. The industry-by-industry exposure profile was previously presented in Section VIII.C of this preamble.

By applying the dose-response relationship to estimates of exposures at or below the current PELs across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given exposures at or below the current PELs (the ''baseline''):

- Fatal cases of lung cancer,
- fatal cases of non-malignant respiratory disease (including silicosis),
- fatal cases of end-stage renal disease, and
- cases of silicosis morbidity.

In addition, it is possible to project the number of these cases that would be avoided under alternative, lower PELs.

[20] Inforum has over 40 years experience designing and using macroeconomic models of the United States (and other countries).

[21] LIFT stands for Long-Term Interindustry Forecasting Tool. This model combines a dynamic input-output core for 97 productive sectors with a full macroeconomic model with more than 800 macroeconomic variables. LIFT employs a ''bottoms-up'' regression approach to macroeconomic modeling (so that aggregate investment, employment, and exports, for example, are the sum of investment and employment by industry and exports by commodity). Unlike some simpler forecasting models, price effects are embedded in the model and the results are time-dependent (that is, they are not static or steady-state, but present year-by-year estimates of impacts consistent with economic conditions at the time).

[22] OSHA worked with Inforum to disaggregate compliance costs into categories that mapped into specific LIFT production sectors. Inforum also established a mapping between OSHA's NAICS-based industries and the LIFT production sectors. OSHA's compliance cost estimates were based on production and employment levels in affected industries in 2006 (although the costs were then inflated to 2009 dollars). Therefore, Inforum benchmarked compliance cost estimates in future years to production and employment conditions in 2006 (that is, compliance costs in a future year were proportionately adjusted to production and employment changes from 2006 to that future year). See Inforum (2011) for a discussion of these and other transformations of OSHA's cost estimates to conform to the specifications of the LIFT model.

[23] Because OSHA's analysis of the hydraulic fracturing industry for the proposed silica rule was not conducted until after the draft PEA had been completed, OSHA's estimates of the compliance costs for this industry were not included in Inforum's analysis of the rule's employment and other macroeconomic impacts on the U.S. economy. It should be noted that, according to the Agency's estimates, compliance costs for the hydraulic fracturing industry represent only about 4 percent of the total compliance costs for all affected industries.

[24] A ''job-year'' is the term of art used to reflect the fact that an additional person is employed for a year, not that a new job has necessarily been permanently created.

As a simplified example, suppose that the risk per worker of a given health endpoint is 2 in 1,000 at 100 μg/m³ and 1 in 1,000 at 50 μg/m³ and that there are 100,000 workers currently exposed at 100 μg/m³. In this example, the proposed PEL would lower exposures to 50 μg/m³, thereby cutting the risk in half and lowering the number of expected cases in the future from 200 to 100.

The estimated benefits for the proposed silica rule represent the additional benefits derived from employers achieving full compliance with the proposed PEL relative to the current PELs. They do not include benefits associated with current compliance that has already been achieved with regard to the new requirements or benefits obtained from future compliance with existing silica requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

The technological feasibility analysis, described earlier in this section of the preamble, demonstrated the effectiveness of controls in meeting or exceeding the proposed OSHA PEL. For purposes of estimating the benefit of reducing the PEL, OSHA has made some simplifying assumptions. On the one hand, given the lack of background information on respirator use related to existing exposure data, OSHA used existing personal exposure measurement information, unadjusted for potential respirator use.[25] On the other hand, OSHA assumed that compliance with the existing and proposed rule would result in reductions in exposure levels to exactly the existing standard and proposed PEL, respectively. However, in many cases, indivisibilities in the application of respirators, as well as certain types of engineering controls, may cause employers to reduce exposures to some point below the existing standard or the proposed PEL. This is particularly true in the construction sector for employers who opt to follow Table 1, which specifies particular controls.

In order to examine the effect of simply changing the PEL, OSHA compared the number of various kinds of cases that would occur if a worker were exposed for an entire working life to PELs of 50 μg/m³ or 100 μg/m³ to the number of cases that would occur at levels of exposure at or below the current PELs. The number of avoided cases over a hypothetical working life of exposure for the current population at a lower PEL is then equal to the difference between the number of cases at levels of exposure at or below the current PEL for that population minus the number of cases at the lower PEL. This approach represents a steady-state comparison based on what would hypothetically happen to workers who received a specific average level of occupational exposure to silica during an entire working life. (In order to incorporate the element of timing to assess the economic value of the health benefits, OSHA presents a modified approach later in this section.)

Based on OSHA's application of the Steenland et al. (2001) log-linear and the Attfield and Costello (2004) models, Table VIII–17 shows the estimated number of avoided fatal lung cancers for PELs of 50 μg/m³ and 100 μg/m³. At the proposed PEL of 50 μg/m³, an estimated 2,404 to 12,173 lung cancers would be prevented over the lifetime of the current worker population, with a midpoint estimate of 7,289 fatal cancers prevented. This is the equivalent of between 53 and 271 cases avoided annually, with a midpoint estimate of 162 cases avoided annually, given a 45-year working life of exposure.

Following Park (2002), as discussed in summary of the Agency's QRA in Section VI of this preamble, OSHA also estimates that the proposed PEL of 50 μg/m³ would prevent an estimated 16,878 fatalities over a lifetime from non-malignant respiratory diseases arising from silica exposure. This is equivalent to 375 fatal cases prevented annually. Some of these fatalities would be classified as silicosis, but most would be classified as other pneumoconioses and chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema.

As also discussed in the summary of the Agency's QRA in Section VI of this preamble, OSHA finds that workers with large exposures to silica are at elevated risk of end-stage renal disease (ESRD). Based on Steenland, Attfield, and Mannetje (2002), OSHA estimates that the proposed PEL of 50 μg/m³ would prevent 6,774 cases of end-stage renal disease over a working life of exposure, or about 151 cases annually.

Combining the three major fatal health endpoints—for lung cancer, non-malignant respiratory diseases, and end-stage renal disease—OSHA estimates that the proposed PEL would prevent between 26,055 and 35,825 premature fatalities over a lifetime, with a midpoint estimate of 30,940 fatalities prevented. This is the equivalent of between 579 and 796 premature fatalities avoided annually, with a midpoint estimate of 688 premature fatalities avoided annually, given a 45-year working life of exposure.

In addition, the rule would prevent a large number of cases of silicosis morbidity. Based on Rosenman et al. (2003), the Agency estimates that between 2,700 and 5,475 new cases of silicosis, at an ILO X-ray rating of 1/0 or higher, occur annually at the present PELs as a result of silica exposure at establishments within OSHA's jurisdiction. Based on the studies summarized in OSHA's QRA, OSHA expects that the proposed rule will eliminate the large majority of these cases.

The Agency has not included the elimination of the less severe silicosis cases in its estimates of the monetized benefits and net benefits of the proposed rule. Instead, OSHA separately estimated the number of silicosis cases reaching the more severe levels of 2/1 and above. Based on a study by Buchannan et al. (2003) of a cohort of coal miners (as discussed in the Agency's QRA), OSHA estimates that the proposed PEL of 50 μg/m³ would prevent 71,307 cases of moderate-to-severe silicosis (registering 2/1 or more, using the ILO method for assessing severity) over a working life, or about 1,585 cases of moderate-to-severe silicosis prevented annually.

Note that the Agency based its estimates of reductions in the number of silica-related diseases over a working life of constant exposure for workers who are employed in a respirable crystalline silica-exposed occupation for their entire working lives, from ages 20 to 65. While the Agency is legally obligated to examine the effect of exposures from a working lifetime of exposure,[26] in an alternative analysis purely for informational purposes, the Agency examined, in Chapter VII of the PEA, the effect of assuming that workers are exposed for only 25 working years, as opposed to the 45 years assumed in the main analysis. While all workers are assumed to have less cumulative exposure under the 25-years-of-

[25] Based on available data, the Agency estimated the weighted average for the relevant exposure groups to match up with the quantitative risk assessment. For the 50–100 μg/m³ exposure range, the Agency estimated an average exposure of 62.5 μg/m³. For the 100–250 μg/m³ range, the Agency estimated an average exposure of 125 μg/m³.

[26] Section (6)(b)(5) of the OSH Act states: ''The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, 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.'' Given that it is necessary for OSHA to reach a determination of significant risk over a working life, it is a logical extension to estimate what this translates into in terms of estimated benefits for the affected population over the same period.

exposure assumption, the effective exposed population over time is proportionately increased. Estimated prevented cases of end-stage renal disease and silicosis morbidity are lower in the 25-year model, whereas cases of fatal non-malignant lung disease are higher. In the case of lung cancer, the effect varies by model, with a lower high-end estimate (Attfield & Costello, 2004) and a higher low-end estimate (Steenland et. al., 2001 log-linear model). Overall, however, the 45-year-working-life assumption yields larger estimates of the number of cases of avoided fatalities and illnesses than does the 25-years-of-exposure assumption. For example, the midpoint estimates of the number of avoided fatalities and illnesses under the proposed PEL of 50 μg/m^3 would decline from 688 and 1,585, respectively, under the 45-year-working-life assumption to 683 and 642, respectively, under the 25-year-working-life assumption. Note the effect, in this case, of going from a 45-year-working-life assumption to a 25-year-working-life assumption would be a 1 percent reduction in the number of avoided fatalities and a 59 percent reduction in the number of avoided illnesses. The divergence reflects differences in the mathematical structure of the risk assessment models that are the basis for these estimates.[27]

OSHA believes that 25 years of worker exposure to respirable crystalline silica may be a reasonable alternative estimate for informational purposes. However, to accommodate the possibility that average worker exposure to silica over a working life may be shorter, at least in certain industries (see the following paragraph), the Agency also examined the effect of assuming only 13 years of exposure for the average worker. The results were broadly similar to the 25 years of exposure—annual fatalities prevented were higher (788), but illnesses prevented lower (399), with the lower average cumulative exposure being offset to a substantial degree by a larger exposed population. The same effect is seen if one assumes only 6.6 years of cumulative exposure to silica for the average worker: estimated fatalities rise to 832 cases annually, with 385 cases of silicosis morbidity. In short, the aggregate estimated benefits of the rule appear to be relatively insensitive to implicit assumptions of average occupational tenure. Nonetheless, the Agency is confident that the typical affected worker sustains an extended period of exposure to silica.

Even in the construction industry, which has an extremely high rate of job turnover, the mean job tenure with one's current employer is 6.6 years (BLS, 2010a), and the median age of construction workers in the U.S. is 41.6 years (BLS, 2010b). OSHA is unaware of any data on job tenure within an industry, but the Agency would expect job tenure in the construction industry would be at least twice the job tenure with one's current employer. Furthermore, many workers may return to the construction industry after unemployment or work in another industry. Of course, job tenure is longer in the other industries affected by the proposed rule.

The proposed rule also contains specific provisions for diagnosing latent tuberculosis (TB) in the silica-exposed population and thereby reducing the risk of TB being spread to the population at large. The Agency currently lacks good methods for quantifying these benefits. Nor has the Agency attempted to assess benefits directly stemming from enhanced medical surveillance in terms of reducing the severity of symptoms from the illnesses that do result from present or future exposure to silica. However, the Agency welcomes comment on the likely magnitude of these currently non-quantified health benefits arising from the proposed rule and on methods for better measuring these effects.

OSHA's risk estimates are based on application of exposure-response models derived from several individual epidemiological studies as well as the pooled cohort studies of Steenland et al. (2001) and Mannetje et al. (2002). OSHA recognizes that there is uncertainty around any of the point estimates of risk derived from any single study. In its preliminary risk assessment (summarized in Section VI of this preamble), OSHA has made efforts to characterize some of the more important sources of uncertainty to the extent that available data permit. This specifically includes characterizing statistical uncertainty by reporting the confidence intervals around each of the risk estimates; by quantitatively evaluating the impact of uncertainties in underlying exposure data used in the cohort studies; and by exploring the use of alternative exposure-response model forms. OSHA believes that these efforts reflect much, but not necessarily all, of the uncertainties associated with the approaches taken by investigators in their respective risk analyses. However, OSHA believes that characterizing the risks and benefits as a range of estimates derived from the full set of available studies, rather than relying on any single study as the basis for its estimates, better reflects the uncertainties in the estimates and more fairly captures the range of risks likely to exist across a wide range of industries and exposure situations.

Another source of uncertainty involves the degree to which OSHA's risk estimates reflect the risk of disease among workers with widely varying exposure patterns. Some workers are exposed to fairly high concentrations of crystalline silica only intermittently, while others experience more regular and constant exposure. Risk models employed in the quantitative assessment are based on a cumulative exposure metric, which is the product of average daily silica concentration and duration of worker exposure for a specific job. Consequently, these models predict the same risk for a given cumulative exposure regardless of the pattern of exposure, reflecting a worker's long-term average exposure without regard to intermittencies or other variances in exposure, and are therefore generally applicable to all workers who are exposed to silica in the various industries. Section VI of this preamble provides evidence supporting the use of cumulative exposure as the preferred dose metric. Although the Agency believes that the results of its risk assessment are broadly relevant to all occupational exposure situations involving crystalline silica, OSHA acknowledges that differences exist in the relative toxicity of crystalline silica particles present in different work settings due to factors such as the presence of mineral or metal impurities on quartz particle surfaces, whether the particles have been freshly fractured or are aged, and size distribution of particles. However, in its preliminary risk assessment, OSHA preliminarily concludes that the estimates from the studies and analyses relied upon are fairly representative of a wide range of workplaces reflecting differences in silica polymorphism, surface properties, and impurities.

Thus, OSHA has a high degree of confidence in the risk estimates associated with exposure to the current and proposed PELs. OSHA acknowledges there is greater uncertainty in the risk estimates for the proposed action level of 0.025 mg/m^3 than exists at the current (0.1 mg/m^3)

[27] Technically, this analysis assumes that workers receive 25 years worth of silica exposure, but that they receive it over 45 working years, as is assumed by the risk models in the QRA. It also accounts for the turnover implied by 25, as opposed to 45, years of work. However, it is possible that an alternate analysis, which accounts for the larger number of post-exposure worker-years implied by workers departing their jobs before the end of their working lifetime, might find larger health effects for workers receiving 25 years worth of silica exposure.

and proposed (0.05 mg/m^3) PELs, particularly given some evidence of a threshold for silicosis between the proposed PEL and action level. Given the Agency's findings that controlling exposures below the proposed PEL would not be technologically feasible for employers, OSHA believes that a precise estimate of the risk for exposures below the proposed action level is not necessary to further inform the Agency's regulatory action. OSHA requests comment on remaining sources of uncertainties in its risk and benefits estimates that have not been specifically characterized by OSHA in its analysis.

Table VIII-17

Estimated Number of Avoided Fatal & Nonfatal Illnesses Resulting from a Reduction in Crystalline Silica Exposure of At-Risk Workers over a 45-Year Working Life Due to Proposed PEL of 50 μg/m³ and Alternative PEL of 100 μg/m³

	Total Number of Avoided Cases						Annual Number of Avoided Cases					
	50			100			50			100		
	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime	Total	Construction	GI & Maritime
Lung Cancers												
High	12,173	9,537	2,636	6,563	6,277	286	271	212	59	146	139	6
Midpoint	7,289	5,852	1,437	3,719	3,573	146	162	130	32	83	79	3
Low	2,404	2,166	238	875	869	6	53	48	5	19	19	0
Silicosis & Other Non-Malignant Respiratory Diseases	16,878	13,944	2,934	8,490	8,403	87	375	310	65	189	187	2
End Stage Renal Disease	6,774	5,722	1,052	2,684	2,655	29	151	127	23	60	59	1
Total Number of Fatal Illnesses Prevented												
High	35,825	29,203	6,622	17,737	17,335	402	796	649	147	394	385	9
Midpoint	30,940	25,517	5,423	14,893	14,631	262	688	567	121	331	325	6
Low	26,055	21,831	4,224	12,049	11,927	122	579	485	94	268	265	3
Total Number of Silicosis Morbidity Cases Prevented*	71,307	48,617	22,689	42,881	41,375	1,506	1,585	1,080	504	953	919	33

*Assessed at 2/1 or higher X-ray, following ILO criteria

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

2. Estimating the Stream of Benefits Over Time

Risk assessments in the occupational environment are generally designed to estimate the risk of an occupationally related illness over the course of an individual worker's lifetime. As previously discussed, the current occupational exposure profile for a particular substance for the current cohort of workers can be matched up against the expected profile after the proposed standard takes effect, creating a ''steady state'' estimate of benefits. However, in order to annualize the benefits for the period of time after the silica rule takes effect, it is necessary to create a timeline of benefits for an entire active workforce over that period.

In order to characterize the magnitude of benefits before the steady state is reached, OSHA created a linear phase-in model to reflect the potential timing of benefits. Specifically, OSHA estimated that, for all non-cancer cases, while the number of cases would gradually decline as a result of the proposed rule, they would not reach the steady-state level until 45 years had passed. The reduction in cases estimated to occur in any given year in the future was estimated to be equal to the steady-state reduction (the number of cases in the baseline minus the number of cases in the new steady state) times the ratio of the number of years since the standard was implemented and a working life of 45 years. Expressed mathematically:

$N_t=(C—S) \times (t/45)$,

where N_t is the number of non-malignant silica-related diseases avoided in year t; C is the current annual number of non-malignant silica-related diseases; S is the steady-state annual number of non-malignant silica-related diseases; and *t* represents the number of years after the proposed standard takes effect, with $t \leq 45$.

In the case of lung cancer, the function representing the decline in the number of cases as a result of the proposed rule is similar, but there would be a 15-year lag before any reduction in cancer cases would be achieved. Expressed mathematically, for lung cancer:

$L_t=(C_m—S_m) \text{ x } ((t\text{-}15)/45))$,

where $15 \leq t \leq 60$ and L_t is the number of lung cancer cases avoided in year t as a result of the proposed rule; C_m is the current annual number of silica-related lung cancers; and S_m is the steady-state annual number of silica-related lung cancers.

A more complete discussion of the functioning and results of this model is presented in Chapter VII of the PEA.

This model was extended to 60 years for all the health effects previously discussed in order to incorporate the 15-year lag, in the case of lung cancer, and a 45-year working life. As a practical matter, however, there is no overriding reason for stopping the benefits analysis at 60 years. An internal analysis by OSHA indicated that, both in terms of cases prevented, and even with regard to monetized benefits, particularly when lower discount rates are used, the estimated benefits of the standard are noticeably larger on an annualized basis if the analysis extends further into the future. The Agency welcomes comment on the merit of extending the benefits analysis beyond the 60 years analyzed in the PEA.

In order to compare costs to benefits, OSHA assumes that economic conditions remain constant and that annualized costs—and the underlying costs—will repeat for the entire 60-year time horizon used for the benefits analysis (as discussed in Chapter V of the PEA). OSHA welcomes comments on the assumption for both the benefit and cost analysis that economic conditions remain constant for sixty years. OSHA is particularly interested in what assumptions and time horizon should be used instead and why.

3. Monetizing the Benefits

To estimate the monetary value of the reductions in the number of silica-related fatalities, OSHA relied, as OMB recommends, on estimates developed from the willingness of affected individuals to pay to avoid a marginal increase in the risk of fatality. While a willingness-to-pay (WTP) approach clearly has theoretical merit, it should be noted that an *individual's* willingness to pay to reduce the risk of fatality would tend to underestimate the total willingness to pay, which would include the willingness of others—particularly the immediate family—to pay to reduce that individual's risk of fatality.[28]

For estimates using the willingness-to-pay concept, OSHA relied on existing studies of the imputed value of fatalities avoided based on the theory of compensating wage differentials in the labor market. These studies rely on certain critical assumptions for their accuracy, particularly that workers understand the risks to which they are exposed and that workers have legitimate choices between high- and low-risk jobs. These assumptions are far from obviously met in actual labor markets.[29] A number of academic studies, as summarized in Viscusi & Aldy (2003), have shown a correlation between higher job risk and higher wages, suggesting that employees demand monetary compensation in return for a greater risk of injury or fatality. The estimated trade-off between lower wages and marginal reductions in fatal occupational risk—that is, workers' willingness to pay for marginal reductions in such risk—yields an imputed value of an avoided fatality: the willingness-to-pay amount for a reduction in risk divided by the reduction in risk.[30] OSHA has used this approach in many recent proposed and final rules. Although this approach has been found to yield results that are less than statistically robust (*see,* for example, Hintermann, Alberini and Markandya, 2010), OSHA views these estimates as the best available, and will use them for its basic estimates. OSHA welcomes comments on the use of willingness-to-pay measures and estimates based on compensating wage differentials.

Viscusi & Aldy (2003) conducted a meta-analysis of studies in the economics literature that use a willingness-to-pay methodology to estimate the imputed value of life-saving programs and found that each fatality avoided was valued at approximately $7 million in 2000 dollars. This $7 million base number in 2000 dollars yields an estimate of $8.7 million in 2009 dollars for each fatality avoided.[31]

In addition to the benefits that are based on the implicit value of fatalities avoided, workers also place an implicit value on occupational injuries or illnesses avoided, which reflect their

[28] See, for example, Thaler and Rosen (1976), pp. 265–266. In addition, see Sunstein (2004), p. 433. ''This point demonstrates a general and badly neglected problem for WTP as it is currently used: agencies consider people's WTP to eliminate statistical risks, without taking account of the fact that others—especially family members and close friends—would also be willing to pay something to eliminate those risks.''

[29] On the former assumption, see the discussion in Chapter II of the PEA on imperfect information. On the latter, see, for example, the discussion of wage compensation for risk for union versus nonunion workers in Dorman and Hagstrom (1998).

[30] For example, if workers are willing to pay $50 each for a 1/100,000 reduction in the probability of dying on the job, then the imputed value of an avoided fatality would be $50 divided by 1/100,000, or $5,000,000. Another way to consider this result would be to assume that 100,000 workers made this trade-off. On average, one life would be saved at a cost of $5,000,000.

[31] An alternative approach to valuing an avoided fatality is to monetize, for each year that a life is extended, an estimate from the economics literature of the value of that statistical life-year (VSLY). See, for instance, Aldy and Viscusi (2007) for discussion of VSLY theory and FDA (2003), pp. 41488–9, for an application of VSLY in rulemaking. OSHA has not investigated this approach, but welcomes comment on the issue.

willingness to pay to avoid monetary costs (for medical expenses and lost wages) and quality-of-life losses as a result of occupational illness. Silicosis, lung cancer, and renal disease can adversely affect individuals for years or even decades in non-fatal cases, or before ultimately proving fatal. Because measures of the benefits of avoiding these illnesses are rare and difficult to find, OSHA has included a range based on a variety of estimation methods.

Consistent with Buchannan et al. (2003), OSHA estimated the total number of moderate to severe silicosis cases prevented by the proposed rule, as measured by 2/1 or more severe X-rays (based on the ILO rating system). However, while radiological evidence of moderate to severe silicosis is evidence of significant material impairment of health, placing a precise monetary value on this condition is difficult, in part because the severity of symptoms may vary significantly among individuals. For that reason, for this preliminary analysis, the Agency employed a broad range of valuation, which should encompass the range of severity these individuals may encounter. Using the willingness-to-pay approach, discussed in the context of the imputed value of fatalities avoided, OSHA has estimated a range in valuations (updated and reported in 2009 dollars) that runs from approximately $62,000 per case—which reflects estimates developed by Viscusi and Aldy (2003), based on a series of studies primarily describing simple accidents—to upwards of $5.1 million per case—which reflects work developed by Magat, Viscusi & Huber (1996) for non-fatal cancer. The latter number is based on an approach that places a willingness-to-pay value to avoid serious illness that is calibrated relative to the value of an avoided fatality. OSHA (2006) previously used this approach in the Final Economic Analysis (FEA) supporting its hexavalent chromium final rule, and EPA (2003) used this approach in its Stage 2 Disinfection and Disinfection Byproducts Rule concerning regulation of primary drinking water. Based on Magat, Viscusi & Huber (1996), EPA used studies on the willingness-to-pay to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing a case of nonfatal cancer at 58.3 percent of the value of a fatal cancer. OSHA's estimate of $5.1 million for an avoided case of non-fatal cancer is based on this 58.3 percent figure.

The Agency believes this range of estimates is descriptive of the value of preventing morbidity associated with moderate to severe silicosis, as well as the morbidity preceding mortality due to other causes enumerated here—lung cancer, lung diseases other than cancer, and renal disease.[32] OSHA therefore is applying these values to those situations as well.

The Agency is interested in public input on the issue of valuing the cost to society of non-fatal cases of moderate to severe silicosis, as well as the morbidity associated with other related diseases of the lung, and with renal disease.

a. The Monetized Benefits of the Proposed Rule

Table VIII–18 presents the estimated annualized (over 60 years, using a 0 percent discount rate) benefits from each of these components of the valuation, and the range of estimates, based on risk model uncertainty (notably in the case of lung cancer), and the range of uncertainty regarding valuation of morbidity. (Mid-point estimates of the undiscounted benefits for each of the first 60 years are provided in the middle columns of Table VII–A–1 in Appendix VII–A in the PEA. The estimates by year reach a peak of $11.9 billion in the 60th year.)

As shown, the full range of monetized benefits, undiscounted, for the proposed PEL of 50 μg/m^3 runs from $3.2 billion annually, in the case of the lowest estimate of lung cancer risk and the lowest valuation for morbidity, up to $10.9 billion annually, for the highest of both. Note that the value of total benefits is more sensitive to the valuation of morbidity (ranging from $3.5 billion to $10.3 billion, given estimates at the midpoint of the lung cancer models) than to the lung cancer model used (ranging from $6.4 to $7.4 billion, given estimates at the midpoint of the morbidity valuation).[33]

This comports with the very wide range of valuation for morbidity. At the low end of the valuation range, the total value of benefits is dominated by mortality ($3.4 billion out of $3.5 billion at the case frequency midpoint), whereas at the high end the majority of the benefits are related to morbidity ($6.9 billion out of $10.3 billion at the case frequency midpoint). Also, the analysis illustrates that most of the morbidity benefits are related to silicosis cases that are not ultimately fatal. At the valuation and case frequency midpoint, $3.4 billion in benefits are related to mortality, $1.0 billion are related to morbidity preceding mortality, and $2.4 billion are related to morbidity not preceding mortality.

[32] There are several benchmarks for valuation of health impairment due to silica exposure, using a variety of techniques, which provide a number of mid-range estimates between OSHA's high and low estimates. For a fuller discussion of these estimates, see Chapter VII of the PEA.

[33] As previously indicated, these valuations include all the various estimated health endpoints. In the case of mortality this includes lung cancer, non-malignant respiratory disease and end-stage renal disease. The Agency highlighted lung cancers in this discussion due to the model uncertainty. In calculating the monetized benefits, the Agency is typically referring to the midpoint of the high and low ends of potential valuation—in this case, the undiscounted midpoint of $3.2 billion and $10.9 billion..

TABLE VIII-18

Estimated Annualized Undiscounted Monetized Benefits of the Silica Proposal for Morbidity and Mortality

PEL	50 μg/m^3			100 μg/m^3		
	Low	Valuation Midpoint	High	Low	Valuation Midpoint	High
Cases						
Fatalities - Total						
Low	$3,074,165,270	$3,074,165,270	$3,074,165,270	$1,433,022,347	$1,433,022,347	$1,433,022,347
Midpoint	$3,436,186,835	$3,436,186,835	$3,436,186,835	$1,643,786,936	$1,643,786,936	$1,643,786,936
High	$3,798,208,401	$3,798,208,401	$3,798,208,401	$1,643,786,936	$1,643,786,936	$1,643,786,936
Morbidity Preceding Mortality						
Low	$21,907,844	$912,002,363	$1,802,096,882	$10,212,343	$425,129,963	$840,047,583
Midpoint	$24,487,768	$1,019,402,094	$2,014,316,421	$11,714,344	$487,656,791	$963,599,238
High	$27,067,692	$1,126,801,826	$2,226,535,959	$11,714,344	$487,656,791	$963,599,238
Morbidity Not Preceding Mortality						
Total	$58,844,551	$2,449,641,696	$4,840,438,842	$35,733,901	$1,487,567,728	$2,939,401,554
TOTAL						
Low	$3,154,917,665	$6,435,809,329	$9,716,700,994	$1,478,968,592	$3,345,720,038	$5,212,471,484
Midpoint	$3,519,519,154	$6,905,230,626	$10,290,942,098	$1,691,235,181	$3,619,011,454	$5,546,787,728
High	$3,884,120,643	$7,374,651,923	$10,865,183,202	$1,691,235,181	$3,619,011,454	$5,546,787,728

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

b. A Suggested Adjustment to Monetized Benefits

OSHA's estimates of the monetized benefits of the proposed rule are based on the imputed value of each avoided fatality and each avoided silica-related disease. To this point, these imputed values have been assumed to remain constant over time.

OSHA now would like to suggest that an adjustment be made to monetized benefits to reflect the fact that the imputed value of avoided fatalities and avoided diseases will tend to increase over time. Two related factors suggest such an increase in value over time.

First, economic theory suggests that the value of reducing life-threatening

and health-threatening risks will increase as real per capita income increases. With increased income, an individual's health and life become more valuable relative to other goods because, unlike other goods, they are without close substitutes and in relatively fixed or limited supply. Expressed differently, as income increases, consumption will increase but the marginal utility of consumption will decrease. In contrast, added years of life (in good health) is not subject to the same type of diminishing returns—implying that an effective way to increase lifetime utility is by extending one's life and maintaining one's good health (Hall and Jones, 2007).

Second, real per capita income has broadly been increasing throughout U.S. history, including recent periods. For example, for the period 1950 through 2000, real per capita income grew at an average rate of 2.31 percent a year (Hall and Jones, 2007) [34] although real per capita income for the recent 25 year period 1983 through 2008 grew at an average rate of only 1.3 percent a year (U.S. Census Bureau, 2010). More important is the fact that real U.S. per capita income is projected to grow significantly in future years. For example, the Annual Energy Outlook (AEO) projections, prepared by the Energy Information Administration (EIA) in the Department of Energy (DOE), show an average annual growth rate of per capita income in the United States of 2.7 percent for the period 2011–2035.[35] The U.S. Environmental Protection Agency prepared its economic analysis of the Clean Air Act using the AEO projections. Although these estimates may turn out to be somewhat higher or lower than predicted, OSHA believes that it is reasonable to use the same AEO projections employed by DOE and EPA, and correspondingly projects that per capita income in the United States will increase by 2.7 percent a year.

On the basis of the predicted increase in real per capita income in the United States over time and the expected resulting increase in the value of avoided fatalities and diseases, OSHA is considering adjusting its estimates of the benefits of the proposed rule to reflect the anticipated increase in their value over time. This type of adjustment has been recognized by OMB (2003), supported by EPA's Science Advisory Board (EPA, 2000), and applied by EPA.[36] OSHA proposes to accomplish this adjustment by modifying benefits in year i from $[B_i]$ to $[B_i * (1 + \eta)^i]$, where ''η'' is the estimated annual increase in the magnitude of the benefits of the proposed rule.

What remains is to estimate a value for ''η'' with which to increase benefits annually in response to annual increases in real per capita income. Probably the most direct evidence of the value of ''η'' comes from the work of Costa and Kahn (2003, 2004). They estimate repeated labor market compensating wage differentials from cross-sectional hedonic regressions using census and fatality data from the Bureau of Labor Statistics for 1940, 1950, 1960, 1970, and 1980. In addition, with the imputed income elasticity of the value of life on per capita GNP of 1.7 derived from the 1940–1980 data, they then predict the value of an avoided fatality in 1900, 1920, and 2000. Given the change in the value of an avoided fatality over time, it is possible to estimate a value of ''η'' of 3.4 percent a year from 1900–2000; of 4.3 percent a year from 1940–1980; and of 2.5 percent a year from 1980–2000. Other, more indirect evidence comes from estimates in the economics literature on the income elasticity for the value of a statistical life. Viscusi and Aldy (2003) performed a meta-analysis on 50 wage-risk studies and concluded that the point estimates across a variety of model specifications ranged between 0.5 and 0.6. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''η'' of about 1.5 percent a year. More recently, Kniesner, Viscusi, and Ziliak (2010), using panel data quintile regressions, developed an estimate of the overall income elasticity of the value of a statistical life of 1.44. Applied to a long-term increase in per capita income of about 2.7 percent a year, this would suggest a value of ''η'' of about 3.9 percent a year.

Based on the preceding discussion of these two approaches for estimating the annual increase in the value of the benefits of the proposed rule and the fact that, as previously noted, the projected increase in real per capita income in the United States has flattened in the most recent 25 year period, OSHA suggests a value of ''η'' of approximately 2 percent a year. The Agency invites comment on this estimate and on estimates of the income elasticity of the value of a statistical life.

While the Agency believes that the rising value, over time, of health benefits is a real phenomenon that should be taken into account in estimating the annualized benefits of the proposed rule, OSHA is at this time only offering these adjusted monetized benefits as analytic alternatives for consideration. Table VIII–19, which follows the discussion on discounting monetized benefits, shows estimates of the monetized benefits of the proposed rule (under alternative discount rates) both with and without this suggested increase in monetized benefits over time. The Agency invites comment on this suggested adjustment to monetized benefits.

4. Discounting of Monetized Benefits

As previously noted, the estimated stream of benefits arising from the proposed silica rule is not constant from year to year, both because of the 45-year delay after the rule takes effect until all active workers obtain reduced silica exposure over their entire working lives and because of, in the case of lung cancer, a 15-year latency period between reduced exposure and a reduction in the probability of disease. An appropriate discount rate [37] is needed to reflect the timing of benefits over the 60-year period after the rule takes effect and to allow conversion to an equivalent steady stream of annualized benefits.

a. Alternative Discount Rates for Annualizing Benefits

Following OMB (2003) guidelines, OSHA has estimated the annualized benefits of the proposed rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent proposed and final rules, OSHA has also estimated, for benchmarking purposes, undiscounted benefits—that is, benefits using a zero percent discount rate.

The question remains, what is the ''appropriate'' or ''preferred'' discount rate to use to monetize health benefits? The choice of discount rate is a controversial topic, one that has been the source of scholarly economic debate for several decades. However, in simplest terms, the basic choices involve a social opportunity cost of capital approach or social rate of time preference approach.

[34] The results are similar if the historical period includes a major economic downturn (such as the United States has recently experienced). From 1929 through 2003, a period in U.S. history that includes the Great Depression, real per capita income still grew at an average rate of 2.22 percent a year (Gomme and Rupert, 2004).

[35] The EIA used DOE's National Energy Modeling System (NEMS) to produce the Annual Energy Outlook (AEO) projections (EIA, 2011). Future per capita GDP was calculated by dividing the projected real gross domestic product each year by the projected U.S. population for that year.

[36] See, for example, EPA (2003, 2008).

[37] Here and elsewhere throughout this section, unless otherwise noted, the term ''discount rate'' always refers to the real discount rate—that is, the discount rate net of any inflationary effects.

The social opportunity cost of capital approach reflects the fact that private funds spent to comply with government regulations have an opportunity cost in terms of foregone private investments that could otherwise have been made. The relevant discount rate in this case is the pre-tax rate of return on the foregone investments (Lind, 1982b, pp. 24–32). The rate of time preference approach is intended to measure the tradeoff between current consumption and future consumption, or in the context of the proposed rule, between current benefits and future benefits. The *individual* rate of time preference is influenced by uncertainty about the availability of the benefits at a future date and whether the individual will be alive to enjoy the delayed benefits. By comparison, the *social* rate of time preference takes a broader view over a longer time horizon—ignoring individual mortality and the riskiness of individual investments (which can be accounted for separately) .

The usual method for estimating the social rate of time preference is to calculate the post-tax real rate of return on long-term, risk-free assets, such as U.S. Treasury securities (OMB, 2003). A variety of studies have estimated these rates of return over time and reported them to be in the range of approximately 1–4 percent.

In accordance with OMB Circular A–4 (2003), OSHA presents benefits and net benefits estimates using discount rates of 3 percent (representing the social rate of time preference) and 7 percent (a rate estimated using the social cost of capital approach). The Agency is interested in any evidence, theoretical or applied, that would inform the application of discount rates to the costs and benefits of a regulation.

b. Summary of Annualized Benefits Under Alternative Discount Rates

Table VIII–19 presents OSHA's estimates of the sum of the annualized benefits of the proposed rule, using alternative discount rates at 0, 3, and 7 percent, with a breakout between construction and general industry, and including the possible alternative of increasing monetized benefits in response to annual increases in per capita income over time.

Given that the stream of benefits extends out 60 years, the value of future benefits is sensitive to the choice of discount rate. As previously established in Table VIII–18, the undiscounted benefits range from $3.2 billion to $10.9 billion annually. Using a 7 percent discount rate, the annualized benefits range from $1.6 billion to $5.4 billion. As can be seen, going from undiscounted benefits to a 7 percent discount rate has the effect of cutting the annualized benefits of the proposed rule approximately in half.

The Agency's best estimate of the total annualized benefits of the proposed rule—using a 3 percent discount rate with no adjustment for the increasing value of health benefits over time— is between $2.4 and $8.1 billion, with a mid-point value of $5.3 billion.

As previously mentioned, OSHA has not attempted to estimate the monetary value of less severe silicosis cases, measured at 1/0 to 1/2 on the ILO scale. The Agency believes the economic loss to individuals with less severe cases of silicosis could be substantial, insofar as they may be accompanied by a lifetime of medical surveillance and lung damage, and potentially may require a change in career. However, many of these effects can be difficult to isolate and measure in economic terms, particularly in those cases where there is no obvious effect yet on physiological function or performance. The Agency invites public comment on this issue.

Table VIII-19

Total Annual Monetized Benefits Resulting from a Reduction in Exposure to Crystalline Silica Due to Proposed PEL of 50 μg/m^3 and Alternative PEL of 100 μg/m^3

($Billions)

PEL		**50**			**100**		
Discount Rate	**Range**	**Total**	**Construction**	**GI & Maritime**	**Total**	**Construction**	**GI & Maritime**
Undiscounted (0%)	Low	$3.2	$2.6	$0.5	$1.5	$1.5	$0.0
	Midpoint	$7.0	$5.4	$1.6	$3.7	$3.6	$0.1
	High	$10.9	$8.2	$2.7	$5.9	$5.7	$0.2
Discounted at 3%, with a suggested increased in monetized benefits over time	Low	$2.9	$2.4	$0.5	$1.4	$1.3	$0.0
	Midpoint	$6.4	$5.0	$1.5	$3.4	$3.3	$0.1
	High	$9.9	$7.5	$2.4	$5.4	$5.2	$0.1
Discounted at 3%	**Low**	**$2.4**	**$2.0**	**$0.4**	**$1.1**	**$1.1**	**$0.0**
	Midpoint	**$5.3**	**$4.1**	**$1.2**	**$2.8**	**$2.7**	**$0.1**
	High	**$8.1**	**$6.1**	**$2.0**	**$4.4**	**$4.3**	**$0.1**
Discounted at 7%, with a suggested increased in monetized benefits over time	Low	$2.0	$1.6	$0.3	$0.9	$0.9	$0.0
	Midpoint	$4.3	$3.3	$1.0	$2.2	$2.2	$0.1
	High	$6.6	$5.0	$1.6	$3.6	$3.5	$0.1
Discounted at 7%	Low	$1.6	$1.3	$0.3	$0.8	$0.8	$0.0
	Midpoint	$3.5	$2.7	$0.8	$1.8	$1.8	$0.0
	High	$5.4	$4.1	$1.3	$2.9	$2.8	$0.1

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

5. Net Benefits of the Proposed Rule

OSHA has estimated, in Table VIII–20, the net benefits of the proposed rule (with a PEL of 50 μg/m³), based on the benefits and costs previously presented. Table VIII–20 also provides estimates of annualized net benefits for an alternative PEL of 100 μg/m³. Both the proposed rule and the alternative rule have the same ancillary provisions and an action level equal to half of the PEL in both cases.

Table VIII–20 is being provided for informational purposes only. As previously noted, the OSH Act requires the Agency to set standards based on eliminating significant risk to the extent feasible. An alternative criterion of maximizing net (monetized) benefits may result in very different regulatory outcomes. Thus, this analysis of net benefits has not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed silica rule.

Table VIII–20 shows net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs and includes a possible adjustment to monetized benefits to reflect increases in real per capita income over time. (An expanded version of Tables VIII–20, with a breakout of net benefits between construction and general industry/maritime, is provided in Table VII–B–1 in Appendix B, of the PEA.) OSHA has relied on a uniform discount rate applied to both costs and benefits. The Agency is interested in any evidence, theoretical or applied, that would support or refute the application of differential discount rates to the costs and benefits of a regulation.

As previously noted, the choice of discount rate for annualizing benefits has a significant effect on annualized benefits. The same is true for net benefits. For example, the net benefits using a 7 percent discount rate for benefits are considerably smaller than the net benefits using a 0 percent discount rate, declining by more than half under all scenarios. (Conversely, as noted in Chapter V of the PEA, the choice of discount rate for annualizing costs has only a very minor effect on annualized costs.)

Based on the results presented in Table VIII–20, OSHA finds:

- While the net benefits of the proposed rule vary considerably—depending on the choice of discount rate used to annualize benefits and on whether the benefits being used are in the high, midpoint, or low range—benefits exceed costs for the proposed 50 μg/m³ PEL in all cases that OSHA considered.
- The Agency's best estimate of the net annualized benefits of the proposed rule—using a uniform discount rate for both benefits and costs of 3 percent—is between $1.8 billion and $7.5 billion, with a midpoint value of $4.6 billion.
- The alternative of a 100 μg/m³ PEL was found to have lower net benefits under all assumptions, relative to the proposed 50 μg/m³ PEL. However, for this alternative PEL, benefits were found to exceed costs in all cases that OSHA considered.

6. Incremental Benefits of the Proposed Rule

Incremental costs and benefits are those that are associated with increasing the stringency of the standard. A comparison of incremental benefits and costs provides an indication of the relative efficiency of the proposed PEL and the alternative PEL. Again, OSHA has conducted these calculations for informational purposes only and has not used this information as the basis for selecting the PEL for the proposed rule.

OSHA provided, in Table VIII–20, estimates of the net benefits of an alternative 100 μg/m³ PEL. The incremental costs, benefits, and net benefits of going from a 100 μg/m³ PEL to a 50 μg/m³ PEL (as well as meeting a 50 μg/m³ PEL and then going to a 25 μg/m³ PEL—which the Agency has determined is not feasible), for alternative discount rates of 3 and 7 percent, are presented in Tables VIII–21 and VIII–22. Table VIII–21 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–22 breaks out costs and benefits by major industry sector. As Table VIII–21 shows, at a discount rate of 3 percent, a PEL of 50 μg/m³, relative to a PEL of 100 μg/m³, imposes additional costs of $339 million per year; additional benefits of $2.5 billion per year, and additional net benefits of $2.16 billion per year. The proposed PEL of 50 μg/m³ also has higher net benefits using either a 3 percent or 7 percent discount rate.

Table VIII–22 continues this incremental analysis but with breakdowns between construction and general industry/maritime. This table shows that construction provides most of the incremental costs, but the incremental benefits are more evenly divided between the two sectors. Nevertheless, both sectors show strong positive net benefits, which are greater for the proposed PEL of 50 μg/m³ than the alternative of 100 μg/m³.

Tables VIII–21 and VIII–22 demonstrate that, across all discount rates, there are net benefits to be achieved by lowering exposures to 100 μg/m³ and then, in turn, lowering them further to 50 μg/m³. However, the majority of the benefits and costs attributable to the proposed rule are from the initial effort to lower exposures to 100 μg/m³. Consistent with the previous analysis, net benefits decline across all increments as the discount rate for annualizing benefits increases.

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These alternatives are discussed in Section VIII.H of this preamble.

TABLE VIII–20—ANNUAL MONETIZED NET BENEFITS RESULTING FROM A REDUCTION IN EXPOSURE TO CRYSTALLINE SILICA DUE TO PROPOSED PEL OF 50 μg/m³ AND ALTERNATIVE PEL OF 100 μg/m³

[$Billions]

PEL		50	100
Discount rate	Range		
Undiscounted (0%)	Low	$2.5	$1.2
	Midpoint	6.4	3.4
	High	10.2	5.6
Discounted at 3%, with a suggested increased in monetized benefits over time.	Low	2.3	1.1
	Midpoint	5.8	3.1
	High	9.3	5.1
3%	Low	1.8	0.8
	Midpoint	4.6	2.5
	High	7.5	4.1

TABLE VIII–20—ANNUAL MONETIZED NET BENEFITS RESULTING FROM A REDUCTION IN EXPOSURE TO CRYSTALLINE SILICA DUE TO PROPOSED PEL OF 50 μg/m³ AND ALTERNATIVE PEL OF 100 μg/m³—Continued

[$Billions]

PEL		50	100
Discount rate	Range		
Discounted at 7%, with a suggested increased in monetized benefits over time.	Low	1.3	0.6
	Midpoint	3.6	1.9
	High	5.9	3.3
7%	Low	1.0	0.5
	Midpoint	2.8	1.5
	High	4.7	2.6

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table VIII-21: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table VIII-22: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

7. Sensitivity Analysis

In this section, OSHA presents the results of two different types of sensitivity analysis to demonstrate how robust the estimates of net benefits are to changes in various cost and benefit parameters. In the first type of sensitivity analysis, OSHA made a series of isolated changes to individual cost and benefit input parameters in order to determine their effects on the Agency's estimates of annualized costs, annualized benefits, and annualized net benefits. In the second type of sensitivity analysis—a so-called ''break-even'' analysis—OSHA also investigated isolated changes to individual cost and benefit input parameters, but with the objective of determining how much they would have to change for annualized costs to equal annualized benefits.

Again, the Agency has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the proposed rule.

Analysis of Isolated Changes to Inputs

The methodology and calculations underlying the estimation of the costs and benefits associated with this rulemaking are generally linear and additive in nature. Thus, the sensitivity of the results and conclusions of the analysis will generally be proportional to isolated variations a particular input parameter. For example, if the estimated time that employees need to travel to (and from) medical screenings were doubled, the corresponding labor costs would double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the economic analysis held up. OSHA first considered changes to input parameters that affected only costs and then changes to input parameters that affected only benefits. Each of the sensitivity tests on cost parameters had only a very minor effect on total costs or net costs. Much larger effects were observed when the benefits parameters were modified; however, in all cases, net benefits remained significantly positive. On the whole, OSHA found that the conclusions of the analysis are reasonably robust, as changes in any of the cost or benefit input parameters still show significant net benefits for the proposed rule. The results of the individual sensitivity tests are summarized in Table VIII–23 and are described in more detail below.

In the first of these sensitivity test where OSHA doubled the estimated portion of employees in regulated areas requiring disposable clothing, from 10 to 20 percent, and estimates of other input parameters remained unchanged, Table VIII–23 shows that the estimated total costs of compliance would increase by $3.6 million annually, or by about 0.54 percent, while net benefits would also decline by $3.6 million, from $4,582 million to $4,528 million annually.

In a second sensitivity test, OSHA decreased the estimated current prevalence of baseline silica training by half, from 50 percent to 25 percent. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $7.9 million annually, or by about 1.19 percent, while net benefits would also decline by $7.9 million annually, from $4,532 million to $4,524 million annually.

Table VIII-23

Sensitivity Tests

Impact Variable	OSHA's Best Estimate	Sensitivity Test	Impact on Annualized Costs	Percentage Impact on Costs		Adjusted Annualized Costs		Adjusted Annualized Net Benefit
Cost								
OSHA's Best Estimate of (a) Annualized Total Cost and (b) Annualized Net Benefits					**(a)**	*$657,892,211*	**(b)**	*$4,531,808,579*
Percentage of employees requiring disposable clothing (in regulated areas)	10%	20%	$3,572,444	0.54%		$661,464,655		$4,528,236,135
Percentage of Employees with Baseline Training	50%	25%	$7,854,808	1.19%		$665,747,020		$4,523,953,770
Travel times for medical exams	60 minutes	120 minutes	$1,422,117	0.22%		$659,314,329		$4,530,386,461
Exposure monitoring--persons per sample area	4	3	$24,807,252	3.77%		$682,699,463		$4,507,001,326
Cost for respirator filters	$332 per year	-40%	-$21,246,533	-3.23%		$636,645,678		$4,553,055,112
Discount rate for costs	7%	3%	$20,562,832	3.13%		$678,455,043		$4,552,371,410
Benefit	**HA's Best Estin**	**Sensitivity Test**	**on Annualized B**	**ntage Impact on Benefits**		**Adjusted Annualized Benefits**	**Adjusted Annualized Net Benefit**	
OSHA's Best Estimate of (c) Annualized Total Benefits and (b) Annualized Net Benefits					**(c)**	*$5,189,700,790*	**(b)**	*$4,531,808,579*
Monetized Benefits (High Morbidity Valuation/High Mortality Case Estimate)	Midpoint	High	$2,926,681,791	56%		$8,116,382,581		$7,458,490,370
Monetized Benefits (Low Morbidity Valuation/Low Mortality Case Estimate)	Midpoint	Low	-$2,797,448,568	-54%		$2,392,252,222		$1,734,360,011
Discount rate for benefits (7%)	3%	7%	-$1,723,993,210	-33%		$3,465,707,579		$2,807,815,368
Discount rate for benefits (3%), with Adjustment to Monetized Benefits to Reflect Increases in Real Per Capita Income Over Time	3%	Adjusted 3%	$1,130,801,817	22%		$6,320,502,607		$5,662,610,396

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

In a third sensitivity test, OSHA doubled the estimated travel time for employees to and from medical exams from 60 to 120 minutes. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $1.4 million annually, or by about 0.22 percent, while net benefits would also decline by $1.4 million annually, from $4,532 million to $4,530 million annually.

In a fourth sensitivity test, OSHA reduced its estimate of the number of workers who could be represented by an exposure monitoring sample from four to three. This would have the effect of increasing such costs by one-third. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $24.8 million annually, or by about 3.77 percent, while net benefits would also decline by $24.8 million annually, from $4,532 million to $4,507 million annually.

In a fifth sensitivity test, OSHA increased by 50 percent the size of the productivity penalty arising from the use of engineering controls in construction. As shown in Table VIII–

23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $35.8 million annually, or by about 5.44 percent (and by 7.0 percent in construction), while net benefits would also decline by $35.8 million annually, from $4,532 million to $4,496 million annually.

In a sixth sensitivity test, based on the discussion in Chapter V of this PEA, OSHA reduced the costs of respirator cartridges to reflect possible reductions in costs since the original costs per filter were developed in 2003, and inflated to current dollars. For this purpose, OSHA reduced respirator filter costs by 40 percent to reflect the recent lower-quartile estimates of costs relative to the costs used in OSHA's primary analysis. As shown in Table VIII–23, the total estimated costs of compliance would be reduced by $21.2 million annually, or by about 3.23 percent, while net benefits would also increase by $21.2 million annually, from $4,532 million to $4,553 million annually.

In a seventh sensitivity test, OSHA reduced the average crew size in general industry and maritime subject to a ''unit'' of engineering controls from 4 to 3. This would have the effect of increasing such costs by one-third. As shown in Table VIII–23, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $20.8 million annually, or by about 3.16 percent (and by 14.2 percent in general industry and maritime), while net benefits would also decline by $20.8 million annually, from $4,532 million to $4,511 million annually.

In an eighth sensitivity test, OSHA considered the effect on annualized net benefits of varying the discount rate for costs and the discount rate for benefits separately. In particular, the Agency examined the effect of reducing the discount rate for costs from 7 percent to 3 percent. As indicated in Table VIII–23, this parameter change lowers the estimated annualized cost by $20.6 million, or 3.13 percent. Total annualized net benefits would increase from $4,532 million annually to $4,552 million annually.

The Agency also performed sensitivity tests on several input parameters used to estimate the benefits of the proposed rule. In the first two tests, in an extension of results previously presented in Table VIII–21, the Agency examined the effect on annualized net benefits of employing the high-end estimate of the benefits, as well as the low-end estimate. As discussed previously, the Agency examined the sensitivity of the benefits to both the number of different fatal lung cancer cases prevented, as well as the valuation of individual morbidity cases. Table VIII–23 presents the effect on annualized net benefits of using the extreme values of these ranges, the high mortality count *and* high morbidity valuation case, and the low mortality count *and* low morbidity valuation case. As indicated, using the high estimate of mortality cases prevented and morbidity valuation, the benefits rise by 56% to $8.1 billion, yielding net benefits of $7.5 billion. For the low estimate of both cases and valuation, the benefits decline by 54 percent, to $2.4 billion, yielding net benefits of $1.7 billion.

In the third sensitivity test of benefits, the Agency examined the effect of raising the discount rate for benefits to 7 percent. The fourth sensitivity test of benefits examines the effect of adjusting monetized benefits to reflect increases in real per capita income over time. The results of these two sensitivity tests were previously shown in Table VIII–20 and are repeated in Table VIII–23. Raising the interest rate to 7 percent lowers the estimated benefits by 33 percent, to $3.5 billion, yielding annualized net benefits of $2.8 billion. Adjusting monetized benefits to reflect increases in real per capita income over time raises the benefits by 22 percent, to $6.3 billion, yielding net benefits of $5.7 billion.

''Break-Even'' Analysis

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the proposed rule. However, for these, the Agency performed a ''break-even'' analysis, asking how much the various cost and benefits inputs would have to vary in order for the costs to equal, or break even with, the benefits. The results are shown in Table VIII–24.

In one break-even test on cost estimates, OSHA examined how much costs would have to increase in order for costs to equal benefits. As shown in Table VIII–24, this point would be reached if costs increased by $4.5 billion, or 689 percent.

In a second test, looking specifically at the estimated engineering control costs, the Agency found that these costs would need to increase by $4.5 billion, or 1,318 percent, for costs to equal benefits.

In a third sensitivity test, on benefits, OSHA examined how much its estimated monetary valuation of an avoided illness or an avoided fatality would need to be reduced in order for the costs to equal the benefits. Since the total valuation of prevented mortality and morbidity are each estimated to exceed $1.9 billion, while the estimated costs are $0.6 billion, an independent break-even point for each is impossible. In other words, for example, if no value is attached to an avoided illness associated with the rule, but the estimated value of an avoided fatality is held constant, the rule still has substantial net benefits. Only through a

Table VIII-24

Break-Even Sensitivity Analysis

	OSHA's Best Estimate of Annualized Cost or Benefit Factor	Factor Value at which Benefits Equal Costs	Required Factor Dollar/Number Change	Percentage Factor Change
Total Costs	$657,892,211	$5,189,700,790	$4,531,808,579	688.8%
Engineering Control Costs	$343,818,700	$4,875,627,279	$4,531,808,579	1318.1%
Benefits Valuation per Case Avoided				
Monetized Benefit per Fatality Avoided*	$8,700,000	$1,102,889	-$7,597,111	-87.3%
Monetized Benefit per Illness Avoided*	$2,575,000	$326,430	-$2,248,570	-87.3%
Cases Avoided				
Deaths Avoided*	688	87	-600	-87.3%
Illnesses Avoided*	1,585	201	-1,384	-87.3%

*Note: The total estimated value of prevented mortality or morbidity alone exceeds the estimated cost of the rule, providing no break-even point. Accordingly, these numbers represent a reduction in the composite valuation of an avoided fatality or illness or in the composite number of cases avoided.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

reduction in the estimated net value of both components is a break-even point possible.

The Agency, therefore, examined how large an across-the-board reduction in the monetized value of all avoided illnesses and fatalities would be necessary for the benefits to equal the costs. As shown in Table VIII–24, an 87 percent reduction in the monetized value of all avoided illnesses and fatalities would be necessary for costs to equal benefits, reducing the estimated value to $1.1 million per life saved, and an equivalent percentage reduction to about $0.3 million per illness prevented.

In a fourth break-even sensitivity test, OSHA estimated how many fewer silica-related fatalities and illnesses would be required for benefits to equal costs. Paralleling the previous discussion, eliminating either the prevented mortality or morbidity cases alone would be insufficient to lower benefits to the break-even point. The Agency therefore examined them as a group. As shown in Table VIII–24, a reduction of 87 percent, for both simultaneously, is required to reach the break-even point—600 fewer mortality cases prevented annually, and 1,384 fewer morbidity cases prevented annually.

Taking into account both types of sensitivity analysis the Agency performed on its point estimates of the annualized costs and annualized benefits of the proposed rule, the results demonstrate that net benefits would be positive in all plausible cases tested. In particular, this finding would hold even with relatively large variations in individual input parameters. Alternately, one would have to imagine extremely large changes in costs or benefits for the rule to fail to produce net benefits. OSHA concludes that its finding of significant net benefits resulting from the proposed rule is a robust one.

OSHA welcomes input from the public regarding all aspects of this sensitivity analysis, including any data or information regarding the accuracy of the preliminary estimates of compliance costs and benefits and how the estimates of costs and benefits may be affected by varying assumptions and methodological approaches.

H. Regulatory Alternatives

This section discusses various regulatory alternatives to the proposed OSHA silica standard. OSHA believes that this presentation of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to respirable crystalline silica. The second is tied to the Agency's statutory requirement, which underlies the proposed rule, to reduce significant risk to the extent feasible. If, based on evidence presented during notice and comment, OSHA is unable to justify its preliminary findings of significant risk and feasibility as presented in this preamble to the proposed rule, the Agency must then consider regulatory alternatives that do satisfy its statutory obligations.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m^3; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

Alternative PELs

OSHA is proposing a new PEL for respirable crystalline silica of 50 μg/m^3 for all industry sectors covered by the rule. OSHA's proposal 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 of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases. As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act (29 U.S.C. 655(b)) requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in this section (Section VIII) of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m^3 is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m^3 is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m^3 or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed 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 revised standard and an evaluation of the potential 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 has preliminarily concluded that compliance with the

requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m³ to 100 μg/m³ for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m³ to 50 μg/m³ (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m³ to 25 μg/m³ for all industry sectors covered by the rule, while the action level would remain at 25 μg/m³ (because of difficulties in accurately measuring exposure levels below 25 μg/m³).

Tables VIII–25 and VIII–26 present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m³ and for the regulatory alternatives of a PEL of 100 μg/m³ and a PEL of 25 μg/m³ (Regulatory Alternatives # 1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m³ to the proposed PEL of 50 μg/m³ and then of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Table VIII–25 breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–26 breaks out costs and benefits by major industry sector.

Table VIII-25: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

Table VIII-26: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
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Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
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Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

* Benefits are assessed over a 60-year time horizon, during which it is assumed that economic conditions remain constant. Costs are annualized over ten years, with the exception of equipment expenditures, which are annualized over the life of the equipment. Annualized costs are assumed to continue at the same level for sixty years, which is consistent with assuming that economic conditions remain constant for the sixty year time horizon.

As Tables VIII–25 and VIII–26 show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its preliminary findings that

the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables VIII–25 and VIII–26 also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables VIII–25 and VIII–26, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other the PEL), including requirements for exposure assessment, medical surveillance, silica training, and regulated areas or access control. As shown in Table VIII–25, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in this preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr.Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) help to ensure the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table VIII–27. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Under Regulatory Alternative #3, the action level would be raised from 25 μg/m³ to 50 μg/m³ while keeping the PEL at 50 μg/m³. As a result, exposure monitoring requirements would be triggered only if workers were exposed

Table VIII-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	—	—	—
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	—	—	—
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

above the proposed PEL of 50 μg/m³. As shown in Table VIII–27, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table VIII–27, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table VIII–27, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table VIII–27, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, 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 employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed

construction standard, employers would be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under this regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

One regulatory alternative (Regulatory Alternative #9) involving the timing of the standard would arise if, contrary to OSHA's preliminary findings, a PEL of 50 μg/m^3 with an action level of 25 μg/m^3 were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 μg/m^3 and an action level of 25 μg/m^3 to take effect in five years, but at the same time issue an interim PEL of 100 μg/m^3 and an action level of 50 μg/m^3 to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 μg/m^3 with an action level of 50 μg/m^3 and those estimated for a PEL of 50 μg/m^3 with an action level of 25 μg/m^3, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), OSHA is soliciting comments on this issue. Such a particularized, multi-year phase-in would have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. A differential phase-in for smaller firms would also aid very small firms by allowing them to gain from the control experience of larger firms. A phase-in would also be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard, recognizing, as described in Chapter VII of the PEA, that the full benefits of the proposal would take a number of years to fully materialize even in the absence of a phase-in.

As previously discussed in the Introduction to this preamble, OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

I. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires the preparation of an Initial Regulatory Flexibility Analysis (IRFA) for proposed rules where there would be a significant economic impact on a substantial number of small entities. (5 U.S.C. 601–612). Under the provisions of the law, each such analysis shall contain:

1. A description of the impact of the proposed rule on small entities;
2. A description of the reasons why action by the agency is being considered;
3. A succinct statement of the objectives of, and legal basis for, the proposed rule;
4. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
5. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
6. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
7. A description and discussion of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities, such as

(a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(b) The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(c) The use of performance rather than design standards; and

(d) An exemption from coverage of the rule, or any part thereof, for such small entities.

5 U.S.C. 603, 607.

The Regulatory Flexibility Act further states that the required elements of the IRFA 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 IRFA. 5 U.S.C. 605.

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 PEA and its supporting materials, this IRFA will summarize the key aspects of OSHA's analysis as they affect small entities.

A Description of the Impact of the Proposed Rule on Small Entities

Section VIII.F of this preamble summarized the impacts of the proposed rule on small entities. Tables VIII–12 and VIII–15 showed costs as a percentage of profits and revenues for small entities in general industry and maritime and in construction, respectively, classified as small by the Small Business Administration, and Tables VIII–13 and VIII–16 showed costs as a percentage of revenues and profits for business entities with fewer than 20 employees in general industry and maritime and in construction, respectively. (The costs in these tables were annualized using a discount rate of 7 percent.)

A Description of the Reasons Why Action by the Agency Is Being Considered

Exposure to crystalline silica has been shown to increase the risk of several serious diseases. Crystalline silica is the only known cause of silicosis, which is a progressive respiratory disease in which respirable crystalline silica particles cause an inflammatory reaction in the lung, leading to lung damage and scarring, and, in some cases, to complications resulting in disability and death. In addition, many well-conducted investigations of exposed workers have shown that exposure increases the risk of mortality from lung cancer, chronic obstructive pulmonary disease (COPD), and renal disease. OSHA's detailed analysis of the scientific literature and silica-related health risks are presented in the background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' (placed in Docket OSHA–2010–0034).

Based on a review of over 60 epidemiological studies covering more than 30 occupational groups, OSHA preliminarily concludes that crystalline silica is a human carcinogen. Most of these studies documented that exposed workers experience higher lung cancer mortality rates than do unexposed workers or the general population, and that the increase in lung cancer mortality is related to cumulative exposure to crystalline silica. These exposure-related trends strongly implicate crystalline silica as a likely causative agent. This is consistent with the conclusions of other government and public health organizations, including the International Agency for Research on Cancer (IARC), the Agency for Toxic Substance and Disease Registry (ATSDR), the World Health Organization (WHO), the U.S. Environmental Protection Agency (EPA), the National Toxicology Program (NTP), the National Academies of Science (NAS), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH).

OSHA believes that the strongest evidence for carcinogenicity comes from studies in five industry sectors (diatomaceous earth, pottery, granite, industrial sand, and coal mining) as well as a study by Steenland et al. (2001) that analyzed pooled data from 10 occupational cohort studies; each of these studies found a positive relationship between exposure to crystalline silica and lung cancer mortality. Based on a variety of relative risk models fit to these data sets, OSHA estimates that the excess lifetime risk to workers exposed over a working life of 45 years at the current general industry permissible exposure limit (PEL) (approximately 100 $\mu g/m^3$ respirable crystalline silica) is between 13 and 60 deaths per 1,000 workers. For exposure over a working life at the current construction and shipyard employment PELs (estimated to range between 250 and 500 $\mu g/m^3$), the estimated risk lies between 37 and 653 deaths per 1,000. Reducing these PELs to the proposed PEL of 50 $\mu g/m^3$ respirable crystalline silica results in a substantial reduction of these risks, to a range estimated to be between 6 and 26 deaths per 1,000 workers.

OSHA has also quantitatively evaluated the mortality risk from non-malignant respiratory disease, including silicosis and COPD. Risk estimates for silicosis mortality are based on a study by Mannetje et al. (2002), which pooled data from six worker cohort studies to derive a quantitative relationship between exposure and death rate for silicosis. For non-malignant respiratory disease, risk estimates are based on an epidemiologic study of diatomaceous earth workers, which included a quantitative exposure-response analysis (Park et al., 2002). For 45 years of exposure to the current general industry PEL, OSHA's estimates of excess lifetime risk are 11 deaths per 1,000 workers for the pooled analysis and 83 deaths per 1,000 workers based on Park et al.'s (2002) estimates. At the proposed PEL, estimates of silicosis and non-malignant respiratory disease mortality are 7 and 43 deaths per 1,000, respectively. As noted by Park et al. (2002), it is likely that silicosis as a cause of death is often misclassified as emphysema or chronic bronchitis; thus, Mannetje et al.'s selection of deaths may tend to underestimate the true risk of silicosis mortality, while Park et al.'s (2002) analysis would more fairly capture the total respiratory mortality risk from all non-malignant causes, including silicosis and COPD.

OSHA also identified seven studies that quantitatively described relationships between exposure to respirable crystalline silica and silicosis morbidity, as diagnosed from chest radiography (*i.e.,* chest x-rays or computerized tomography). Estimates of silicosis morbidity derived from these cohort studies range from 60 to 773 cases per 1,000 workers for a 45-year exposure to the current general industry PEL, and approach unity for a 45-year exposure to the current construction/shipyard PEL. Estimated risks of silicosis morbidity range from 20 to 170 cases per 1,000 workers for a 45-year exposure to the proposed PEL, reflecting a substantial reduction in the risk associated with exposure to the current PELs.

OSHA's estimates of crystalline silica-related renal disease mortality risk are derived from an analysis by Steenland et al. (2002), in which data from three cohort studies were pooled to derive a quantitative relationship between exposure to silica and the relative risk of end-stage renal disease mortality. The cohorts included workers in the U.S. gold mining, industrial sand, and granite industries. From this study, OSHA estimates that exposure to the current general industry and proposed PELs over a working life would result in a lifetime excess renal disease risk of 39 and 32 deaths per 1,000 workers, respectively. For exposure to the current construction/shipyard PEL, OSHA estimates the excess lifetime risk to range from 52 to 63 deaths per 1,000 workers.

A Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed rule is to reduce the numbers of fatalities and illnesses occurring among employees exposed to respirable crystalline silica in general industry, maritime, and construction sectors. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, exposure monitoring, medical surveillance, and other protective

measures 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. Sec. 655(b)(5). See Section II of this preamble for a more detailed discussion of the Secretary's legal authority to promulgate standards.

A Description of and Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

OSHA has completed a preliminary analysis of the impacts associated with this proposal, including an analysis of the type and number of small entities to which the proposed rule would apply, as described above. 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 470,000 small business or government entities would be affected by the proposed standard. Within these small entities, roughly 1.3 million workers are exposed to crystalline silica and would be protected by the proposed standard. A breakdown, by industry, of the number of affected small entities is provided in Table III–3 in Chapter III of the PEA.

OSHA estimates that approximately 356,000 very small entities would be affected by the proposed standard. Within these very small entities, roughly 580,000 workers are exposed to crystalline silica and would be protected by the proposed standard. A breakdown, by industry, of the number of affected very small entities is provided in Table III–4 in Chapter III of the PEA.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

Tables VIII–28 and VIII–29 show the average costs of the proposed standard by NAICS code and by compliance requirement for, respectively, small entities (classified as small by SBA) and very small entities (fewer than 20 employees). For the average small entity in general industry and maritime, the estimated cost of the proposed rule would be about $2,103 annually, with engineering controls accounting for 67 percent of the costs and exposure monitoring accounting for 23 percent of the costs. For the average small entity in construction, the estimate cost of the proposed rule would be about $798 annually, with engineering controls accounting for 47 percent of the costs, exposure monitoring accounting for 17 percent of the costs, and medical surveillance accounting for 15 percent of the costs.

For the average very small entity in general industry and maritime, the estimate cost of the proposed rule would be about $616 annually, with engineering controls accounting for 55 percent of the costs and exposure monitoring accounting for 33 percent of the costs. For the average very small entity in construction, the estimate cost of the proposed rule would be about $533 annually, with engineering controls accounting for 45 percent of the costs, exposure monitoring accounting for 16 percent of the costs, and medical surveillance accounting for 16 percent of the costs.

Table VIII–30 shows the unit costs which form the basis for these cost estimates for the average small entity and very small entity.

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
324121	Asphalt paving mixture and block manufacturing.	$232	$4	$13	$1	$74	$1	$326
324122	Asphalt shingle and roofing materials	5,721	297	1,887	103	114	111	8,232
325510	Paint and coating manufacturing	0	10	36	3	15	4	69
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	6,310	428	2,065	150	162	160	9,274
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	1,679	114	663	41	47	42	2,586
327113	Porcelain electrical supply mfg	6,722	458	2,656	162	188	170	10,355
327121	Brick and structural clay mfg	28,574	636	3,018	226	237	236	32,928
327122	Ceramic wall and floor tile mfg	10,982	245	1,160	87	91	91	12,655
327123	Other structural clay product mfg	10,554	235	1,115	83	87	87	12,162
327124	Clay refractory manufacturing	1,325	92	653	33	81	34	2,218
327125	Nonclay refractory manufacturing	1,964	136	802	48	110	51	3,110
327211	Flat glass manufacturing	4,068	160	520	56	50	60	4,913
327212	Other pressed and blown glass and glassware manufacturing.	889	34	110	12	11	13	1,068
327213	Glass container manufacturing	2,004	76	248	27	24	29	2,408
327320	Ready-mixed concrete manufacturing	1,728	460	1,726	163	121	171	4,369
327331	Concrete block and brick mfg	3,236	245	1,257	87	134	91	5,049
327332	Concrete pipe mfg	5,105	386	1,983	137	211	143	7,966
327390	Other concrete product mfg	3,016	228	1,171	81	125	85	4,705
327991	Cut stone and stone product manufacturing.	2,821	207	1,040	74	65	77	4,284
327992	Ground or treated mineral and earth manufacturing.	12,034	174	3,449	62	191	65	15,975
327993	Mineral wool manufacturing	1,365	56	185	20	17	21	1,664
327999	All other misc. nonmetallic mineral product mfg.	2,222	168	863	60	92	62	3,467
331111	Iron and steel mills	604	34	138	12	11	13	812

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
331112	Electrometallurgical ferroalloy product manufacturing.	514	29	118	10	10	11	692
331210	Iron and steel pipe and tube manufacturing from purchased steel.	664	38	154	13	13	14	896
331221	Rolled steel shape manufacturing	583	33	135	12	11	12	787
331222	Steel wire drawing	638	36	148	13	12	14	862
331314	Secondary smelting and alloying of aluminum.	577	33	133	11	11	12	777
331423	Secondary smelting, refining, and alloying of copper.	534	30	125	11	10	11	722
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	548	31	128	11	11	12	741
331511	Iron foundries	9,143	522	2,777	185	200	194	13,021
331512	Steel investment foundries	11,874	675	3,596	240	249	251	16,885
331513	Steel foundries (except investment)	9,223	526	2,802	187	202	196	13,135
331524	Aluminum foundries (except die-casting).	7,367	419	2,231	149	155	156	10,476
331525	Copper foundries (except die-casting)	4,563	260	1,382	92	96	96	6,489
331528	Other nonferrous foundries (except die-casting).	3,895	222	1,179	79	82	82	5,539
332111	Iron and steel forging	531	30	161	11	12	11	756
332112	Nonferrous forging	533	30	162	11	12	11	760
332115	Crown and closure manufacturing	514	29	156	10	11	11	732
332116	Metal stamping	533	30	162	11	12	11	759
332117	Powder metallurgy part manufacturing	535	31	163	11	12	11	762
332211	Cutlery and flatware (except precious) manufacturing.	518	30	157	10	11	11	738
332212	Hand and edge tool manufacturing	542	31	165	11	12	12	772
332213	Saw blade and handsaw manufacturing.	528	30	160	11	12	11	752
332214	Kitchen utensil, pot, and pan manufacturing.	560	32	170	11	12	12	798
332323	Ornamental and architectural metal work.	524	20	102	7	11	8	673
332439	Other metal container manufacturing	550	31	167	11	12	12	784
332510	Hardware manufacturing	531	30	161	11	12	11	756
332611	Spring (heavy gauge) manufacturing	529	30	161	11	12	11	754
332612	Spring (light gauge) manufacturing	585	33	178	12	13	12	834
332618	Other fabricated wire product manufacturing.	537	31	163	11	12	11	765
332710	Machine shops	518	30	157	10	11	11	738
332812	Metal coating and allied services	843	33	165	12	18	12	1,083
332911	Industrial valve manufacturing	528	30	160	11	12	11	752
332912	Fluid power valve and hose fitting manufacturing.	532	30	162	11	12	11	757
332913	Plumbing fixture fitting and trim manufacturing.	528	30	160	11	12	11	752
332919	Other metal valve and pipe fitting manufacturing.	536	31	163	11	12	11	764
332991	Ball and roller bearing manufacturing	545	31	131	11	11	12	741
332996	Fabricated pipe and pipe fitting manufacturing.	529	30	161	11	12	11	754
332997	Industrial pattern manufacturing	517	29	157	10	11	11	736
332998	Enameled iron and metal sanitary ware manufacturing.	484	23	97	8	10	9	630
332999	All other miscellaneous fabricated metal product manufacturing.	521	30	158	11	11	11	742
333319	Other commercial and service industry machinery manufacturing.	526	30	160	11	12	11	750
333411	Air purification equipment manufacturing.	525	30	160	11	11	11	748
333412	Industrial and commercial fan and blower manufacturing.	555	32	169	11	12	12	791
333414	Heating equipment (except warm air furnaces) manufacturing.	520	30	158	11	11	11	741
333511	Industrial mold manufacturing	522	30	159	11	11	11	743
333512	Machine tool (metal cutting types) manufacturing.	524	30	159	11	11	11	746
333513	Machine tool (metal forming types) manufacturing.	532	30	162	11	12	11	758
333514	Special die and tool, die set, jig, and fixture manufacturing.	522	30	158	11	11	11	743
333515	Cutting tool and machine tool accessory manufacturing.	524	30	159	11	11	11	746

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
333516	Rolling mill machinery and equipment manufacturing.	522	30	159	11	11	11	744
333518	Other metalworking machinery manufacturing.	537	31	163	11	12	11	765
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	546	31	166	11	12	12	777
333613	Mechanical power transmission equipment manufacturing.	529	30	161	11	12	11	754
333911	Pump and pumping equipment manufacturing.	535	31	163	11	12	11	762
333912	Air and gas compressor manufacturing	532	30	162	11	12	11	758
333991	Power-driven handtool manufacturing	514	29	156	10	11	11	732
333992	Welding and soldering equipment manufacturing.	523	30	159	11	11	11	745
333993	Packaging machinery manufacturing	521	30	158	11	11	11	742
333994	Industrial process furnace and oven manufacturing.	531	30	161	11	12	11	757
333995	Fluid power cylinder and actuator manufacturing.	531	30	161	11	12	11	756
333996	Fluid power pump and motor manufacturing.	542	31	165	11	12	11	772
333997	Scale and balance (except laboratory) manufacturing.	537	31	163	11	12	11	764
333999	All other miscellaneous general purpose machinery manufacturing.	523	30	159	11	11	11	745
334518	Watch, clock, and part manufacturing	514	29	156	10	11	11	732
335211	Electric housewares and household fans.	523	20	76	7	9	8	643
335221	Household cooking appliance manufacturing.	529	20	77	7	9	8	649
335222	Household refrigerator and home freezer manufacturing.	1,452	56	210	19	26	21	1,784
335224	Household laundry equipment manufacturing.	1,461	56	212	19	26	21	1,795
335228	Other major household appliance manufacturing.	523	20	101	7	11	8	671
336111	Automobile manufacturing	1,309	75	297	25	23	28	1,757
336112	Light truck and utility vehicle manufacturing.	4,789	273	1,085	92	86	102	6,425
336120	Heavy duty truck manufacturing	1,211	69	275	23	22	26	1,626
336211	Motor vehicle body manufacturing	579	33	137	11	11	12	784
336212	Truck trailer manufacturing	525	30	160	11	11	11	748
336213	Motor home manufacturing	792	45	181	15	15	17	1,064
336311	Carburetor, piston, piston ring, and valve manufacturing.	525	30	160	11	11	11	748
336312	Gasoline engine and engine parts manufacturing.	522	30	120	10	10	11	703
336322	Other motor vehicle electrical and electronic equipment manufacturing.	524	30	121	10	10	11	706
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	526	30	120	10	10	11	708
336340	Motor vehicle brake system manufacturing.	527	30	121	10	10	11	710
336350	Motor vehicle transmission and power train parts manufacturing.	528	30	121	10	10	11	710
336370	Motor vehicle metal stamping	556	32	169	11	12	12	792
336399	All other motor vehicle parts manufacturing.	535	30	123	10	10	11	721
336611	Ship building and repair	13,685	0	718	692	47	75	15,217
336612	Boat building	2,831	0	202	149	11	16	3,209
336992	Military armored vehicle, tank, and tank component manufacturing.	624	35	149	12	12	13	845
337215	Showcase, partition, shelving, and locker manufacturing.	527	30	160	11	12	11	751
339114	Dental equipment and supplies manufacturing.	671	39	145	14	11	15	895
339116	Dental laboratories	12	7	130	3	44	3	199
339911	Jewelry (except costume) manufacturing.	120	92	475	33	41	34	795
339913	Jewelers' materials and lapidary work manufacturing.	151	115	596	41	51	43	997
339914	Costume jewelry and novelty manufacturing.	87	44	229	16	19	16	412
339950	Sign manufacturing	465	20	107	7	11	8	618
423840	Industrial supplies, wholesalers	313	29	257	10	15	11	636

TABLE VIII–28—AVERAGE COSTS FOR SMALL ENTITIES AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
482110	Rail transportation	.....	.....	.....	.....	.....	.....	.....
621210	Dental offices	3	2	32	1	11	1	50
	Total—General Industry and Maritime	1,399	93	483	46	46	36	2,103
236100	Residential Building Construction	264	43	34	37	27	15	419
236200	Nonresidential Building Construction	234	104	67	89	66	14	575
237100	Utility System Construction	978	89	172	78	185	30	1,531
237200	Land Subdivision	104	9	25	8	30	3	180
237300	Highway, Street, and Bridge Construction.	692	109	179	95	227	26	1,329
237900	Other Heavy and Civil Engineering Construction.	592	60	134	52	175	18	1,032
238100	Foundation, Structure, and Building Exterior Contractors.	401	359	113	307	91	49	1,319
238200	Building Equipment Contractors	156	18	21	16	27	7	244
238300	Building Finishing Contractors	289	24	23	50	27	9	421
238900	Other Specialty Trade Contractors	460	43	65	52	79	30	729
999000	State and Local Governments [c]	108	16	31	14	43	11	222
	Total—Construction	375	132	72	122	71	26	798

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
324121	Asphalt paving mixture and block manufacturing.	$74	$1	$5	$0	$26	$0	$107
324122	Asphalt shingle and roofing materials	914	48	476	17	23	18	1,496
325510	Paint and coating manufacturing	0	7	33	3	13	3	58
327111	Vitreous china plumbing fixtures & bathroom accessories manufacturing.	851	58	422	21	26	22	1,400
327112	Vitreous china, fine earthenware, & other pottery product manufacturing.	705	48	349	17	22	18	1,160
327113	Porcelain electrical supply mfg	851	58	422	21	26	22	1,400
327121	Brick and structural clay mfg	2,096	47	277	17	19	17	2,474
327122	Ceramic wall and floor tile mfg	2,385	53	316	19	22	20	2,815
327123	Other structural clay product mfg	2,277	51	301	18	21	19	2,687
327124	Clay refractory manufacturing	301	21	186	8	20	8	543
327125	Nonclay refractory manufacturing	471	33	291	12	32	12	852
327211	Flat glass manufacturing	842	34	163	12	12	12	1,075
327212	Other pressed and blown glass and glassware manufacturing.	873	34	164	12	12	12	1,107
327213	Glass container manufacturing	873	34	164	12	12	12	1,107
327320	Ready-mixed concrete manufacturing	475	127	595	46	37	47	1,328
327331	Concrete block and brick mfg	966	74	470	27	44	27	1,608
327332	Concrete pipe mfg	1,046	80	509	29	48	29	1,741
327390	Other concrete product mfg	854	65	416	23	39	24	1,422
327991	Cut stone and stone product manufacturing.	1,158	86	535	31	30	32	1,872
327992	Ground or treated mineral and earth manufacturing.	3,564	52	1,280	19	63	19	4,997
327993	Mineral wool manufacturing	823	34	166	12	12	13	1,061
327999	All other misc. nonmetallic mineral product mfg.	797	61	388	22	37	22	1,327
331111	Iron and steel mills	517	30	197	11	13	11	777
331112	Electrometallurgical ferroalloy product manufacturing.	0	0	0	0	0	0	0
331210	Iron and steel pipe and tube manufacturing from purchased steel.	514	30	196	11	12	11	774
331221	Rolled steel shape manufacturing	514	30	196	11	12	11	774
331222	Steel wire drawing	514	30	196	11	12	11	774
331314	Secondary smelting and alloying of aluminum.	514	30	196	11	12	11	774
331423	Secondary smelting, refining, and alloying of copper.	0	0	0	0	0	0	0
331492	Secondary smelting, refining, and alloying of nonferrous metal (except cu & al).	514	30	196	11	12	11	774
331511	Iron foundries	1,093	63	416	23	26	23	1,644
331512	Steel investment foundries	1,181	68	448	24	28	25	1,774
331513	Steel foundries (except investment)	1,060	61	404	22	26	22	1,595

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
331524	Aluminum foundries (except die-casting).	1,425	82	541	29	33	30	2,141
331525	Copper foundries (except die-casting)	1,503	86	570	31	35	32	2,257
331528	Other nonferrous foundries (except die-casting).	1,401	80	532	29	33	30	2,104
332111	Iron and steel forging	514	30	196	11	12	11	774
332112	Nonferrous forging	514	30	196	11	12	11	774
332115	Crown and closure manufacturing	514	30	196	11	12	11	774
332116	Metal stamping	515	30	196	11	12	11	775
332117	Powder metallurgy part manufacturing	514	30	196	11	12	11	774
332211	Cutlery and flatware (except precious) manufacturing.	514	30	196	11	12	11	774
332212	Hand and edge tool manufacturing	514	30	196	11	12	11	774
332213	Saw blade and handsaw manufacturing.	514	30	196	11	12	11	774
332214	Kitchen utensil, pot, and pan manufacturing.	0	0	0	0	0	0	0
332323	Ornamental and architectural metal work.	520	20	127	7	12	8	694
332439	Other metal container manufacturing	524	30	199	11	13	11	788
332510	Hardware manufacturing	517	30	197	11	13	11	777
332611	Spring (heavy gauge) manufacturing	523	30	199	11	13	11	786
332612	Spring (light gauge) manufacturing	514	30	196	11	12	11	774
332618	Other fabricated wire product manufacturing.	514	30	196	11	12	11	774
332710	Machine shops	515	30	196	11	12	11	774
332812	Metal coating and allied services	519	20	127	7	12	8	694
332911	Industrial valve manufacturing	514	30	196	11	12	11	774
332912	Fluid power valve and hose fitting manufacturing.	514	30	196	11	12	11	774
332913	Plumbing fixture fitting and trim manufacturing.	514	30	196	11	12	11	774
332919	Other metal valve and pipe fitting manufacturing.	519	30	198	11	13	11	781
332991	Ball and roller bearing manufacturing	514	30	196	11	12	11	774
332996	Fabricated pipe and pipe fitting manufacturing.	514	30	196	11	12	11	774
332997	Industrial pattern manufacturing	514	30	196	11	12	11	774
332998	Enameled iron and metal sanitary ware manufacturing.	484	23	153	8	12	9	690
332999	All other miscellaneous fabricated metal product manufacturing.	514	30	196	11	12	11	774
333319	Other commercial and service industry machinery manufacturing.	514	30	196	11	12	11	774
333411	Air purification equipment manufacturing.	514	30	196	11	12	11	774
333412	Industrial and commercial fan and blower manufacturing.	514	30	196	11	12	11	774
333414	Heating equipment (except warm air furnaces) manufacturing.	517	30	197	11	13	11	777
333511	Industrial mold manufacturing	515	30	196	11	12	11	774
333512	Machine tool (metal cutting types) manufacturing.	516	30	196	11	13	11	776
333513	Machine tool (metal forming types) manufacturing.	514	30	196	11	12	11	774
333514	Special die and tool, die set, jig, and fixture manufacturing.	515	30	196	11	12	11	774
333515	Cutting tool and machine tool accessory manufacturing.	515	30	196	11	12	11	775
333516	Rolling mill machinery and equipment manufacturing.	514	30	196	11	12	11	774
333518	Other metalworking machinery manufacturing.	514	30	196	11	12	11	774
333612	Speed changer, industrial high-speed drive, and gear manufacturing.	514	30	196	11	12	11	774
333613	Mechanical power transmission equipment manufacturing.	514	30	196	11	12	11	774
333911	Pump and pumping equipment manufacturing.	514	30	196	11	12	11	774
333912	Air and gas compressor manufacturing	514	30	196	11	12	11	774
333991	Power-driven handtool manufacturing	514	30	196	11	12	11	774
333992	Welding and soldering equipment manufacturing.	514	30	196	11	12	11	774
333993	Packaging machinery manufacturing	514	30	196	11	12	11	774
333994	Industrial process furnace and oven manufacturing.	514	30	196	11	12	11	774

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
333995	Fluid power cylinder and actuator manufacturing.	514	30	196	11	12	11	774
333996	Fluid power pump and motor manufacturing.	514	30	196	11	12	11	774
333997	Scale and balance (except laboratory) manufacturing.	514	30	196	11	12	11	774
333999	All other miscellaneous general purpose machinery manufacturing.	514	30	196	11	12	11	774
334518	Watch, clock, and part manufacturing	514	30	196	11	12	11	774
335211	Electric housewares and household fans.	0	0	0	0	0	0	0
335221	Household cooking appliance manufacturing.	523	20	127	7	12	8	698
335222	Household refrigerator and home freezer manufacturing.	0	0	0	0	0	0	0
335224	Household laundry equipment manufacturing.	0	0	0	0	0	0	0
335228	Other major household appliance manufacturing.	0	0	0	0	0	0	0
336111	Automobile manufacturing	514	30	196	11	12	11	774
336112	Light truck and utility vehicle manufacturing.	514	30	196	11	12	11	774
336120	Heavy duty truck manufacturing	514	30	196	11	12	11	774
336211	Motor vehicle body manufacturing	514	30	196	11	12	11	774
336212	Truck trailer manufacturing	514	30	196	11	12	11	774
336213	Motor home manufacturing	514	30	196	11	12	11	774
336311	Carburetor, piston, piston ring, and valve manufacturing.	514	30	196	11	12	11	774
336312	Gasoline engine and engine parts manufacturing.	514	30	196	11	12	11	774
336322	Other motor vehicle electrical and electronic equipment manufacturing.	514	30	196	11	12	11	774
336330	Motor vehicle steering and suspension components (except spring) manufacturing.	514	30	196	11	12	11	774
336340	Motor vehicle brake system manufacturing.	514	30	196	11	12	11	774
336350	Motor vehicle transmission and power train parts manufacturing.	514	30	196	11	12	11	774
336370	Motor vehicle metal stamping	517	30	197	11	13	11	778
336399	All other motor vehicle parts manufacturing.	514	30	196	11	12	11	774
336611	Ship building and repair	2,820	0	253	151	13	16	3,252
336612	Boat building	2,816	0	252	151	12	15	3,247
336992	Military armored vehicle, tank, and tank component manufacturing.	0	0	0	0	0	0	0
337215	Showcase, partition, shelving, and locker manufacturing.	514	30	196	11	12	11	774
339114	Dental equipment and supplies manufacturing.	663	39	180	14	12	14	922
339116	Dental laboratories	8	5	107	2	32	2	156
339911	Jewelry (except costume) manufacturing.	45	35	225	13	17	13	348
339913	Jewelers' materials and lapidary work manufacturing.	52	40	256	14	19	15	397
339914	Costume jewelry and novelty manufacturing.	50	26	166	9	12	10	274
339950	Sign manufacturing	459	20	132	7	12	7	639
423840	Industrial supplies, wholesalers	262	24	215	9	13	9	531
482110	Rail transportation							
621210	Dental offices	3	2	32	1	11	1	49
	Total—General Industry and Maritime	337	29	205	12	23	11	616
236100	Residential Building Construction	264	43	42	38	30	15	432
236200	Nonresidential Building Construction	117	52	42	46	37	7	301
237100	Utility System Construction	326	30	71	27	69	10	532
237200	Land Subdivision	104	9	25	8	30	3	180
237300	Highway, Street, and Bridge Construction.	275	44	89	39	102	10	559
237900	Other Heavy and Civil Engineering Construction.	202	20	57	18	67	6	372
238100	Foundation, Structure, and Building Exterior Contractors.	228	204	80	180	58	28	778
238200	Building Equipment Contractors	156	18	26	16	30	7	253
238300	Building Finishing Contractors	289	24	28	51	30	9	431
238900	Other Specialty Trade Contractors	276	26	49	32	53	18	454
999000	State and Local Governments [c]	N/A	N/A	N/A	N/A	N/A	N/A	N/A

TABLE VIII–29—AVERAGE COSTS FOR VERY SMALL ENTITIES (<20 EMPLOYEES) AFFECTED BY THE PROPOSED SILICA STANDARD FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

[2009 dollars]

NAICS	Industry	Engineering controls (includes abrasive blasting)	Respirators	Exposure monitoring	Medical surveillance	Training	Regulated areas or access control	Total
	Total—Construction	242	87	56	83	49	17	533

Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Saw enclosure	8′ x 8′ x 8′ wood/plastic.	N/A	$487.70	$48.77	$118.95	Fabrication costs estimated by ERG, assuming in-plant work. Five-year life.
Cab enclosures	Enclosed cabs	N/A	15,164.82	5,307.69	3,698.56	ERG estimate based on vendor interviews.
LEV for hand held grinders.	Shrouds + vacuum	N/A	1,671.63	585.07	407.70	Vacuum plus shroud adapter (*http://www.proventilation.com/products/productDetail.asp?id=15*); 35% for maintenance and operating costs.
Upgraded abrasive blast cabinet.	Improved maintenance and purchases for some.	N/A	4,666.10	1,000.00	664.35	Assumes add. maintenance (of up to $2,000) or new cabinets ($8,000) (Norton, 2003).
Improved spray booth for pottery.	Maintenance time & materials.	N/A	116.65	114.68	231.33	Annual: $100 materials plus 4 hours maintenance time.
Improved LEV for ceramics spray booth.	Increased air flow; per cfm.	N/A	3.21	0.88	3.21	25% of installed CFM price.
Exhaust for saw, cut stone industry.	Based on saw LEV (*e.g.,* pg. 10–158, 159, 160, ACGIH, 2001).	450	5,774.30	1,577.35	822.13	ERG based on typical saw cfm requirements.
LEV for hand chipping in cut stone.	Granite cutting and finishing; (pg. 10–94, ACGIH, 2001).	600	7,699.06	2,103.14	1,096.17	ERG estimate of cfm requirements.
Exhaust trimming machine.	Based on abrasive cut-off saw; (pg. 10–134) (ACGIH, 2001).	500	6,415.89	1,752.61	913.48	Opening of 2 sq ft assumed, with 250 cfm/sq.ft.
Bag opening	Bag opening station; (pg. 10–19, ACGIH, 2001).	1,513	19,414.48	5,303.41	2,764.18	3.5′ x 1.5′ opening; with ventilated bag crusher (200 cfm).
Conveyor ventilation	Conveyor belt ventilation; (pg. 10–70, ACGIH, 2001).	700	8,982.24	2,453.66	1,278.87	Per take-off point, 2′ wide belt.
Bucket elevator ventilation.	Bucket elevator ventilation (pg. 10–68; ACGIH, 2001).	1,600	20,530.84	5,608.36	2,923.13	2′ x 3′ x 30′ casing; 4 take-offs @250 cfm; 100 cfm per sq ft of cross section.
Bin and hopper ventilation.	Bin and hopper ventilation (pg. 10–69; ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	350 cfm per ft2; 3' belt width.
Screen ventilation	Ventilated screen (pg. 10–173, ACGIH, 2001).	1,200	15,398.13	4,206.27	2,192.35	4′ x 6′ screen; 50 cfm per ft^2.
Batch operator workstation.	Bin & hopper ventilation for unvented mixers (pg. 10–69, ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	ERG estimate of cfm requirements.
LEV for hand grinding operator (pottery).	Hand grinding bench (pg. 10–135, ACGIH, 2001).	3,750	48,119.16	13,144.60	6,851.09	ERG estimate of cfm requirements.

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
LEV, mixer and muller hood.	Mixer & muller hood (pg. 10–87, ACGIH, 2001).	1,050	13,473.36	3,680.49	1,918.30	ERG estimate of cfm requirements.
LEV for bag filling stations.	Bag filling station (pg. 10–15, ACGIH, 2001).	1,500	19,247.66	5,257.84	2,740.43	Includes costs for air shower.
Installed manual spray mister.	Manual controls, system covers 100 ft of conveyor.	N/A	10,207.09	1,020.71	1,453.26	National Environmental Services Company (Kestner, 2003).
Install cleaning hoses, reslope floor, drainage.	Plumbing for hose installations, floor resloping and troughs.	N/A	36,412.40	3,258.87	5,184.31	ERG estimate. Includes cost of water and labor time.
Shakeout conveyor enclosure.	Ventilated shakeout conveyor enclosure.	10,000	128,317.75	35,052.26	18,269.56	ERG estimate.
Shakeout side-draft ventilation.	Shakeout double side-draft table (pg. 10–23, ACGIH, 2001).	28,800	369,555.11	100,950.52	52,616.33	ERG estimate of cfm requirements.
Shakeout enclosing hood.	Ventilated enclosing hood (pg. 10–23, ACGIH, 2001); 4′ x 4′ openings.	7,040	90,335.69	24,676.79	12,861.77	ERG estimate of opening size required.
Small knockout table ..	Portable grinding table pg. 10–136), ACGIH, 2001), 3′ x 3′ opening.	1,350	17,322.90	4,732.06	2,466.39	ERG estimate of opening size required.
Large knockout table ..	Hand grinding table pg. 10–135), ACGIH, 2001), 4′ x 6′ surface.	4,800	61,592.52	16,825.09	8,769.39	ERG estimate of bench surface area.
Ventilated abrasive cutoff saw.	Ventilated cut-off saw (pg. 10–134, ACGIH, 2001, 2′ x 3′ opening.	1,500	19,247.66	5,257.84	2,740.43	ERG estimate of opening size required.
Hand grinding bench (foundry).	Bench with LEV (pg. 10–135, ACGIH, 2001); 3′ x 5′.	3,750	48,119.16	13,144.60	6,851.09	ERG estimate of cfm requirements; 250 cfm/sq. ft.
Forming operator bench (pottery).	Bench with LEV (pg. 10–149, ACGIH, 2001), 3′ x 4′.	1,400	17,964.48	4,907.32	2,557.74	ERG estimate of cfm requirements; 125 cfm per linear foot.
Hand grinding bench (pottery).	Bench with LEV (pg. 10–135, ACGIH, 2001); 3′ x 4′.	2,400	30,796.26	8,412.54	4,384.69	ERG estimate of cfm requirements; 200 cfm/sq. ft.
Hand tool hardware	Retrofit suction attachment.	200	464.21	701.05	66.09	ERG estimate of cfm requirements.
Clean air island	Clean air supplied directly to worker.	2,500	32,079.44	8,763.07	4,567.39	ERG estimate of cfm requirements; 125 cfm/sq. ft. for 20 square feet.
Water fed chipping equipment drum cleaning.	Shop-built water feed equipment.	N/A	116.65	0.00	116.65	ERG estimate. $100 in annual costs.
Ventilation for drum cleaning.	Ventilation blower and ducting.	N/A	792.74	198.18	193.34	Electric blower (1,277 cfm) and 25 ft. of duct. Northern Safety Co. (p. 193).
Control room	10′ x 10′ ventilated control room with HEPA filter.	200	19,556.79	701.05	2,784.45	ERG estimate based on RSMeans (2003), ACGIH (2001).
Control room improvement.	Repair and improve control room enclosure.	N/A	2,240.00	N/A	318.93	ERG estimate. Assumes repairs are 20% of new control room cost.
Improved bag valves ..	Bags with extended polyethylene valve, incremental cost per bag.	N/A	0.01	N/A	N/A	Cecala et. al., (1986).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Dust suppressants	Kleen Products 50 lb poly bag green sweeping compound.	N/A	N/A	634.54	0.00	0.28/lb, 2 lbs/day; 5 minutes/day (*www.fastenal.com*).
HEPA vacuum for housekeeping.	NILFISK VT60 wet/dry hepa vac, 15 gal.	N/A	3,494.85	511.20	852.36	Nilfisk, HEPA vacuum (*http://www.sylvane.com/nilfisk.html*).
HEPA vacuum for housekeeping.	NILFISK, large capacity.	N/A	7,699.06	988.90	1,877.73	Nilfisk, HEPA vacuum (McCarthy, 2003).
Yard dust suppression	100 ft, 1" contractor hose and nozzle.	N/A	204.14	0.00	112.91	Contactor hose and nozzle; 2 year life; (*www.pwmall.com*).
Wet methods to clean concrete mixing equip..	10 mins per day per operator.	N/A	0.00	916.82	0.00	10 mins per day per mixer operator.
HEPA vacuum substitute for compressed air.	Incremental time to remove dust by vacuum.	N/A	N/A	494.54	0.00	5 min per day per affected worker.
Spray system for wet concrete finishing.	Shop-built sprayer system.	N/A	204.67	20.47	113.20	Assumes $100 in materials and 4 hours to fabricate. Also 10% for maintenance.
Substitute alt., non-silica, blasting media.	Alternative media estimated to cost 22 percent more.	N/A	0.00	33,646.00	0.00	Based on 212,000 square feet of coverage per year per crew.
Abrasive blasting cost per square foot (dry blasting).	125 blasting days per year.	N/A	N/A	2.00	N/A	ERG estimate based on RSMeans (2009).
Half-mask, non-powered, air-purifying respirator.	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	570.13	N/A	
Full-face nonpowered air-purifying respirator.	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	637.94	N/A	
Half-face respirator (construction).	Unit cost includes expenses for accessories, training, fit testing, and cleaning.	N/A	N/A	468.74	N/A	
Industrial Hygiene Fees/personal breathing zone.	Consulting IH technician—rate per sample. Assumes IH rate of $500 per day and samples per day of 2, 6, and 8 for small, medium, and large establishments, respectively.	N/A	N/A	500	N/A	
Exposure assessment lab fees and shipping cost.	.....	N/A	N/A	133.38	N/A	Lab fees (EMSL Laboratory, 2000) and OSHA estimates. Inflated to 2009 values.
Physical examination by knowledgeable Health Care Practitioner.	Evaluation and office consultation including detailed examination.	N/A	N/A	100.00	N/A	ERG, 2013.
Chest X-ray	Tri-annual radiologic examination, chest; stereo, frontal. Costs include consultation and written report.	N/A	N/A	79.61	N/A	

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Pulmonary function test.	Tri-annual spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurements(s), and/or maximal voluntary ventilation.	N/A	N/A	54.69	N/A	
Examination by a pulmonary specialist [c].	Office consultation and evaluation by a pulmonary specialist.	N/A	N/A	190.28	N/A	
Training instructor cost per hour.	.....	N/A	N/A	34.09	N/A	Based on supervisor wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Training materials for class per attendee.	Estimated cost of $2 per worker for the training/reading materials.	N/A	N/A	2.00	N/A	
Value of worker time spent in class.	.....	N/A	N/A	17.94	N/A	Based on worker wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Cost—disposable particulate respirator (N95).	1.00 per respirator per day, typical cost for N95 disposable respirator.	N/A	N/A	1.00	N/A	Lab Safety Supply, 2010.
Disposable clothing	Per suit, daily clothing costs for 10% of workers.	N/A	N/A	5.50	N/A	Lab Safety Supply, 2010.
Hazard tape	Per regulated area for annual set-up (300 ft).	N/A	N/A	5.80	N/A	Lab Safety Supply, 2010.
Warning signs (6 per regulated area).	25.30 per sign	N/A	N/A	151.80	N/A	Lab Safety Supply, 2010.
Wet kit, with water tank.	.....	N/A	226.73	[d] 0.18	125.40	Contractors Direct (2009); Berland House of Tools (2009); mytoolstore (2009).
Dust shrouds: grinder	.....	N/A	97.33	[d] 0.14	97.33	Contractors Direct (2009); Berland House of Tools (2009); Dust-Buddy (2009); Martin (2008).
Water tank, portable (unspecified capacity).	.....	N/A	N/A	[e] 15.50	N/A	RSMeans—based on monthly rental cost.
Water tank, small capacity (hand pressurized).	.....	N/A	73.87	[d] 0.11	79.04	Contractors Direct (2009); mytoolstore (2009).
Hose (water), 20′, 2″ diameter.	.....	N/A	N/A	[e] 1.65	N/A	RSMeans—based on monthly cost.
Custom water spray nozzle and attachments.	.....	N/A	363	[d] 0.54	388.68	New Jersey Laborers' Health and Safety Fund (2007).
Hose (water), 200′, 2″ diameter.	.....	N/A	N/A	[e] 16.45	N/A	RSMeans—based on monthly rental cost.
Vacuum, 10–15 gal with HEPA.	.....	N/A	725	[d] 0.56	400.99	ICS (2009); Dust Collection (2009); EDCO (2009); CS Unitec (2009).
Vacuum, large capacity with HEPA.	.....	N/A	2,108	[d] 1.63	1,165.92	ICS (2009); EDCO (2009); Aramsco (2009).

TABLE VIII–30—SOURCE INFORMATION FOR THE UNIT COST ESTIMATES USED IN OSHA'S PRELIMINARY COST ANALYSIS FOR GENERAL INDUSTRY, MARITIME, AND CONSTRUCTION—Continued

Control [a]	Description	Ventilation airflow (cfm)	Capital cost [b]	Operating cost	Annualized capital cost	Comment or source
Dust extraction kit (rotary hammers).	.....	N/A	215	[d] 0.30	214.81	Grainger (2009); mytoolstore (2009); Toolmart (2009).
Dust control/quarry drill.	.....	N/A	N/A	[e] 17.33	N/A	RSMeans Heavy Construction Cost Data (2008).
Dustless drywall sander.	.....	N/A	133	[d] 0.19	133.33	Home Depot (2009); LSS (2009); Dustless Tech (2009).
Cab enclosure/w ventilation and air conditioning.	.....	N/A	13,000	[d] 2.59	1,850.91	Estimates from equipment suppliers and retrofitters.
Foam dust suppression system.	.....	N/A	14,550	[e] 162.07	2,071.59	Midyette (2003).
Water tank, engine driven discharge, 5000 gal..	.....	N/A	N/A	[d] 121.50	N/A	RSMeans (2008)—based on monthly rental cost.
Tunnel dust suppression system supplement.	.....	N/A	7,928	[e] 2.71	1,933.47	Raring (2003).
Training instructor cost per hour (Construction).	.....	N/A	N/A	43.12	N/A	Based on supervisor wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Value of worker time spent in class (Construction).	.....	N/A	N/A	22.22	N/A	Based on worker wage, adjusted for fringe benefits (BLS, 2008, updated to 2009 dollars).
Warning signs (3 per regulated area) (Construction).	25.30 per sign	N/A	N/A	75.90	N/A	Lab Safety Supply, 2010.
Per-worker costs for written access control plan or regulated area setup implementation (Construction).	Weighted average annual cost per worker; Applies to workers with exposures above the PEL.			175.56		

[a] For local exhaust ventilation (LEV), maintenance, and conveyor covers, OSHA applied the following estimates:
LEV: capital cost = $12.83 per cfm; operating cost = $3.51 per cfm; annualized capital cost = $1.83 per cfm; based on current energy prices and the estimates of consultants to ERG (2013).
Maintenance: estimated as 10% of capital cost.
Conveyor Covers: estimated as $17.10 per linear foot for 100 ft. (Landola, 2003); capital cost = $19.95 per linear ft., including all hardware; annualized capital cost = $2.84 per linear ft.
[b] Adjusted from 2003 price levels using an inflation factor of 1.166, calculated as the ratio of average annual GDP Implicit Price Deflator for 2009 and 2003.
[c] Mean expense per office-based physician visit to a pulmonary specialist for diagnosis and treatment, based on data from the 2004 Medical Expenditure Panel Survey. Inflated to 2009 dollars using the consumer price inflator for medical services.
Costs for physical exams and tests, chest X-ray, and pulmonary tests are direct medical costs used in bundling services under Medicare (Intellimed International, 2003). Costs are inflated by 30% to eliminate the effect of Medicare discounts that are unlikely to apply to occupational medicine environments.
[d] Daily maintenance and operating cost.
[e] Daily equipment costs derived from RS Means (2008) monthly rental rates, which include maintenance and operating costs.
Source: U.S. Dept. of Labor, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on ERG (2013).

Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule.

OSHA has not identified any other Federal rules which may duplicate, overlap, or conflict with the proposal, and requests comments from the public regarding this issue.

1. Alternatives to the Proposed Rule which Accomplish the Stated Objectives of Applicable Statutes and which Minimize any Significant Economic Impact of the Proposed Rule on Small Entities

This section first discusses several provisions in the proposed standard that OSHA has adopted or modified based on comments from small entity representatives (SERs) during the SBREFA Panel process or on recommendations made by the SBREFA Panel as potentially alleviating impacts on small entities. Then, the Agency presents various regulatory alternatives to the proposed OSHA silica standard.

a. Elements of Proposed Rule To Reduce Impacts on Small Entities

The SBREFA Panel was concerned that changing work conditions in the construction industry would make it

difficult to apply some of the provisions that OSHA suggested at the time of the Panel. OSHA has preliminarily decided to change its approach in this sector. OSHA is proposing two separate standards, one for general industry and maritime and one for construction. As described earlier in this preamble, in construction, OSHA has provided a table—labeled Table 1, Exposure Control Methods for Selected Construction Operations—that for special operations enables the employer to implement engineering controls, work practices, and respiratory protection without the need for exposure assessment. Table 1 in the proposed construction standard presents engineering and work practice controls and respiratory protection options for special operations. Where employees perform the special operations listed in the table and the employer has fully implemented the engineering controls, work practices, and respiratory protection specified in the table, the employer is not required to assess the exposure of employees performing such operations.

As an alternative to the regulated area provision, OSHA is proposing that employers be permitted the option of establishing written access control plans that must contain provisions for a competent person; procedures for notifying employees of the presence of exposure to respirable crystalline silica and demarcating such areas from the rest of the workplace; in multi-employer workplaces, the methods for informing other employers of the presence and location of areas where silica exposures may exceed the PEL; provisions for limiting access to areas where silica exposures are likely; and procedures for providing respiratory protection to employees entering areas with controlled access. Further discussion on this alternative is found in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control.*

OSHA believes that, although the estimated per-worker cost for written access control plans averages somewhat higher than the per-worker cost for regulated areas ($199.29 per worker for the control plans vs. $167.65 per worker for the regulated area), access control plans may be significantly less costly and more protective than regulated areas in certain work situations.

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 provisions regarding housekeeping, protective clothing, and hygiene facilities. For this proposed rule, OSHA removed the requirement for hygiene facilities, which has resulted in the elimination of compliance costs for change rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. OSHA also restricted the provision for protective clothing (or, alternatively, any other means to remove excessive silica dust from work clothing) to situations where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica.

b. Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion of the various regulatory alternatives to the proposed OSHA silica standard presented in the Introduction and in Section VIII.H of this preamble.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's findings of significant risk and feasibility. To facilitate comment, the regulatory alternatives have been organized into four categories: (1) Alternative PELs to the proposed PEL of 50 μg/m³; (2) regulatory alternatives that affect proposed ancillary provisions; (3) a regulatory alternative that would modify the proposed methods of compliance; and (4) regulatory alternatives concerning when different provisions of the proposed rule would take effect.

Alternative PELs

OSHA is proposing a new PEL for respirable crystalline silica of 50 μg/m³ for all industry sectors covered by the rule. OSHA's proposal 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 of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

OSHA has conducted an extensive review of the literature on adverse health effects associated with exposure to respirable crystalline silica. The Agency has also developed estimates of the risk of silica-related diseases assuming exposure over a working lifetime at the proposed PEL and action level, as well as at OSHA's current PELs. These analyses are presented in a background document entitled ''Respirable Crystalline Silica—Health Effects Literature Review and Preliminary Quantitative Risk Assessment'' and are summarized in this preamble in Section V, Health Effects Summary, and Section VI, Summary of OSHA's Preliminary Quantitative Risk Assessment, respectively. The available evidence indicates that employees exposed to respirable crystalline silica well below the current PELs are at increased risk of lung cancer mortality and silicosis mortality and morbidity. Occupational exposures to respirable crystalline silica also may result in the development of kidney and autoimmune diseases and in death from other nonmalignant respiratory diseases. As discussed in Section VII, Significance of Risk, in this preamble, OSHA preliminarily finds that worker exposure to respirable crystalline silica constitutes a significant risk and that the proposed standard will substantially reduce this risk.

Section 6(b) of the OSH Act (29 U.S.C. 655(b)) requires OSHA to determine that its standards are technologically and economically feasible. OSHA's examination of the technological and economic feasibility of the proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA), and is summarized in this section (Section VIII) of this preamble. For general industry and maritime, OSHA has preliminarily concluded that the proposed PEL of 50 μg/m³ is technologically feasible for all affected industries. For construction, OSHA has preliminarily determined that the proposed PEL of 50 μg/m³ is feasible in 10 out of 12 of the affected activities. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain silica exposures to the proposed PEL of 50 μg/m³ or below in most operations most of the time in the affected industries. For those few operations within an industry or activity where the proposed PEL is not technologically feasible even when workers use recommended engineering and work practice controls, employers can supplement controls with respirators to achieve exposure levels at or below the proposed PEL.

OSHA developed quantitative estimates of the compliance costs of the proposed 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 revised standard and an evaluation of the potential 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 has preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

OSHA has examined two regulatory alternatives (named Regulatory Alternatives #1 and #2) that would modify the PEL for the proposed rule. Under Regulatory Alternative #1, the proposed PEL would be changed from 50 μg/m^3 to 100 μg/m^3 for all industry sectors covered by the rule, and the action level would be changed from 25 μg/m^3 to 50 μg/m^3 (thereby keeping the action level at one-half of the PEL). Under Regulatory Alternative #2, the proposed PEL would be lowered from 50 μg/m^3 to 25 μg/m^3 for all industry sectors covered by the rule, while the action level would remain at 25 μg/m^3 (because of difficulties in accurately measuring exposure levels below 25 μg/m^3).

Tables VIII–31A and VIII–31B present, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed PEL of 50 μg/m^3 and for the regulatory alternatives of a PEL of 100 μg/m^3 and a PEL of 25 μg/m^3 (Regulatory Alternatives # 1 and #2), using alternative discount rates of 3 and 7 percent. These two tables also present the incremental costs, the incremental benefits, and the incremental net benefits of going from a PEL of 100 μg/m^3 to the proposed PEL of 50 μg/m^3 and then of going from the proposed PEL of 50 μg/m^3 to a PEL of 25 μg/m^3. Table VIII–31A breaks out costs by provision and benefits by type of disease and by morbidity/mortality, while Table VIII–31B breaks out costs and benefits by major industry sector.

Table VIII-31A: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Engineering Controls (includes Abrasive Blasting)		$330	$344		$0	$0		$330	$344		$187	$197		$143	$147
Respirators		$421	$422		$330	$331		$91	$91		$88	$88		$2	$3
Exposure Assessment		$203	$203		$131	$129		$73	$74		$26	$26		$47	$48
Medical Surveillance		$219	$227		$143	$148		$76	$79		$28	$29		$48	$50
Training		$49	$50		$0	$0		$49	$50		$0	$0		$49	$50
Regulated Area or Access Control		$85	$86		$66	$66		$19	$19		$10	$10		$9	$10
Total Annualized Costs (point estimate)		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Fatal Lung Cancers (midpoint estimate)	237			75			162			79			83		
Fatal Silicosis & other Non-Malignant Respiratory Diseases	527			152			375			186			189		
Fatal Renal Disease	258			108			151			91			60		
Silica-Related Mortality	1,023	$4,811	$3,160	335	**$1,543**	**$1,028**	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity	1,770	$2,219	$1,523	186	**$233**	**$160**	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

Table VIII-31B: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Silica Standard of 50 μg/m³ and 100 μg/m³ Alternative, by Major Industry Sector
Millions ($2009)

	25 μg/m³			Incremental Costs/Benefits			50 μg/m³			Incremental Costs/Benefits			100 μg/m³		
Discount Rate		3%	7%		3%	7%		3%	7%		3%	7%		3%	7%
Annualized Costs															
Construction		$1,043	$1,062		$548	$551		$495	$511		$233	$241		$262	$270
General Industry/Maritime		$264	$270		$122	$123		$143	$147		$106	$110		$36	$37
Total Annualized Costs		**$1,308**	**$1,332**		**$670**	**$674**		**$637**	**$658**		**$339**	**$351**		**$299**	**$307**
Annual Benefits: Number of Cases Prevented	Cases			Cases			Cases			Cases			Cases		
Silica-Related Mortality															
Construction	802	$3,804	$2,504	235	$1,109	$746	567	$2,695	$1,758	242	$1,158	$760	325	$1,537	$998
General Industry/Maritime	221	$1,007	$657	100	$434	$283	121	$573	$374	115	$545	$356	6	$27	$18
Total	1,023	$4,811	$3,160	335	$1,543	$1,028	688	$3,268	$2,132	357	$1,704	$1,116	331	$1,565	$1,016
Silicosis Morbidity															
Construction	1,157	$1,451	$996	77	$96	$66	1,080	$1,354	$930	161	$202	$139	919	$1,152	$791
General Industry/Maritime	613	$768	$528	109	$136	$94	504	$632	$434	471	$590	$405	33	$42	$29
Total	1,770	$2,219	$1,523	186	$233	$160	1,585	$1,986	$1,364	632	$792	$544	953	$1,194	$820
Monetized Annual Benefits (midpoint estimate)															
Construction		$5,255	$3,500		$1,205	$812		$4,049	$2,688		$1,360	$898		$2,690	$1,789
General Industry/Maritime		$1,775	$1,184		$570	$377		$1,205	$808		$1,135	$761		$69	$47
Total		**$7,030**	**$4,684**		**$1,776**	**$1,188**		**$5,254**	**$3,495**		**$2,495**	**$1,659**		**$2,759**	**$1,836**
Net Benefits															
Construction		$4,211	$2,437		$657	$261		$3,555	$2,177		$1,127	$658		$2,427	$1,519
General Industry/Maritime		$1,511	$914		$448	$254		$1,062	$661		$1,029	$651		$33	$10
Total		**$5,722**	**$3,352**		**$1,105**	**$514**		**$4,617**	**$2,838**		**$2,157**	**$1,308**		**$2,460**	**$1,529**

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

As Tables VIII–31A and VIII–31B show, going from a PEL of 100 μg/m³ to a PEL of 50 μg/m³ would prevent, annually, an additional 357 silica-related fatalities and an additional 632 cases of silicosis. Based on its

preliminary findings that the proposed PEL of 50 μg/m³ significantly reduces worker risk from silica exposure (as demonstrated by the number of silica-related fatalities and silicosis cases avoided) and is both technologically and economically feasible, OSHA cannot propose a PEL of 100 μg/m³ (Regulatory Alternative #1) without violating its statutory obligations under the OSH Act. However, the Agency will consider evidence that challenges its preliminary findings.

As previously noted, Tables VIII–31A and VIII–31B also show the costs and benefits of a PEL of 25 μg/m³ (Regulatory Alternative #2), as well as the incremental costs and benefits of going from the proposed PEL of 50 μg/m³ to a PEL of 25 μg/m³. Because OSHA determined that a PEL of 25 μg/m³ would not be feasible (that is, engineering and work practices would not be sufficient to reduce and maintain silica exposures to a PEL of 25 μg/m³ or below in most operations most of the time in the affected industries), the Agency did not attempt to identify engineering controls or their costs for affected industries to meet this PEL. Instead, for purposes of estimating the costs of going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³, OSHA assumed that all workers exposed between 50 μg/m³ and 25 μg/m³ would have to wear respirators to achieve compliance with the 25 μg/m³ PEL. OSHA then estimated the associated additional costs for respirators, exposure assessments, medical surveillance, and regulated areas (the latter three for ancillary requirements specified in the proposed rule).

As shown in Tables VIII–31A and VIII–31B, going from a PEL of 50 μg/m³ to a PEL of 25 μg/m³ would prevent, annually, an additional 335 silica-related fatalities and an additional 186 cases of silicosis. These estimates support OSHA's preliminarily finding that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has preliminarily determined that a PEL of 25 μg/m³ (Regulatory Alternative #2) is not technologically feasible, and for that reason, cannot propose it without violating its statutory obligations under the OSH Act.

Regulatory Alternatives That Affect Ancillary Provisions

The proposed rule contains several ancillary provisions (provisions other the PEL), including requirements for exposure assessment, medical surveillance, silica training, and regulated areas or access control. As shown in Table VIII–31A, these ancillary provisions represent approximately $223 million (or about 34 percent) of the total annualized costs of the rule of $658 million (using a 7 percent discount rate). The two most expensive of the ancillary provisions are the requirements for medical surveillance, with annualized costs of $79 million, and the requirements for exposure monitoring, with annualized costs of $74 million.

As proposed, the requirements for exposure assessment are triggered by the action level. As described in the preamble, OSHA has defined the action level for the proposed standard as an airborne concentration of respirable crystalline silica of 25 μg/m³ calculated as an eight-hour time-weighted average. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees have not been exposed to respirable crystalline silica concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure assessment provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr.Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (D.C. Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA's preliminary conclusion is that the requirements triggered by the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level for exposure monitoring of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As specified in the proposed rule, all workers exposed to respirable crystalline silica above the PEL of 50 μg/m³ are subject to the medical surveillance requirements. This means that the medical surveillance requirements would apply to 15,172 workers in general industry and 336,244 workers in construction. OSHA estimates that 457 possible silicosis cases will be referred to pulmonary specialists annually as a result of this medical surveillance.

OSHA has preliminarily determined that these ancillary provisions will: (1) Help to ensure the PEL is not exceeded, and (2) minimize risk to workers given the very high level of risk remaining at the PEL. OSHA did not estimate, and the benefits analysis does not include, monetary benefits resulting from early discovery of illness.

Because medical surveillance and exposure assessment are the two most costly ancillary provisions in the proposed rule, the Agency has examined four regulatory alternatives (named Regulatory Alternatives #3, #4, #5, and #6) involving changes to one or the other of these ancillary provisions. These four regulatory alternatives are defined below and the incremental cost impact of each is summarized in Table VIII–32. In addition, OSHA is including a regulatory alternative (named Regulatory Alternative #7) that would remove all ancillary provisions.

Under Regulatory Alternative #3, the action level would be raised from 25 μg/m³ to 50 μg/m³ while keeping the PEL at 50 μg/m³. As a result, exposure monitoring requirements would be triggered only if workers were exposed

Table VIII-32: Cost of Regulatory Alternatives Affecting Ancillary Provisions

3% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$494,826,699	$142,502,681	$637,329,380	—	—	—
Option 3: PEL=50; AL=50	$457,686,162	$117,680,601	$575,366,763	-$37,140,537	-$24,822,080	-$61,962,617
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$606,697,624	$173,701,827	$780,399,451	$111,870,925	$31,199,146	$143,070,071
Option 5: PEL=50; AL=25, with medical exams annually	$561,613,766	$145,088,559	$706,702,325	$66,787,067	$2,585,878	$69,372,945
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$775,334,483	$203,665,685	$979,000,168	$280,507,784	$61,163,004	$341,670,788

7% Discount Rate	Cost			Incremental Cost Relative to Proposal		
	Construction	GI/M	Total	Construction	GI/M	Total
Proposed Rule	$511,165,616	$146,726,595	$657,892,211	—	—	—
Option 3: PEL=50; AL=50	$473,638,698	$121,817,396	$595,456,093	-$37,526,918	-$24,909,200	-$62,436,118
Option 4: PEL=50; AL =25, with medical surveillance triggered by AL	$627,197,794	$179,066,993	$806,264,787	$132,371,095	$36,564,312	$168,935,407
Option 5: PEL=50; AL=25, with medical exams annually	$575,224,843	$149,204,718	$724,429,561	$64,059,227	$2,478,122	$66,537,350
Option 6: PEL=50; AL=25, with surveillance triggered by AL and medical exams annually	$791,806,358	$208,339,741	$1,000,146,099	$280,640,742	$61,613,145	$342,253,887

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis

above the proposed PEL of 50 μg/m³. As shown in Table VIII–32, Regulatory Option #3 would reduce the annualized cost of the proposed rule by about $62 million, using a discount rate of either 3 percent or 7 percent.

Under Regulatory Alternative #4, the action level would remain at 25 μg/m³ but medical surveillance would now be triggered by the action level, not the PEL. As a result, medical surveillance requirements would be triggered only if workers were exposed at or above the proposed action level of 25 μg/m³. As shown in Table VIII–32, Regulatory Option #4 would increase the annualized cost of the proposed rule by about $143 million, using a discount rate of 3 percent (and by about $169 million, using a discount rate of 7 percent).

Under Regulatory Alternative #5, the only change to the proposed rule would be to the medical surveillance requirements. Instead of requiring workers exposed above the PEL to have a medical check-up every three years, those workers would be required to have a medical check-up annually. As shown in Table VIII–32, Regulatory Option #5 would increase the annualized cost of the proposed rule by about $69 million, using a discount rate of 3 percent (and by about $66 million, using a discount rate of 7 percent).

Regulatory Alternative #6 would essentially combine the modified requirements in Regulatory Alternatives #4 and #5. Under Regulatory Alternative #6, medical surveillance would be triggered by the action level, not the PEL, and workers exposed at or above the action level would be required to have a medical check-up annually rather than triennially. The exposure monitoring requirements in the proposed rule would not be affected. As shown in Table VIII–32, Regulatory Option #6 would increase the annualized cost of the proposed rule by about $342 million, using a discount rate of either 3 percent or 7 percent.

OSHA is not able to quantify the effects of these preceding four regulatory alternatives on protecting workers exposed to respirable crystalline silica at levels at or below the proposed PEL of 50 μg/m³—where significant risk remains. The Agency solicits comment on the extent to which these regulatory options may improve or reduce the effectiveness of the proposed rule.

The final regulatory alternative affecting ancillary provisions, Regulatory Alternative #7, would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, training, and regulated areas or access control. However, it should be carefully noted that elimination of the ancillary provisions does not mean that all costs for ancillary provisions would disappear. In order to meet the PEL, 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 employers would increasingly follow the many recommendations to provide medical surveillance for employees. OSHA has not attempted to estimate the extent to which the costs of these activities would be reduced if they were not formally required, but OSHA welcomes comment on the issue.

As indicated previously, OSHA preliminarily finds that there is significant risk remaining at the proposed PEL of 50 μg/m³. However, the Agency has also preliminarily determined that 50 μg/m³ is the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. OSHA anticipates that these ancillary provisions will reduce the risk beyond the reduction that will be achieved by a new PEL alone.

OSHA's reasons for including each of the proposed ancillary provisions are detailed in Section XVI of this preamble, Summary and Explanation of the Standards. In particular, OSHA believes that requirements for exposure assessment (or alternately, using specified exposure control methods for selected construction operations) would provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is particularly important because individuals exposed above the PEL (which triggers medical surveillance in the proposed rule) are at significant risk of death and illness. Medical surveillance would allow for identification of respirable crystalline silica-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA believes that regulated areas and access control are important because they serve to limit exposure to respirable crystalline silica to as few employees as possible. Finally, OSHA believes that worker training is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize potential health hazards. Worker training on silica-related work practices is particularly important in controlling silica exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule. For example, OSHA believes that the effectiveness of the proposed rule depends on regulated areas or access control to further limit exposures and on medical surveillance to identify disease cases when they do occur.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to respirable crystalline silica. For example, the industry consensus standards for crystalline silica, ASTM E 1132–06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica, and ASTM E 2626–09, Standard Practice for Controlling Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities, as well as the draft proposed silica standard for construction developed by the Building and Construction Trades Department, AFL–CIO, have each included comprehensive programs. These recommended standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance (ASTM, 2006; 2009; BCTD 2001). Moreover, as mentioned previously, where there is continuing significant risk, the decision in the Asbestos case (*Bldg. and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1274 (DC Cir. 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. OSHA preliminarily concludes that the additional requirements in the ancillary provisions of the proposed standard clearly exceed this threshold.

A Regulatory Alternative That Modifies the Methods of Compliance

The proposed standard in general industry and maritime would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the PEL. Where engineering and/or work practice controls are insufficient, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. Under the proposed

construction standard, employers would be given two options for compliance. The first option largely follows requirements for the general industry and maritime proposed standard, while the second option outlines, in Table 1 (Exposure Control Methods for Selected Construction Operations) of the proposed rule, specific construction exposure control methods. Employers choosing to follow OSHA's proposed control methods would be considered to be in compliance with the engineering and work practice control requirements of the proposed standard, and would not be required to conduct certain exposure monitoring activities.

One regulatory alternative (Regulatory Alternative #8) involving methods of compliance would be to eliminate Table 1 as a compliance option in the construction sector. Under this regulatory alternative, OSHA estimates that there would be no effect on estimated benefits but that the annualized costs of complying with the proposed rule (*without* the benefit of the Table 1 option in construction) would increase by $175 million, totally in exposure monitoring costs, using a 3 percent discount rate (and by $178 million using a 7 percent discount rate), so that the total annualized compliance costs for all affected establishments in construction would increase from $495 to $670 million using a 3 percent discount rate (and from $511 to $689 million using a 7 percent discount rate).

Regulatory Alternatives That Affect the Timing of the Standard

The proposed rule would become effective 60 days following publication of the final rule in the **Federal Register**. Provisions outlined in the proposed standard would become enforceable 180 days following the effective date, with the exceptions of engineering controls and laboratory requirements. The proposed rule would require engineering controls to be implemented no later than one year after the effective date, and laboratory requirements would be required to begin two years after the effective date.

One regulatory alternative (Regulatory Alternative #9) involving the timing of the standard would arise if, contrary to OSHA's preliminary findings, a PEL of 50 μg/m³ with an action level of 25 μg/m³ were found to be technologically and economically feasible some time in the future (say, in five years), but not feasible immediately. In that case, OSHA might issue a final rule with a PEL of 50 μg/m³ and an action level of 25 μg/m³ to take effect in five years, but at the same time issue an interim PEL of 100 μg/m³ and an action level of 50 μg/m³ to be in effect until the final rule becomes feasible. Under this regulatory alternative, and consistent with the public participation and ''look back'' provisions of Executive Order 13563, the Agency could monitor compliance with the interim standard, review progress toward meeting the feasibility requirements of the final rule, and evaluate whether any adjustments to the timing of the final rule would be needed. Under Regulatory Alternative #9, the estimated costs and benefits would be somewhere between those estimated for a PEL of 100 μg/m³ with an action level of 50 μg/m³ and those estimated for a PEL of 50 μg/m³ with an action level of 25 μg/m³, the exact estimates depending on the length of time until the final rule is phased in. OSHA emphasizes that this regulatory alternative is contrary to the Agency's preliminary findings of economic feasibility and, for the Agency to consider it, would require specific evidence introduced on the record to show that the proposed rule is not now feasible but would be feasible in the future.

Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), OSHA is soliciting comments on this issue. Such a particularized, multi-year phase-in would have several advantages, especially from the viewpoint of impacts on small businesses. First, it would reduce the one-time initial costs of the standard by spreading them out over time, a particularly useful mechanism for small businesses that have trouble borrowing large amounts of capital in a single year. A differential phase-in for smaller firms would also aid very small firms by allowing them to gain from the control experience of larger firms. A phase-in would also be useful in certain industries—such as foundries, for example—by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However a phase-in would also postpone the benefits of the standard.

As previous discussed in the Introduction and in Section VIII.H of this preamble, OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them.

SBREFA Panel

Table VIII–33 lists all of the SBREFA Panel recommendations and OSHA's responses to these recommendations.

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA give consideration to the alternative of improved enforcement of and expanded outreach for the existing rule rather than a new rule. In addition, the Panel recommended that OSHA carefully study the effects of existing compliance and outreach efforts, such as the Special Emphasis Program on silica, with a view to better delineating the effects of such efforts. This examination should include (1) a year-by-year analysis of the extent of noncompliance discovered in OSHA compliance inspections, and (2) the kinds of efforts OSHA made to improve enforcement and outreach.	As discussed in Chapter II of the PEA, Need for Regulation (and summarized in Section VIII.B of this Preamble), OSHA has reviewed existing enforcement and outreach programs, as well as other legal and administrative remedies, and believes that a standard would be the most effective means to protect workers from exposure to silica. A review of OSHA's compliance assistance efforts and an analysis of compliance with the current PELs for respirable crystalline silica are discussed in Section III of the preamble, Events Leading to the Proposed Standard.

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(General Industry) The Panel recommended that OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs, and that the Agency compare OSHA's revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA has reviewed its cost estimates in response to the comments received from the SERs and evaluated the alternative estimates and methodologies suggested by the SERs. In some cases (such as for exposure monitoring and training) OSHA has revised its cost estimates in response to SER comments. However, OSHA has not made all cost changes suggested by the SERs, but has retained (or simply updated) those cost estimates that OSHA determined reflect sound methodology and reliable data. OSHA requests comments on the Agency's estimated costs and on the assumptions applied in the cost analysis, and has included this topic in Section I. Issues (*See* Compliance Costs) and in Chapter V of the PEA.
The Panel recommended that, as time permits, OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs and that the Agency compare the OSHA revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA has extensively reviewed its costs estimates, changed many of them in response to SER comments, and solicits comments on these revised cost estimates. A few examples of OSHA's cost changes are given in the responses to specific issues below (*e.g.,* exposure monitoring, medical exams, training and familiarization). OSHA requests comments on the Agency's estimated costs and on the assumptions applied in the cost analysis, and has included this topic in Section I. Issues (*See* Compliance Costs) and in Chapter V of the PEA.
The Panel recommended that prior to publishing a proposed standard, OSHA should carefully consider the ability of each potentially affected industry to meet any proposed PEL for silica, and that OSHA should recognize, and incorporate in its cost estimates, specific issues or hindrances that different industries may have in implementing effective controls.	The PEA reflects OSHA's judgment on technological feasibility and includes responses to specific issues raised by the Panel and SERs. OSHA solicits comment on the accuracy and reasonableness of these judgments and has included this topic in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL and Compliance Costs).
The Panel recommended that OSHA carefully review the basis for its estimated exposure monitoring costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	Table 1 in the proposed standard is designed to relieve establishments in construction from requirements for exposure assessment when certain controls are established. OSHA developed cost estimates in the PEA for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. OSHA estimated higher exposure monitoring costs for small entities because an industrial hygienist could not take as many samples a day in a small establishment as in a large one. OSHA believes that its unit cost estimates for exposure monitoring are realistic but will raise that as an issue. See Chapter V of the PEA for details of OSHA's unit costs for exposure monitoring in general industry and maritime.
The Panel recommended that OSHA carefully review the basis for its estimated health screening compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA's cost estimates for health screening are a function of the size of the establishment. OSHA's cost estimates now reflect the fact that smaller entities will tend to experience larger unit costs. OSHA estimated higher medical surveillance costs (than was estimated in the Preliminary Initial Regulatory Flexibility Analysis (PIRFA)) for small entities because smaller establishments would be more likely to send the workers off-site for medical testing. In addition, OSHA significantly increased the total costs of exposure sampling and x-rays in medical surveillance by assuming no existing compliance with the those provisions in the proposed rule (as compared to an average of 32.6 percent and 34.8 percent existing compliance, respectively, in the PIRFA).
(Construction) The Panel recommended that OSHA carefully review the basis for its estimated hygiene compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA removed the specific hygiene provisions in the proposed rule, which has resulted in the elimination of compliance costs for changing rooms, shower facilities, lunch rooms, and hygiene-specific housekeeping requirements. However, OSHA has retained requirements and cost estimates for disposable clothing (in regulated areas) where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica.
The Panel recommended that OSHA carefully review the issue of dry sweeping in the analysis, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	Dry sweeping remains a prohibited activity in the proposed standard and OSHA has estimated the costs for the use of wet methods to control dust (*see* Table VIII–30, above). OSHA requests comment on the use of wet methods as a substitute for dry sweeping and has included this topic in Section I. Issues (*See* Compliance Costs and Provisions of the Standards—Methods of compliance).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA carefully review the basis for its training costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	One participant in the silica SBREFA process objected to ERG's analytical assumption (used in OSHA's Preliminary Initial Regulatory Flexibility Analysis) that training is needed only for those workers exposed above the action level and suggested that training might be necessary for all at-risk workers. For the proposed rule, the scope of this requirement was revised so that the provision now would apply to workers with any potential occupational exposure to respirable crystalline silica; OSHA has estimated training costs in the PEA accordingly. OSHA estimated higher training costs for small entities because of smaller-sized training classes and significantly increased training costs by assuming only half compliance for half of the affected establishments (compared to an average of 56 percent existing compliance for all establishments in the PIRFA).
(Construction) SERs raised cost issues similar to those in general industry, but were particularly concerned about the impact in construction, given the high turnover rates in the industry. The Panel recommended that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	The cost estimates in the PEA reflect OSHA's best judgment and take the much higher labor turnover rates in construction into account when calculating costs. For the proposed rule, OSHA used the most recent BLS turnover rate of 64 percent for construction (versus a turnover rate of 27.2 percent for general industry). OSHA believes that the estimates in the PEA capture the effect of high turnover rates in construction and solicits comments on this issue in Section I. Issues (*See* Compliance Costs).
(Construction) The Panel recommended that OSHA (1) carefully review the basis for its estimated labor costs, and issues related to the use of FTEs in the analysis, (2) consider the concerns raised by the SERs, and (3) ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA used the exposure profiles to estimate the number of full-time-equivalent (FTE) workers in construction who are exposed above the PEL. This would be the exposure profile if all exposed workers worked full-time only at the specified silica-generating tasks. In OSHA's analysis, the actual number of workers exposed above the PEL is represented by two to five times the number of FTE workers, depending on the activity. The estimate of the total number of at-risk workers takes into account the fact that most workers, regardless of construction occupation, spend some time working on jobs where no silica contamination is present. For the control cost analysis, however, it matters only how many worker-days there are in which exposures are above the PEL. These are the worker-days in which controls are required. The control costs (as opposed to the program costs) are independent of the number of at-risk workers associated with these worker-days. OSHA emphasizes that the use of FTEs does not ''discount'' its estimates of aggregate control costs.
(Construction) Some SERs requested that OSHA apply a 30-day exclusion for implementing engineering and work practice controls, as was reflected in the draft standard for general industry and maritime. The Panel recommended that OSHA consider this change and request comment on the appropriateness of exempting operations that are conducted fewer than 30 days per year from the hierarchy requirement.	A 30-day exemption from the requirement to implement engineering and work practice controls was not included in the proposed standard for construction, and has been removed from the proposed standard for general industry. OSHA requests comment on a 30-day exemption, and has included this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(Construction) The Panel recommended that OSHA consider and seek comment on the need to prohibit employee rotation as a means of complying with the PEL and the likelihood that employees would be exposed to other serious hazards if the Agency were to retain this provision.	The proposed prohibition on rotation is explained in the Summary and Explanation for paragraph (f) *Methods of Compliance.* OSHA solicits comment on the prohibition of employee rotation to achieve compliance when exposure levels exceed the PEL, and has included this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(Construction) Some SERs questioned the scientific and legal basis for the draft prohibitions on the use of compressed air, brushing, and dry sweeping of silica-containing debris. Others raised feasibility concerns such as in instances where water or electric power was unavailable or where use of wet methods could damage construction materials. The Panel recommended that OSHA carefully consider the need for and feasibility of these prohibitions given these concerns, and that OSHA *see*k comment on the appropriateness of such prohibitions.	As discussed in the Summary and Explanation of paragraph (f) *Methods of Compliance,* the prohibition against the use of compressed air, brushing, and dry sweeping applies to situations where such activities could contribute to employee exposure that exceeds the PEL. OSHA solicits comment on this issue, and has included this topic in Section I. Issues (See Provisions of the Standards—Methods of compliance).
(Construction) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* the proposed standard includes a provision for implementation of ''access control plans'' in lieu of establishing regulated areas. Clarification for establishing either a regulated area or an access control plan is provided in the Summary and Explanation.
(Construction) The Panel recommended that OSHA clarify how the regulated area requirements would apply to multi-employer worksites in the draft standard or preamble, and solicit comments on site control issues.	The Summary and Explanation for paragraph (e) *Regulated Areas and Access Control* clarifies this requirement. OSHA requests comment on this topic, and has included this topic in Section I. Issues (*See* Compliance Costs and Provisions of the Standards—Methods of compliance).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(Construction) Many SERs were concerned with the extent to which they felt the draft proposed standard would require the use of respirators in construction activities. The Panel recommended that OSHA carefully consider its respiratory protection requirements, the respiratory protection requirements in Table 1, and the PEL in light of this concern.	OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. However, as described in the Summary and Explanation of paragraphs (f) *Methods of Compliance* and (g) *Respiratory Protection* and in the Technological Feasibility chapter of the PEA, use of respiratory protection will be required for some operations. OSHA solicits comment on this issue in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL).
(Construction) The Panel recommended that OSHA carefully address the issues of reliability of exposure measurement for silica and laboratory requirements. The Panel also recommended that OSHA seek approaches to a construction standard that can mitigate the need for extensive exposure monitoring to the extent possible.	OSHA discusses the reliability of measuring respirable crystalline silica in the Technological Feasibility chapter of the PEA. An exemption for monitoring is also provided where the employer uses Table 1. As discussed in the Summary and Explanation for paragraph (d) *Exposure Assessment,* the proposed standard also allows a performance option for exposure assessment that is expected to reduce the amount of monitoring needed. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).
(Construction) As in general industry, many SERs were concerned about all of these provisions because, they contended, silica is not recognized as either a take-home or dermal hazard. Further, many said that these provisions would be unusually expensive in the context of construction work. Other SERs pointed out that protective clothing could lead to heat stress problems in some circumstances. The Panel recommended that OSHA carefully re-examine the need for these provisions in the construction industry and solicit comment on this issue.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* OSHA has proposed a limited requirement for use of protective clothing or other means to remove silica dust from contaminated clothing. This requirement would apply only in regulated areas where there is the potential for work clothing to become grossly contaminated with silica dust. No requirement for hygiene facilities is included in the proposed standard. OSHA solicits comment regarding appropriate requirements for use of protective clothing and hygiene facilities in Section I. Issues (*See* Provisions of the Standards—Regulated areas and access control).
(Construction) The Panel recommended that OSHA explicitly examine the issue of availability of specialists called for by these provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	The provisions requiring B-readers and pulmonary specialists are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance,* and the numbers of available specialists are reported. OSHA solicits comment on this issue in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(Construction) The Panel recommended that OSHA carefully consider the need for pre-placement physicals in construction, the possibility of delayed initial screening (so only employees who had been on the job a certain number of days would be required to have initial screening), and solicit comment on this issue.	As described in the Summary and Explanation for paragraph (n) *Medical Surveillance,* an initial examination is required within 30 days after initial assignment to a job with exposure above the action level for more than 30 days per year. OSHA solicits comment on this proposed requirement in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(Construction) Like the general industry SERs, construction SERs raised the issue that they would prefer a warning label with wording similar to that used in asbestos and lead. The Panel recommended that OSHA consider this suggestion and solicit comment on it.	The proposed standard does not specify wording for labels. OSHA solicits comment on this issue in Section I. Issues (*See* Provisions of the Standards—Hazard communication).
(Construction) Some SERs questioned whether hazard communication requirements made sense on a construction site where there are tons of silica-containing dirt, bricks, and concrete. The Panel recommended OSHA consider how to address this issue in the context of hazard communication.	The proposed standard requires hazard communication for employees who are potentially exposed to respirable crystalline silica. Many of the proposed requirements are already required by OSHA's Hazard Communication Standard. The Agency requests comment on the proposed requirements in Section I. Issues (*See* Provisions of the Standards—Hazard communication).
(Construction) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	OSHA has reviewed the recordkeeping requirements as required by the Paperwork Reduction Act. Detailed analysis of the recordkeeping requirements can be found in OSHA's information collection request submitted to OMB. The recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) *Recordkeeping.* OSHA solicits comment on these requirements in Section I. Issues (*See* Provisions of the Standards—Recordkeeping).
The Panel recommended that OSHA, to the extent permitted by the availability of economic data, update economic data to better reflect recent changes in the economic status of the affected industries consistent with its statutory mandate.	OSHA has prepared the PEA using the most current economic data available.
SERs in construction, and some in general industry, felt the estimate of affected small entities and employees did not give adequate consideration to workers who would be subject to exposure at a site but were not directly employed by firms engaged in silica-associated work, such as employees of other subcontractors at a construction site, visitors to a plant, etc. The Panel recommended that OSHA carefully examine this issue, considering both the possible costs associated with such workers, and ways of clarifying what workers are covered by the standard	The scope of the proposed standard is discussed in the Summary and Explanation for paragraph (a) *Scope and Application.*

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA clarify in any rulemaking action how its action is or is not related to designating silica-containing materials as hazardous wastes.	The relationship between the proposed rule and EPA requirements is discussed in Section XVI, Environmental Impacts.
Some SERs also noted the issue that the use of wet methods in some areas may violate EPA rules with respect to suspended solids in runoff unless provision is made for recycling or settling the suspended solids out of the water. The Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment on this issue.	Silica wastes are not classified as hazardous. Therefore OSHA believes that the incremental disposal costs resulting from dust collected in vacuums and other sources are likely to be quite small. An analysis of wet methods for dust controls suggests that in most cases the amount of slurry discharged are not sufficient to cause a run off to storm drains. OSHA solicits comments on this topic in Section I. Issues (*See* Environmental Impacts).
The Panel recommended that OSHA (1) carefully consider and solicit comment on the alternative of improved outreach and support for the existing standard; (2) examine what has and has not been accomplished by existing outreach and enforcement efforts; and (3) examine and fully discuss the need for a new standard and if such a standard can accomplish more than improved outreach and enforcement.	A review of OSHA's outreach efforts is provided in Section III, Events Leading to the Proposed Standards. OSHA solicits comment on this topic in Section I. Issues (*See* Alternatives/Ways to Simplify a New Standard).
The Panel recommended, if there is to be a standard for construction, that OSHA: (1) seek ways to greatly simplify the standard and restrict the number of persons in respirators; (2) consider the alternative of a standard oriented to engineering controls and work practices in construction; and (3) analyze and solicit comment on ways to simplify the standard.	OSHA has made a preliminary determination that compliance with the proposed PEL can be achieved in most operations most of the time through the use of engineering and work practice controls. However, as described in the Summary and Explanation of paragraphs (f) *Methods of Compliance* and (g) *Respiratory Protection* and in the Technological Feasibility chapter of the PEA, use of respiratory protection will be required for some operations. OSHA solicits comment on this topic in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL). OSHA also solicits comment on ways to simplify the standard in Section I. Issues (*See* Alternatives/Ways to Simplify a New Standard).
The Panel recommended that, if there is to be a standard, OSHA consider and solicit comment on maintaining the existing PEL. The Panel also recommends that OSHA examine each of the ancillary provisions on a provision-by-provision basis in light of the comments of the SERs on the costs and lack of need for some of these provisions.	As discussed in the Summary and Explanation for paragraph (c) *Permissible Exposure Limit (PEL),* OSHA has made a preliminary determination that the proposed PEL is necessary to meet the legal requirements to reduce significant risk to the extent feasible. Because the proposed PEL is a fixed value, OSHA also believes it is easier to understand when compared to the current PEL. OSHA solicits comment on the proposed PEL in Section I. Issues (*See* Provisions of the Standards—PEL and action level).
(General Industry) The Panel recommended that OSHA carefully examine the technological and economic feasibility of the draft proposed standard in light of these SER comments.	The PEA reflects OSHA's judgment on the technological and economic feasibility of the proposed standard and includes responses to specific issues raised by the Panel. OSHA solicits comment on the accuracy and reasonableness of these judgments in Section I. Issues (*See* Technological and Economic Feasibility of the Proposed PEL).
(General Industry) Some SERs were concerned that the prohibition on dry sweeping was not feasible or cost effective in their industries. The Panel recommended that OSHA consider this issue and solicit comment on the costs and necessity of such a prohibition.	OSHA has proposed to limit the prohibition on dry sweeping to situations where this activity could contribute to exposure that exceeds the PEL. The Agency solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
(General Industry) The Panel recommended that OSHA carefully consider whether regulated area provisions should be included in the draft proposed standard, and, if so, where and how regulated areas are to be established. OSHA should also clarify in the preamble and in its compliance assistance materials how compliance is expected to be achieved in the various circumstances raised by the SERs.	Proposed regulated area provisions are explained in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control.* The proposed standard also includes a provision for implementation of ''access control plans'' in lieu of establishing regulated areas. Clarification for establishing an access control plan is provided in the Summary and Explanation.
(General Industry) The Panel recommended that OSHA carefully examine the issues associated with reliability of monitoring and laboratory standards in light of the SER comments, and solicit comment on these issues.	OSHA has made a preliminary determination in the proposed rule that only certain sampling and analytical methods can be used to measure airborne crystalline silica at the proposed PEL. Issues related to sampling and analytical methods are discussed in the Technological Feasibility section of the PEA. OSHA solicits comment on the Agency's preliminary determination in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).
(General Industry) Some SERs preferred the more performance-oriented Option 2 provision included in the draft exposure assessment requirements, stating that fixed-frequency exposure monitoring can be unnecessary and wasteful. However, other SERs expressed concern over whether such a performance-oriented approach would be consistently interpreted by enforcement officers. The Panel recommended that OSHA continue to consider Option 2 but, should OSHA decide to include it in a proposed rule, clarify what would constitute compliance with the provision. Some SERs were also concerned about the wording of the exposure assessment provision.	The proposed standard provides two options for periodic exposure assessment; (1) a fixed schedule option, and (2) a performance option. The performance option provides employers flexibility in the methods used to determine employee exposures, but requires employers to accurately characterize employee exposures. The proposed approach is explained in the Summary and Explanation for paragraph (d) *Exposure Assessment.* OSHA solicits comments on the proposed exposure assessment provision in Section I. Issues (*See* Provisions of the Standards—Exposure Assessment).

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
(General Industry) Some SERs were also concerned about the wording of the exposure assessment provision of the draft proposed standard. These SERs felt that the wording could be taken to mean that an employer needed to perform initial assessments annually.	
The Panel recommended that OSHA clarify this issue.	The requirement for initial exposure assessment is clarified in the Summary and Explanation of paragraph (d) *Exposure Assessment.* The term ''initial'' indicates that this is the first action required to assess exposure and is required only once.
(General Industry) While some SERs currently provide both protective clothing and hygiene facilities, others provide neither. Those SERs that do not currently provide either felt that these provisions were both highly expensive and unnecessary. Some SERs stated that these provisions were pointless because silica is not a take-home hazard or a dermal hazard. Others suggested that such provisions only be required when the PEL is exceeded.	As described in the Summary and Explanation for paragraph (e) *Regulated Areas and Access Control,* OSHA has proposed a limited requirement for use of protective clothing or other means to remove silica dust from contaminated clothing. This requirement would apply only in regulated areas where there is the potential for work clothing to become grossly contaminated with silica dust. No requirement for hygiene facilities is included in the proposed standard. OSHA solicits comment regarding appropriate requirements for use of protective clothing and hygiene facilities in Section I. Issues (*See* Provisions of the Standards—Regulated areas and access control).
The Panel recommended that OSHA carefully consider the need for these provisions, and solicit comment on the need for these provisions, and how they might be limited.	
(General Industry) The SER comments included several suggestions regarding the nature and wording of the health screening requirements. (*See, e.g.,* OSHA, 2003, pp. 25–28.).	OSHA has considered these comments and revised the proposed standard where appropriate. The revisions are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance.*
The Panel recommended that OSHA consider revising the standard in light of these comments, as appropriate.	
(General Industry) The Panel recommended that OSHA explicitly examine and report on the availability of specialists called for by these provisions, and re-examine the costs and feasibility of such requirements based on their findings with respect to availability, as needed.	The provisions requiring B-readers and pulmonary specialists are discussed in the Summary and Explanation of paragraph (n) *Medical Surveillance,* and the numbers of available specialists are reported. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
(General Industry) Though the provision for hazard communication simply repeats such provisions already in existence, some SERs urged OSHA to use this opportunity to change the requirement so that warning labels would only be required of substances that were more than 1% (rather than the current 0.1%) by weight of silica.	OSHA has preliminarily determined to rely on the provisions of the Hazard Communication Standard (HCS) in the proposed rule. The HCS requires labels for mixtures that contain more than 0.1% of a carcinogen. OSHA solicits comment on this topic in Section I. Issues (*See* Provisions of the Standards—Medical surveillance).
The Panel recommended that OSHA consider this suggestion and solicit comment on it.	
(General Industry) The Panel recommended that OSHA carefully review the recordkeeping requirements with respect to both their utility and burden.	The recordkeeping requirements are discussed in the Summary and Explanation for paragraph (j) *Recordkeeping.* OSHA solicits comment on these requirements in Section I. Issues (*See* Provisions of the Standards—Recordkeeping).
(Construction) The Panel recommended that OSHA continue to evaluate the appropriateness of and consider modifications to scope Option 2 that can more readily serve to limit the scope of the standard.	OSHA has made the preliminary determination that scope Option 1 is most appropriate. OSHA solicits comment on this subject in Section I. Issues (*See* Provisions of the Standards—Scope).
(Construction) Many SERs found the requirements for a competent person hard to understand. Many SERs took the competent person requirement as requiring a person with a high level of skills, such as the ability to conduct monitoring. Other SERs said this requirement would require training a high percentage of their employees as competent persons because they typically had many very small crews at many sites. In general, the SERs thought this requirement as written would be difficult to comply with and costly.	The standard requires a competent person only in limited circumstances when an employer selects the option to implement an ''access control plan'' in lieu of establishing a regulated area. Further clarification is provided in the Summary and Explanation of paragraph (e) *Regulated Areas and Access Control.*
The Panel recommended that OSHA seek ways to clarify OSHA's intent with respect to this requirement and more clearly delineate the responsibilities of competent persons.	
(Construction) Many SERs did not understand that Table 1 was offered as an alternative to exposure assessment and demonstration that the PEL is being met. Some SERs, however, understood the approach and felt that it had merit. These SERs raised several issues concerning the use of Table 1, including:. • The Table should be expanded to include all construction activities covered by the standard, or the scope of the standard should be reduced to only those activities covered by Table 1; • The control measures endorsed in Table 1 need to be better established, as necessary; and • Table 1 should require less use of, and possibly no use of, respirators.	

TABLE VIII–33—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA Panel recommendation	OSHA response
The Panel recommended that OSHA carefully consider these suggestions, expand Table 1, and make other modifications, as appropriate	The rationale for the operations and control measures to be included in Table 1 is provided in the Summary and Explanation for paragraph (f) *Methods of Compliance.* Table 1 includes some operations for which it is anticipated that even with the implementation of control measures, exposure levels will routinely exceed the proposed PEL, and thus reliance on the use of respiratory protection is appropriate. Table 1 has been modified to limit requirements for respirator use where operations are performed for less than 4 hours per day. OSHA solicits comment on the proposed requirements in Section I. Issues (*See* Provisions of the Standards—Methods of compliance).
The Panel recommends that OSHA thoroughly review the economic impacts of compliance with a proposed silica standard and develop more detailed feasibility analyses where appropriate..	OSHA significantly expanded its economic impact and economic feasibility analyses in Chapter VI of the PEA. As part of the impact analysis, OSHA added data on normal year-to-year variations in prices and profit rates in affected industries to provide a context for evaluating potential price and profit impacts of the proposed rule. A section was also added to estimate the potential international trade impacts of the proposed rule. OSHA solicits comments in Chapter VI of the PEA on the issues of the economic impacts and the economic feasibility of the proposed rule.
(Construction) The panel recommends that OSHA re-examine its cost estimates for respirators to make sure that the full cost of putting employees in respirators is considered.	OSHA re-examined and updated its cost estimates for each type of respirator. Unit respirator costs included the cost of the respirator itself and the annualized cost of respirator use, to include accessories (*e.g.,* filters), training, fit testing, and cleaning. All costs were updated to 2009 dollars. In addition, OSHA added a cost for employers to establish a respirator program. OSHA solicits comments on this issue in Chapter V of the PEA.
(Construction) Some SERs indicated that the unit costs were underestimated for monitoring, similar to the general industry issues raised previously. In addition, special issues for construction were raised (*i.e.,* unpredictability of exposures), suggesting the rule would be costly, if not impossible to comply with.	To reflect the fact that an industrial hygienist could not typically take as many samples a day in a small establishment as in a large one, OSHA developed cost estimates for exposure monitoring as a function of the size of the establishment. OSHA's cost estimates therefore now reflect the fact that smaller entities will tend to experience larger unit costs for exposure monitoring.
The Panel recommends that OSHA carefully review the basis for its estimated compliance costs, consider the concerns raised by the SERs, and ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	To reflect possible problems of unpredictability of exposure in construction, Table 1 in the proposed standard has been designed to allow establishments in construction the option, for certain operations, to implement engineering controls, work practices, and respiratory protection without the need for exposure assessment. OSHA has carefully reviewed the basis for its exposure monitoring cost estimates and considered the concerns raised by the SERs. OSHA solicits comments on this issue in Chapter V of the PEA.
(General Industry) The Panel recommends that OSHA use the best scientific evidence and methods available to determine the significance of risks and magnitude of benefits for occupational exposure to silica. The Panel further recommends that OSHA evaluate existing state silicosis surveillance data to determine whether there are industry-specific differences in silicosis risks, and whether or how the draft standard should be revised to reflect such differences.	OSHA has conducted a comprehensive review of the scientific evidence from toxicological and epidemiological studies on adverse health effects associated with occupational exposure to respirable crystalline silica. This review is summarized in Section V of this preamble, Health Effects Summary, and estimates of the risks of developing silica-related diseases are summarized in Section VI, Summary of the Preliminary Quantitative Risk Assessment. The significance of these risks is examined in Section VII, Significance of Risk. The benefits associated with the proposed rule are summarized in Section VIII.G, Benefits and Net Benefits. Although OSHA's preliminary analysis indicates that a variety of factors may affect the toxicologic potency of crystalline silica found in different work environments, OSHA has not identified information that would allow the Agency to calculate how these influences may affect disease risk to workers in any particular workplace setting.
The SERs, however, also had many specific issues concerning what OSHA should do if it chooses to go forward with a proposed rule. In order to reflect these specific issues, the Panel has made many recommendations concerning issues to be considered if the Agency goes forward with a rule. The Panel also recommends that OSHA take great care in reviewing and considering all comments made by the SERs.	OSHA has carefully considered the Panel recommendations, and the Agency's responses are listed in this table. In addition, specific issues raised in comments by individual SERs are addressed throughout the preamble.

IX. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

The proposed general industry/maritime and construction standards (''the standards'') for respirable crystalline silica 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–95), 44 U.S.C. 3501 *et seq,* and OMB's regulations at 5 CFR part 1320. PRA–95 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)). Under PRA–95, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it, and the agency displays a currently valid OMB control number.

B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) for the collection of information requirements identified in this NPRM to OMB for review in accordance with 44 U.S.C. 3507(d). The Agency solicits comments on the proposed new collection of information requirements and the estimated burden hours associated with these requirements, including comments on the following items:

- Whether the proposed collection of information requirements 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 information collection requirements, 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.

C. Proposed Revisions to Information Collection Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about this ICR.

1. *Title:* Respirable Crystalline Silica Standards for General Industry/Maritime (§ 1910.1053) and Construction (§ 1926.1053)

2. *Description of the ICR:* The proposed respirable crystalline silica 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 exposures to crystalline silica, the medical effects of such exposures, and means to reduce or eliminate respirable crystalline silica overexposures.

3. *Summary of the Collections of Information:*

1910.1053(d) and 1926.1053(d)—Exposure Assessment

Under paragraph (d)(6) of the proposed rule, employers covered by the general industry/maritime standard must notify each affected employee within 15 working days of completing an exposure assessment. In construction, employers must notify each affected employee not more than 5 working days after completing the exposure assessment. In these standards, the following provisions require exposure assessment monitoring: § 1910.1053(d)(1) and § 1926.1053(d)(1), General; § 1910.1053(d)(2) and § 1926.1053(d)(2), Initial Exposure Assessment; § 1910.1053(d)(3) and § 1926.1053(d)(3), Periodic Exposure Assessments; § 1910.1053 (d)(4) and § 1926.1053(d)(4), Additional Exposure Assessments; and § 1926.1053(d)(8)(ii), Specific Operations.

Under § 1910.1053(d)(6)(i) and § 1926.1053(d)(6)(i), employers must either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, paragraph (d)(6)(ii) of § 1910.1053 and § 1926.1053 require that whenever the employer exceeds the permissible exposure limit (PEL), the written notification must contain a description of the corrective action(s) the employer is taking to reduce employee exposures to or below the PEL.

1910.1053(e)(3) and 1926.1053(e)(3)—Written Access Control Plan

The standard provides employers with the option to develop and implement a written access control plan in lieu of establishing regulated areas under paragraph (e)(3). Paragraph (e)(3)(ii) sets out the requirements for a written access control plan. The plan must contain provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL. It must describe how the employer will notify employees of the presence and location of areas where exposures are, or can reasonably be expected to be, in excess of the PEL, and how the employer will demarcate these areas from the rest of the workplace. For multi-employer workplaces, the plan must identify the methods the employers will use to inform other employers of the presence, and the location, of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures the employers need to take to protect employees. The written plan must contain provisions for restricting access to these areas to minimize the number of employees exposed, and the level of employee exposure. The plan also must describe procedures for providing each employee entering areas where respirable crystalline silica exposures may exceed the PEL, with an appropriate respirator in accordance with paragraph (g) of the proposed rule; the employer also must provide this information to the employee's designated representative. Additionally, where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the plan must include provisions for the employer to provide either appropriate protective clothing or other means to remove excessive silica dust from contaminated clothing, as well as provisions for the removal or cleaning of such clothing.

The employer must review and evaluate the effectiveness of the written access control plan at least annually, and update it as necessary. The written access control plan must be available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary, and the Director.

1910.1053(f)—Methods of Compliance

Where the employer conducts abrasive blasting operations, paragraph (f)(2) in the general industry/maritime standard requires the employer to comply with the requirements of 29 CFR part 1915, subpart I (Personal Protective Equipment), as applicable. Subpart I contains several information collection requirements. Under subpart I, when conducting hazard assessments, the employer must: (1) Select the type of personal protective equipment (PPE) that will protect the affected employee from the hazards identified in the occupational hazard assessment; (2) communicate selection decisions to affected employees; (3) select PPE that properly fits each affected employee; and (4) verify that the required occupational hazard assessment has been performed. Additionally, subpart I requires employers to provide training and verification of training for each employee required to wear PPE.

1910.1053(g) and 1926.1053(g)—Respiratory Protection

Paragraph (g) in the standards requires the employer to institute a respiratory protection program in accordance with 29 CFR 1910.134. The Respiratory Protection Standard's information collection requirements

provide that employers must: develop a written respirator program; obtain and maintain employee medical evaluation records; provide the physician or other licensed health care professional (PLHCP) with information about the employee's respirator and the conditions under which the employee will use the respirator; administer fit tests for employees who will use negative- or positive-pressure, tight-fitting facepieces; and establish and retain written information regarding medical evaluations, fit testing, and the respirator program.

1910.1053(h) and 1926.1053(h)—Medical Surveillance

Paragraph (h)(2) in the standards requires employers to make available to covered employees an initial medical examination within 30 days after initial assignment unless the employee received a medical examination provided in accordance with the standard within the past three years. Proposed paragraphs (h)(2)(i)–(vi) specify that the baseline medical examination provided by the PLHCP must consist of the following information:

1. A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease; history of tuberculosis; and smoking status and history;
2. A physical examination with special emphasis on the respiratory system;
3. A chest X-ray interpreted and classified according to the International Labour Organization International Classification of Radiographs of Pneumoconioses by a National Institute for Occupational Safety and Health (NIOSH)-certified ''B'' reader, or an equivalent diagnostic study;
4. A pulmonary function test administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;
5. Testing for latent tuberculosis infection; and
6. Any other tests deemed appropriate by the PLHCP.

Paragraph (h)(3) in the standards requires periodic medical examinations administered by a PLHCP, every three years or more frequently if recommended by the PLHCP, for covered employees, including medical and work history, physical examination emphasizing the respiratory system, chest X-rays or equivalent diagnostic study, pulmonary function tests, and other tests deemed to be appropriate by the PLHCP.

Paragraph (h)(4) in the standards requires the employer to provide the examining PLHCP with a copy of the standard. In addition, for each employee receiving a medical examination, the employer must provide the PLHCP with the following information: a description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica; the employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica; a description of any PPE used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

Paragraph (h)(5) in the standards requires the employer to obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The employer must provide the employee with a copy the PLHCPs' written medical opinion within two weeks of receipt. This written opinion must contain the following information:

1. A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;
2. Any recommended limitations upon the employee's exposure to respirable crystalline silica or on the use of PPE such as respirators;
3. A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) if the ''B'' reader classifies the chest X-ray as 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and
4. A statement that the PLHCP explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

If the PLHCP's written medical opinion indicates that a pulmonary specialist should examine an employee, paragraph (h)(6) in the standards requires the employer to make available for the employee a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion. The employer must provide the examining pulmonary specialist with information specified by paragraph (h)(4). The employer must obtain a written opinion from the pulmonary specialist within 30 days of the examination. The written opinion must be comparable to the written opinion obtained from the original PLHCP. The pulmonary specialist also must state in the written opinion that the specialist explained these findings to the employee. The employer also must provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

1910.1053(i) and 1926.1053(i)—Communication of Respirable Crystalline Silica Hazards to Employees

Paragraph (i)(1) of the standards requires compliance with the Hazard Communication Standard (29 CFR 1910.1200), and lists cancer, lung effects, immune system effects, and kidney effects as hazards that the employer must address in its hazard communication program. Additionally, employers must ensure that each employee has access to labels on containers of crystalline silica and safety data sheets. Under paragraph (i)(2)(ii), the employer must make a copy of this section readily available without cost to each affected employee.

1910.1053(j) and 1926.1053(j)—Recordkeeping

Paragraph (j)(1)(i) of the standards requires that employers maintain an accurate record of all employee exposure measurement results as prescribed in paragraph (d) of these standards. The record must include the following information: the date of measurement for each sample taken; the operation monitored; sampling and analytical methods used; number, duration, and results of samples taken; identity of the laboratory that performed the analysis; type of PPE, such as respirators, worn by the employees monitored; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were monitored. The employer must maintain, and make available, employee exposure records in accordance with 29 CFR 1910.1020.

Paragraph (j)(2)(i) requires the employer to maintain an accurate record of all objective data relied on to comply

with the proposed requirements of this section. The record must include the following information: the crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; and a description of the process, operation, or activity, and how the data support the assessment; and other data relevant to the process, operation, activity, material, or employee exposures. The employer must maintain, and make available, the objective data records in accordance with 29 CFR 1910.1020.

Paragraph (j)(3)(i) requires the employer to establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h). The record must include the following information: the employee's name and social security number; a copy of the PLHCP's and pulmonary specialist's written opinions; and a copy of the information provided to the PLHCP and pulmonary specialist as required by paragraph (h)(4) of the proposed rule. The employer must maintain, and make available, the medical surveillance records in accordance with 29 CFR 1910.1020.

4. *Number of respondents:* Employers in general industry, maritime, or construction that have employees working in jobs affected by respirable crystalline silica exposure (543,041 businesses).

5. *Frequency of responses:* Frequency of response varies depending on the specific collection of information.

6. *Number of responses:* 4,242,296.

7. *Average time per response:* Varies from 5 minutes (.08 hour) for the employer to provide a copy of the written physician's opinion to the employee, to 8 hours to establish a new respiratory protection program in large establishments.

8. *Estimated total burden hours:* 2,585,164.

9. *Estimated costs (capital-operation and maintenance):* $273,504,281.

D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN–1218–AB70), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.* The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA–2010–0034), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES.** Comments submitted in response to this notice are public records; therefore, OSHA cautions commenters about submitting personal information such as Social Security numbers and date of birth.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete Information Collection Request (ICR) (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this notice titled **ADDRESSES**. You also may obtain an electronic copy of the complete ICR by visiting the Web page at *http://www.reginfo.gov/public/do/PRAMain,* scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

OSHA notes that a federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless the collection of information displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no person 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.

X. Federalism

The Agency reviewed the proposed crystalline silica rule according to the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, Aug. 10, 1999), which 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 Executive Order 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; States that obtain Federal approval for such a plan are referred to 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 requirements for occupational safety and health standards.

While OSHA drafted the proposed rule to protect employees in every State, Section 18(c)(2) of the OSHA Act permits State-Plan States to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in the proposed rule if it is promulgated.

In summary, the proposed rule complies with Executive Order 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.

XI. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 27 State 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).

The State may demonstrate that a standard change is not necessary

because, for example, the State standard is already the same as or at least as effective as the Federal standard change. 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 27 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 five states and territories whose OSHA-approved State plans cover only public-sector employees are: Connecticut, Illinois, New Jersey, New York, and the Virgin Islands.

This proposed crystalline silica rule applies to general industry, construction and maritime, and would impose additional or more stringent requirements. If adopted as proposed, all State Plan States would be required to revise their general industry and construction standards appropriately within six months of Federal promulgation. In addition, State plans that cover private sector maritime employment issues and/or have public employees working in the maritime industry covered by this standard would be required to adopt comparable provisions to their maritime employment standards within six months of publication of the final rule.

XII. Unfunded Mandates

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'' in any one year before issuing a notice of proposed rulemaking. OSHA's proposal 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. (*See* 29 U.S.C. 652(5).) Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. The OSH Act also does not cover tribal governments in the performance of traditional governmental functions, though it does when tribal governments engage in commercial activity. However, the proposal would not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, although OSHA may include compliance costs for affected governmental entities in its analysis of the expected impacts associated with a proposal, the proposal does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Preliminary Economic Analysis (*see* Section VIII above), OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. The Preliminary Economic Analysis constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits required under Section 202(a) of the UMRA (2 U.S.C. 1532).

XIII. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 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. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely effect 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, product use).

The proposed respirable crystalline silica rule is economically significant under Executive Order 12866 (*see* Section VIII of this preamble). However, after reviewing the proposed respirable crystalline silica rule, OSHA has determined that the rule would not impose environmental health or safety risks to children as set forth in Executive Order 13045. The proposed rule would require employers to limit employee exposure to respirable crystalline silica and take other precautions to protect employees from adverse health effects associated with exposure to respirable crystalline silica. OSHA is not aware of any studies showing that exposure to respirable crystalline silica disproportionately affects children or that employees under 18 years of age who may be exposed to respirable crystalline silica are disproportionately affected by such exposure. Based on this preliminary determination, OSHA believes that the proposed respirable crystalline silica rule does not constitute a covered regulatory action as defined by Executive Order 13045. However, if such conditions exist, children who are exposed to respirable crystalline silica in the workplace would be better protected from exposure to respirable crystalline silica under the proposed rule than they are currently.

XIV. Environmental Impacts

OSHA has reviewed the silica proposal according to the National Environmental Policy Act (NEPA) of 1969 (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). Based on that review, OSHA does not expect that the proposed rule, in and of itself, would create additional environmental issues. However, as noted in the SBREFA report (OSHA, 2003, p. 77), some Small Entity Representatives (SERs) raised the possibility that the use of wet methods to limit occupational (and environmental) exposures in some areas may violate EPA rules with respect to suspended solids in runoff unless provision is made for recycling or settling the suspended solids out of the water. The SBREFA Panel recommended that OSHA investigate this issue, add appropriate costs if necessary, and solicit comment on this issue.

Some large construction projects may already require a permit to address storm water runoff, independent of any OSHA requirements to limit worker exposure to silica. These environmental

requirements come from or reference the Clean Water Act of 1987. As applied to construction activities, EPA requirements generally pertain to projects of one acre or more and impose the use of Best Management Practices (BMPs) to minimize the pollution, via water runoff, of storm water collection systems and surface waters. In some cases, these requirements are administered by States.

Otherwise, the use of wet methods to control silica dust as mandated by an OSHA silica standard is not directly addressed by EPA requirements. Local governments, however, might require compliance with EPA BMPs when granting construction permits. As an example, the California Department of Transportation's Construction Site Best Management Practice (BMP) Field Manual and Troubleshooting Guide includes the following guidance for paving and grinding operations: ''Do not allow wastes, such as AC [asphalt concrete] pieces, PCC [Portland concrete cement] grinding residue/slurry, sand/gravel, exposed aggregate concrete residue, or dig-out materials into storm drains or receiving waters. Sweep, vacuum, and collect such wastes and recycle or dispose of properly'' (State of California, Department of Transportation, 2003). Contractors following these BMPs would need to take steps to prevent water used for dust control from running into storm drains, drainage ditches, or surface waters. Slurries left on paved areas would need to be swept or vacuumed to prevent subsequent runoff during storms.

It should be noted that the objective of these BMPs is a reduction in the amount of pollutants washed into storm drain systems or surface waters, rather than reductions in discharges per se. The environmental concern is that the use of wet methods to control silica dust would, besides creating silica slurry, facilitate discharges of other pollutants.

The silica controls costed by OSHA in Chapter VI of the Preliminary Economic Analysis show six tasks where wet methods are suggested: stationary masonry saws, hand-held masonry saws, walk-behind and other large concrete saws, concrete grinding with walk-behind equipment, asphalt milling, and pavement breaking and other demolition with jackhammers. A detailed review of the control measures for these equipment types suggests that only the use of wet methods with pavement breakers has the potential to directly result in runoff discharges to storm drains or surface waters. Even then, the water required would most often not create a runoff potential. The control costs for each of these jobs contains a productivity impact factor, part of which is intended to account for extra cleanup time associated with use of wet methods to control dust, including sweeping or vacuuming of silica slurry. However, such efforts may be less laborious than having to clean up free silica dust and may result in a net decrease in silica (and any other contaminants related to its production) running off into the water supply. OSHA's estimate of the potential environmental impact of each of these six equipment types is summarized below:

- Stationary masonry saws: Most stationary saws come equipped with a water basin that typically holds several gallons of water and a pump for recycling water for wet cutting. The water is recirculated and, thus, not continually discharged. When emptied, the amount of water is not sufficient to produce a runoff.
- Hand-held masonry saws: Large quantities of water typically are not required. Water is supplied from a small capacity water tank. Any slurry residue after cutting could be dealt with by sweeping or vacuuming.
- Walk-behind and other large concrete saws: Larger concrete saws are equipped with a tank to supply water to the blade while cutting. These saws leave a slurry residue, but do not require so much water as to create a runoff.
- Walk-behind concrete grinders and millers: Some tools are equipped with a water-feed system. In these, a water line from a tank, a garden hose, or other water supply leads to the grinding head and delivers water to spray or flood the cutting tool and/or the work surface. When an automatic water feed is not available, a helper can apply water directly to the cutting surface. While such wet methods might generate enough water to create a runoff, these grinding and milling activities are typically done during the finishing stages of structure construction (*e.g.,* parking garages) and often inside the structure. Thus, direct discharges to storm drains or surface waters are unlikely.
- Asphalt milling for pavement resurfacing: A typical asphalt milling machine has a built-in reservoir from which water is applied to the cutting drum. The amount of water used, however, is insufficient to produce a runoff.
- Impact drillers/pavement breakers: Water for dust suppression can be applied manually, or using a semi-automated water-feed device. In the simplest method for suppressing dust, a dedicated helper directs a constant spray of mist at the impact point while another worker operates the jackhammer. The helper can use a hose with a garden-style spray nozzle to maintain a steady and carefully directed mist at the impact point where material is broken and crushed. Jackhammers retrofitted with a focused water mist aimed at the tip of the blade offer a dramatic decrease in silica exposure. Although water-fed jackhammers are not commercially available, it is neither expensive nor difficult to retrofit equipment. Studies suggest that a water flow rate of ⅛ to ¼ gallon per minute is best for silica dust control. At this rate, about 7.5 to 15 gallons of water per hour would be applied to (*i.e.,* sprayed on) the work area. It is unclear whether this quantity of water applied to a moveable work area at a constant rate would produce a runoff. If the work were in sufficient proximity to a storm drain or surface water, the contractor might need to use a simple barrier to prevent the water from entering the drain, or filter it. Because the volume of water is relatively small, the costs for such barriers are likely insubstantial. However, because this type of runoff could happen occasionally, OSHA has added costs for barriers in costing silica controls for this task.

As a result of this review, OSHA has made a determination that the silica proposal would have little potential impact on air, water, or soil quality; plant or animal life; the use of land; or aspects of the external environment. As described above in this section, effective abatement measures are available where the potential for environmental impacts exist. Therefore, OSHA preliminarily concludes that the proposed standard would have no significant environmental impacts. However, while the Agency does not believe that the proposed rule would create significant costs, or otherwise pose a significant challenge, for employers to comply with existing environmental rules, OSHA welcomes comment on this or any other environmentally related issues, or potential conflicts with other agency rules.

XV. Public Participation

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal and by providing oral testimony and documentary evidence at the informal public hearings that the Agency will convene after the comment period ends. The Agency invites interested persons having knowledge of, or experience with, occupational exposure to silica and the issues raised by the proposed rule to participate in this process, and welcomes any

pertinent data and information that will provide it with the best available evidence on which to develop the final regulatory requirements.

The Agency has scheduled time during the informal rulemaking hearing in Washington, DC, for participants to testify on the Health Effects Literature Review and Preliminary Quantitative Risk Assessment in the presence of peer reviewers. Peer reviewers will subsequently be able to submit amended final comments to the record. As described in OSHA's peer review agenda, peer reviewers have reviewed OSHA's draft Health Effects Literature Review and Preliminary Quantitative Risk Assessment and have submitted written reports that the Agency has considered prior to publication of the proposed rule. The open comment period and informal hearing will provide the public an opportunity to submit information to the record that it believes will benefit the peer review, and to testify in the presence of the reviewers. This section describes the procedures the public must use to submit their comments to the docket in a timely manner, and to schedule an opportunity to deliver oral testimony and provide documentary evidence at informal public hearings on the proposal. Comments, notices of intention to appear, hearing testimony and documentary evidence will be available for inspection and copying at the OSHA Docket Office. You also should read the sections above titled **DATES** and **ADDRESSES** for additional information on submitting comments, documents, the presence of peer reviewers at the hearings, and requests to the Agency for consideration in this rulemaking.

Written Comments. OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised in Section I of this preamble. When submitting comments, persons must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES**. The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the record and will be available for public inspection and copying at the OSHA Docket Office as well as online at *www.regulations.gov* (Docket Number OSHA–2010–0034).

Informal Public Hearings. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity to provide oral testimony concerning the issues raised in this proposal at informal public hearings. The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of the hearing is an administrative law judge (ALJ) and questioning of witnesses is allowed on crucial issues, the proceeding is largely informal and essentially legislative in purpose. Therefore, the hearing provides interested persons with an opportunity to make oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. The hearing is not an adjudicative proceeding subject to the technical rules of evidence. Instead, it is an informal administrative proceeding convened for the purpose of gathering and clarifying information. The regulations that govern the hearings and the prehearing guidelines issued for the hearing will ensure that participants are treated fairly and provided due process. This approach will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will be resolved in favor of developing a clear, accurate, and complete record. Conduct of the hearing will conform to 29 CFR 1911.15. In addition, the Assistant Secretary may, on reasonable notice, issue additional or alternative procedures to expedite the proceedings, to provide greater procedural protections to interested persons or to further any other good cause consistent with applicable law (29 CFR 1911.4).

Although the ALJ presiding over the hearing makes no decision or recommendation on the merits of the proposal, the ALJ has the responsibility and authority necessary to ensure the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested persons receive a full and fair hearing, the ALJ has the power to regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine presentations to matters pertinent to the issues the proposed rule raises; use appropriate means to regulate the conduct of persons present at the hearing; question witnesses and permit others to do so; limit the time for such questioning; and leave the record open for a reasonable time after the hearing for the submission of additional data, evidence, comments and arguments (29 CFR 1911.16).

At the close of the hearing the ALJ will establish a post-hearing comment period for interested persons who filed a timely notice of intention to appear at the hearing. During the first part of the post-hearing period, those persons may submit additional data and information to OSHA. During the second part they may submit final briefs, arguments, and summations.

Notice of Intention to Appear to Provide Testimony at the Informal Public Hearing. Interested persons who intend to provide oral testimony at the informal public hearing must file a notice of intention to appear by using the procedures specified above in the sections titled **DATES** and **ADDRESSES**. This notice must provide the following information:

Name, address, email address, and telephone number of each individual who will give oral testimony;

Name of the establishment or organization each individual represents, if any;

Occupational title and position of each individual testifying;

Approximate amount of time required for each individual's testimony;

If the individual requests to present testimony related to the Health Effects Literature Review and Preliminary Quantitative Risk Assessment, the notice should specify if the submitter requests this testimony be provided in the presence of peer reviewers;

A brief statement of the position each individual will take with respect to the issues raised by the proposed rule; and

A brief summary of documentary evidence each individual intends to present.

Participants who need projectors and other special equipment for their testimony must contact Frank Meilinger at OSHA's Office of Communications, telephone (202) 693–1999, no later than one week before the hearing begins.

OSHA emphasizes that the hearings are open to the public; however, only individuals who file a notice of intention to appear may question witnesses and participate fully at the hearing. If time permits, and at the discretion of the ALJ, an individual who did not file a notice of intention to appear may be allowed to testify at the hearing, but for no more than 10 minutes.

Hearing testimony and documentary evidence. Individuals who request more than 10 minutes to present their oral testimony at the hearing or who will submit documentary evidence at the

hearing must submit (transmit, send, postmark, deliver) the full text of their testimony and all documentary evidence no later than December 11, 2013.

The Agency will review each submission and determine if the information it contains warrants the amount of time the individual requested for the presentation. If OSHA believes the requested time is excessive, the Agency will allocate an appropriate amount of time for the presentation. The Agency also may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements, and may request that the participant return for questioning at a later time. Before the hearing, OSHA will notify participants of the time the Agency will allow for their presentation and, if less than requested, the reasons for its decision. In addition, before the hearing OSHA will provide the pre-hearing guidelines and hearing schedule to each participant.

Certification of the hearing record and Agency final determination. Following the close of the hearing and the post-hearing comment periods, the ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The record will consist of all of the written comments, oral testimony and documentary evidence received during the proceeding. The ALJ, however, will not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review all the evidence received into the record and will issue the final rule based on the record as a whole.

XVI. Summary and Explanation of the Standards

(a) Scope and application

OSHA is proposing to issue one standard addressing respirable crystalline silica exposure in general industry and maritime and a separate standard addressing exposure in the construction industry. The scope provisions are contained in paragraph (a) of the proposed standards. The proposed standard for the construction industry is similar to the proposed standard for general industry and maritime, and the standards are intended to provide equivalent protection for all workers while accounting for the different work activities, anticipated exposures, and other conditions in these sectors. The limited differences between the proposed construction and general industry/maritime standards exist because OSHA believes, based on the record developed to date, that certain activities in construction are different enough to warrant modified requirements.

The proposed standards do not cover the agricultural sector, due to limited data on exposures and control measures in this sector. 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 workers. Consolidated Appropriations Act, 1976, Public Law 94–439, 90 Stat. 1420, 1421 (1976) (and subsequent appropriations acts). However, some evidence indicates that certain agricultural operations may result in exposures to respirable silica in excess of the proposed PEL. A literature review conducted by Swanepoel *et al.* (2010) identified studies that examined respirable quartz exposure and associated diseases in agricultural settings. Three of the exposure studies measured respirable quartz in the personal breathing zone of workers (Popendorf *et al.* 1982; Archer *et al.* 2002; Lee *et al.* 2004). Popendorf *et al.* (1982) investigated exposures among citrus, peach, and grape harvesters; Archer *et al.* (2002) reported on farmworkers in eastern North Carolina; and Lee *et al.* (2004) examined citrus and grape harvesters in California. Each of these studies identified instances where exposures exceeded the proposed PEL. In particular, Archer *et al.* (2002) reported respirable quartz concentrations as high as 3910 $\mu g/m^3$ among farmworkers during sweet potato transplanting. Area samples reported in two other studies support the belief that agricultural operations can generate high levels of respirable quartz. Gustafsson *et al.* (1978) reported average respirable quartz concentrations of 2000 $\mu g/m^3$ in open tractor cabs, while Lawson *et al.* (1995) reported respirable quartz concentrations ranging from 20–90 $\mu g/m^3$ during rice farming operations. Little evidence was reported in the literature regarding diseases associated with respirable crystalline silica exposure in agricultural workers (Swanepoel *et al.,* 2010). OSHA is interested in additional evidence relating to exposures to respirable crystalline silica that occur in agriculture and to associated control measures, as well as information related to the development of respirable crystalline silica-related diseases among workers in the agricultural sector, and is requesting such information in the ''Issues'' section (Section I) of this preamble.

In paragraph (b) (definition of ''respirable crystalline silica''), OSHA proposes to cover quartz, cristobalite, and tridymite under the standard. The Agency believes the evidence supports this approach. OSHA currently has different permissible exposure limits (PELs) for different forms of crystalline silica. The current general industry PELs for cristobalite and tridymite are one half of the general industry PEL for quartz. This difference was based on the fact that early animal studies appeared to suggest that cristobalite and tridymite were more toxic to the lung than quartz. However, as discussed in OSHA's Review of Health Effects Literature and summarized in Section V of this preamble, reviews of more recent studies have led OSHA to preliminarily conclude that cristobalite and tridymite are comparable to quartz in their toxicities. Also, a difference in toxicity between cristobalite and quartz has not been observed in epidemiologic studies. Exposure to tridymite has not been the subject of epidemiologic study.

OSHA's preliminary conclusion that quartz, cristobalite, and tridymite should be addressed under a single standard and subject to the same PEL is consistent with the recommendation of the National Institute for Occupational Safety and Health (NIOSH), which has a single Recommended Exposure Limit (REL) covering all forms of respirable crystalline silica. In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has issued a single Threshold Limit Value (TLV) for quartz and cristobalite.

In 2003, OSHA presented respirable crystalline silica draft standards for both general industry and construction to the Small Business Regulatory Enforcement Fairness Act (SBREFA) review panel. The general industry scope has remained unchanged, while the SBREFA construction draft standard included two alternative scope provisions. The first option, which is included in the proposal, stated that the rule applied to all construction operations covered by 29 CFR part 1926. The second option was more restrictive, indicating the rule would apply only to abrasive blasting and other specified operations (cutting, sanding, drilling, crushing, grinding, milling, sawing, scabbling, scrapping, mixing, jack hammering, excavating, or disturbing materials that contain crystalline silica). The SBREFA panel recommended that OSHA continue to evaluate and consider modifications to the second option that could serve to limit the scope of the standard.

OSHA is proposing to cover all occupational exposures to respirable crystalline silica in construction work, as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926, because the Agency wants to ensure that all activities are covered by the standard if they involve exposures that present a significant risk to workers. The second scope option in the SBREFA draft included activities that are typically associated with higher worker exposures to crystalline silica, but would not cover all operations that present a significant risk.

Collectively, the proposed standards apply to occupational exposure in which respirable crystalline silica is present in an occupationally related context. Exposure of employees to the ambient environment, which may contain small concentrations of respirable crystalline silica unrelated to occupational activities, is not subject to the proposed standards.

(b) Definitions

''Action level'' is defined as an airborne concentration of respirable crystalline silica of 25 micrograms per cubic meter of air (25 μg/m^3) calculated as an eight-hour time-weighted average (TWA). The action level triggers requirements for periodic exposure monitoring. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of respirable crystalline silica, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to respirable crystalline silica at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day fall below the PEL but are above the action level, there is a reasonable chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. Previous standards have recognized a statistical basis for using an action level of one-half the PEL (*e.g.,* acrylonitrile, 29 CFR 1910.1045; ethylene oxide, 29 CFR 1910.1047). In brief, OSHA previously determined (based in part on research conducted by Leidel *et al.*) that where exposure measurements are above one-half the PEL, the employer cannot be reasonably confident that the employee is not exposed above the PEL on days when no measurements are taken (Leidel, *et al.,* 1975). Therefore, requiring periodic exposure measurements when the action level is exceeded provides employers with additional assurance that employees are being protected from exposures above the PEL.

As exposures are lowered, the risk of adverse health effects among workers decreases. In addition, there is an economic benefit to employers who reduce exposure levels below the action level: They can avoid the costs associated with periodic exposure monitoring requirements. Some employers will be able to reduce exposures below the action level in all work areas, and other employers in some work areas.

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed PEL of 50 μg/m^3. At least one court has held that OSHA has a duty to impose additional requirements on employers to eliminate remaining significant risk when those requirements will afford benefits to workers and are feasible. *Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1269 (D.C. Cir 1988). OSHA's preliminary conclusion is that the action level will result in a very real and necessary further reduction in risk beyond that provided by the PEL alone. OSHA's decision to propose an action level of one-half of the PEL is based, in part, on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

''Competent person'' means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them. The competent person concept has been broadly used in OSHA construction standards, particularly in safety standards. In OSHA shipyard standards, a defined role for the competent person focuses on confined space hazards, hot work, and explosive environments. Competent person requirements also apply to powder actuated tools. It is not the intent of this proposal to modify the existing competent person requirements in shipyard standards.

As explained below in section (e) (Regulated areas and access control), employers have the option to develop a written access control plan in lieu of establishing regulated areas to minimize exposures to employees not directly involved in operations that generate respirable crystalline silica in excess of the PEL. The access control plan would require that a competent person identify areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL.

The proposed standard does not specify particular training requirements for competent persons. Rather, the requirement for a competent person is performance-based; the competent person must be capable of effectively performing the duties assigned under the standard. Therefore, the competent person must have the knowledge and experience necessary to identify in advance tasks or operations during which exposures are reasonably expected to exceed the PEL, so that affected employees can be notified of the presence and location of areas where such exposures may occur, and the employer can take steps to limit access to these areas and provide appropriate respiratory protection.

OSHA included more extensive competent person requirements in both the draft general industry/maritime and construction standards presented for review to the Small Business Regulatory Enforcement Fairness Act (SBREFA) review panel. The SBREFA draft standards included requirements for a competent person at each worksite to ensure compliance with the provisions of the standard. Specifically, the SBREFA draft standards required that the competent person: Evaluate workplace exposures and the effectiveness of controls, and implement corrective measures to ensure that employees are not exposed in excess of the PEL; establish regulated areas wherever the airborne concentration of respirable crystalline silica exceeds or can reasonably be expected to exceed the PEL, taking into consideration factors that could affect exposures such as wind direction, changes in work processes, and proximity to other workplace operations; and check the regulated area daily to ensure the boundary is maintained. The SBREFA draft standards also required the employer to ensure that the competent person inspect abrasive blasting activities as necessary to ensure that controls are being properly used and remain effective; participate in the evaluation of alternative blast media; and communicate with other employers to inform them of the boundaries of regulated areas established around abrasive blasting operations.

Many small entity representatives (SERs) from the construction industry who reviewed the SBREFA draft standard found the requirements for a competent person hard to understand (OSHA, 2003). Many believed that the competent person required a high skill level, while others thought that a large proportion of their employees would

need to be trained. SERs thought that the requirements would be difficult to comply with and costly. These concerns may have been due to the specific regulatory language used in the SBREFA draft, rather than the general concept of competent person requirements. OSHA's Advisory Committee on Construction Safety and Health recommended that the Agency retain the requirement and responsibilities for a competent person in the proposed rule (ACCSH, 2009). The Building and Construction Trades Department, AFL–CIO has also consistently recommended including competent person requirements in a proposed silica standard.

OSHA has proposed limited competent person requirements because the Agency has preliminarily concluded that the provisions of the proposed standard will generally be effective without the involvement of an individual specifically designated as a competent person. For example, the proposed standard requires that the employer use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL. OSHA believes that this provision adequately communicates this requirement to employers, and that an additional requirement for a ''competent person'' to evaluate the effectiveness of these controls and implement corrective measures in this standard is not necessary. However, the Agency is aware that competent person requirements have been included in other health and safety standards, and that some parties believe such requirements would be useful in the silica standard. OSHA is interested in information and comment on the appropriate role of a competent person in the respirable crystalline silica standard, and has included this topic in the ''Issues'' section (Section I) of this preamble.

''Employee exposure'' means exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator. This definition is included to clarify the requirement that employee exposure be measured as if no respiratory protection were being worn. It is consistent with OSHA's previous use of the term in other standards.

''Objective data'' means information, such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product, material, process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations. Objective data is further discussed below in section (d) (Exposure Assessment).

''Physician or other licensed health care professional (PLHCP)'' means 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 care services required by paragraph (h) of this section. This definition is included because the proposed standard requires that all medical examinations and procedures be performed by or under the supervision of a PLHCP.

Any PLHCP may perform the medical examinations and procedures required under the standard when they are licensed, registered, or certified by state law to do so. The Agency recognizes that this means that the personnel qualified to provide the required medical examinations and procedures may vary from state to state, depending on state licensing or certification laws. This provision of the proposed rule grants the employer the flexibility to retain the services of a variety of qualified licensed health care professionals, provided that these individuals are licensed to perform, or be delegated the responsibility to perform, the specified service. OSHA believes that this flexibility will reduce cost and compliance burdens for employers and increase convenience for employees. The approach taken in this proposed standard is consistent with the approach OSHA has taken in other recent standards, such as chromium (VI) (29 CFR 1910.1026), bloodborne pathogens (29 CFR 1910.1030), and respiratory protection (29 CFR 1910.134).

''Regulated area'' means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL. This definition is consistent with the use of the term in other standards, including those for chromium (VI) (29 CFR 1910.1026), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

''Respirable crystalline silica'' means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

The Agency's proposed definition for respirable crystalline silica seeks to harmonize the Agency's practice with current aerosol science and the ISO definition of respirable particulate mass. Thus, the proposed definition would encompass the polymorphs of silica covered under current OSHA standards and would be consistent with the international consensus that the ISO definition of respirable particulate mass represents. The American Conference of Governmental Industrial Hygienists (ACGIH) and the European Committee for Standardization (CEN) have adopted the ISO definition of respirable particulate mass. The National Institute for Occupational Safety and Health (NIOSH) has also adopted the ISO definition of respirable particulate mass in its Manual of Sampling and Analytical Methods. Adoption of this definition by OSHA would allow for workplace sampling for respirable crystalline silica exposures to be conducted using any particulate sampling device that conforms to the ISO definition (*i.e.,* that collects dust according to the particle collection efficiency curve specified in the ISO standard). OSHA's current respirable crystalline silica PELs are measured according to a particle collection efficiency curve formerly specified by ACGIH, which is now obsolete. The relationship between the ISO definition of respirable particulate mass and the ACGIH criteria is discussed in greater detail in the Technological Feasibility chapter of the Preliminary Economic Analysis, and is summarized in section VIII of this preamble.

The definitions for ''Assistant Secretary,'' ''Director,'' ''High-efficiency particulate air [HEPA] filter,'' and ''This section'' are consistent with OSHA's previous use of these terms in other health standards.

(c) Permissible Exposure Limit (PEL)

In paragraph (c), OSHA proposes to set an 8-hour time-weighted average (TWA) exposure limit of 50 micrograms of respirable crystalline silica per cubic meter of air (50 $\mu g/m^3$). This limit means that over the course of any 8-hour work shift, the average exposure to respirable crystalline silica cannot exceed 50 $\mu g/m^3$. The proposed PEL is

the same for both general industry/maritime [38] and construction.

OSHA currently expresses the general industry PEL for respirable crystalline silica in the form of quartz in two ways. The first, which is based on gravimetric measurement, is derived from the formula (PEL = (10 mg/m^3)/(% quartz + 2) as respirable dust). This is approximately equivalent to 100 μg/m^3 of respirable crystalline silica. The current general industry PELs for the polymorphs cristobalite and tridymite are one-half of the value calculated from this formula, or approximately 50 μg/m^3 of respirable crystalline silica. The proposed PEL is thus approximately equivalent to the current general industry PELs for cristobalite and tridymite. In cases where exposures to quartz, cristobalite, and/or tridymite occur at the same time, the PEL is calculated following the procedure specified in 29 CFR 1910.1000(d)(2) for exposures to mixtures of substances having an additive effect on the body or target organ system.

The second way OSHA expresses the general industry PEL for respirable crystalline silica in the form of quartz is based on a now-obsolete particle count sampling method, and is presented in terms of millions of particles per cubic foot (mppcf). This PEL is based on the formula (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust). The current general industry PELs for cristobalite and tridymite are one-half of the value calculated from this formula. These two parallel PELs in general industry were originally believed to be equivalent values (Ayer, 1995). However, as discussed below, the values are now considered to differ substantially.

The current PEL for crystalline silica in the form of quartz in construction and shipyards (PEL_{mppcf} = 250/(% quartz + 5) as respirable dust) is expressed only in terms of mppcf. This is the same formula as the parallel PEL for respirable crystalline silica in the form of quartz in general industry that is expressed in mppcf. The Mineral Dusts tables that contain the silica PELs for construction and shipyards do not clearly express PELs for cristobalite and tridymite. 29 CFR 1926.55; 29 CFR 1915.1000. This lack of textual clarity likely results from a transcription error during the codification of these rules. OSHA's current proposal provides the same PEL for quartz, cristobalite, and tridymite, in general industry, construction, and shipyards.

The current PELs in general industry, construction, and shipyards are 8-hour TWA exposure limits. Both formulas express the PEL in terms of a permissible level of exposure to respirable dust, rather than a permissible level of exposure to respirable crystalline silica. The higher the percentage of crystalline silica in the sample, the lower the level of respirable dust allowed.

The current PELs for construction and shipyards (and the parallel PEL presented for general industry) are based on a particle count method long rendered obsolete by gravimetric respirable mass sampling, which yields results reported in milligrams or micrograms per cubic meter of air (mg/m^{3}or μg/m^3). Gravimetric sampling methods are the only methods currently available to OSHA compliance personnel. Since the current construction and shipyard PELs are expressed only in terms of mppcf, the results of the gravimetric sampling must be converted to an equivalent mppcf value.

In order to determine a formula for converting from mg/m^3 to mppcf, OSHA requested assistance from the National Institute for Occupational Safety and Health (NIOSH). Based on its review of published studies comparing the particle count and gravimetric methods, NIOSH recommended a conversion factor of 0.1 mg/m^3 respirable dust to 1 mppcf. OSHA has determined that this conversion factor should be applied to silica sampling results used to characterize exposures in construction and shipyard operations. Appendix E to CPL 03–00–007, OSHA's National Emphasis Program for Crystalline Silica, illustrates how the conversion factor is applied to enforce the current PEL for crystalline silica in the construction and shipyard industries. Applying the conversion factor to a sample consisting of pure (*i.e.,* 100%) crystalline silica indicates that the current PEL for construction and shipyards is approximately equivalent to 250 μg/m^3 of respirable crystalline silica.

OSHA's current PELs for respirable crystalline silica are expressed as respirable dust, or respirable particulate mass. The proposed PEL is expressed as respirable crystalline silica, or the amount of crystalline silica that is present as respirable particulate mass. Respirable particulate mass refers to airborne particulate matter that is capable of entering the gas-exchange region of the lung, where crystalline silica particles cause pathological damage. Only very small particles (particles of about 10 μg/m or less) are able to penetrate into the gas-exchange region of the lung. As particle size decreases, the relative proportion of particles that is expected to reach the gas-exchange region of the lung increases.

Under the proposed definition of respirable crystalline silica in paragraph (b), respirable crystalline silica means airborne particles that contain quartz, cristobalite, and tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for particle-size-selective samplers specified in International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling. This definition of respirable particulate mass is intended to correspond with airborne particulate matter that is capable of entering the gas-exchange region of the lung. It provides a formula for determining the respirable fraction based on the aerodynamic diameter of the particles, and represents an international consensus that has been adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) and the European Committee for Standardization (CEN). The ISO definition is also used by the National Institute for Occupational Safety and Health (NIOSH) in its Manual of Sampling and Analytical Methods. The ISO definition of respirable particulate mass is discussed in greater detail in the Technological Feasibility chapter of the Preliminary Economic Analysis.

OSHA currently has a PEL for exposure to total quartz dust (PEL = (30 mg/m^3)/(% quartz + 2) as total dust) in general industry. As with the PEL for respirable dust, the PELs for cristobalite and tridymite are one-half of the value calculated from this formula. The Agency does not have a PEL for exposure to total quartz dust for construction or shipyards. OSHA proposes to delete the PELs for exposure to total crystalline silica dust, because the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment clearly relates development

[38] OSHA regulates silica exposure in three maritime-related activities: Shipyards (29 CFR 1915.1000, Table Z), Marine Terminals (29 CFR 1917.1(a)(2)(xiii)), and Longshoring (29 CFR 1918.1(b)(9)). Marine Terminals and Longshoring incorporate by reference the toxic and hazardous substance requirements in subpart Z of the general industry standard, which includes both a particle-counting formula and a mass formula for the silica PEL (29 CFR 1910.1000, Table Z–3). Shipyards has its own subpart Z, which uses the particle-counting formula for the silica PEL. Thus, under the current scheme, Marine Terminals and Longshoring use two alternative PEL formulas, while Shipyards uses a single PEL formula. The proposal eliminates this discrepancy by adopting a single PEL (50 μg/m^3) for all three maritime sectors, in addition to construction and general industry.

In this section, the Agency distinguishes between the *proposed maritime PEL* (50 μg/m^3 for all three maritime sectors) and the *current shipyard PEL* (the particle-counting formula required for shipyards and construction).

of crystalline silica-related disease to respirable, rather than total, dust exposure. This view is consistent with ACGIH, which no longer has a TLV for total crystalline silica dust. NIOSH does not have a Recommended Exposure Level for total crystalline silica exposure, and neither the National Toxicology Program nor the International Agency for Research on Cancer has linked exposure to total crystalline silica dust exposure to cancer, as they have with respirable crystalline silica exposure.

OSHA proposes a new PEL of 50 μg/m³ because the Agency has preliminarily determined that occupational exposure to respirable crystalline silica at the current PEL results in a significant risk of material health impairment among exposed workers, and that compliance with the proposed standard will substantially reduce that risk. OSHA's Preliminary Quantitative Risk Assessment, summarized in Section VI of this preamble, indicates that a 45-year exposure to respirable crystalline silica at the current general industry PEL would lead to between 13 and 60 excess deaths from lung cancer, 9 deaths from silicosis, 83 deaths from all forms of non-malignant respiratory disease (including silicosis), and 39 deaths from renal disease per 1000 workers. Exposures at the current construction and shipyard PEL would result in even higher levels of risk. As discussed in Section VII of this preamble, these results clearly represent a risk of material impairment of health that is significant within the context of the ''*Benzene*'' decision. *Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607 (1980). OSHA believes that lowering the PEL to 50 μg/m³ would reduce the lifetime excess risk of death per 1000 workers to between 6 and 26 deaths from lung cancer, 7 deaths from silicosis, 43 deaths from all forms of non-malignant respiratory disease (including silicosis), and 32 deaths from renal disease.

OSHA considers the level of risk remaining at the proposed PEL to be significant. However, the proposed PEL is set at the lowest level that the Agency believes to be technologically feasible. As discussed in the Technological Feasibility chapter of the Preliminary Economic Analysis and summarized in section VIII of this preamble, OSHA's analysis indicates that exposures at the proposed PEL can be measured with a reasonable degree of precision and accuracy. In addition, the analysis presented in the Technological Feasibility chapter of the Preliminary Economic Analysis makes clear that many industries and operations could not achieve an alternative PEL of 25 μg/m³ with engineering and work practice controls alone. As guided by the 1988 ''*Asbestos*'' decision (*Bldg & Constr. Trades Dep't* v. *Brock,* 838 F.2d 1258, 1266 (DC Cir. 1988)), OSHA is proposing additional requirements to further reduce the remaining risk. OSHA anticipates that the ancillary provisions in the proposed standard, including requirements for regulated areas and medical surveillance, will further reduce the risk beyond the reduction that would be achieved by the proposed PEL alone. OSHA also believes that a new PEL, expressed as a gravimetric measurement of respirable crystalline silica, will improve compliance because the PEL is simple and relatively easy to understand. In comparison, the existing PELs require application of a formula to account for the crystalline silica content of the dust sampled and, in the case of the construction and shipyard PELs, a conversion of mppcf to mg/m³ as well.

OSHA believes that it is appropriate to establish a single PEL that applies to respirable quartz, cristobalite, and tridymite. As explained in the Review of Health Effects Literature and Preliminary Quantitative Risk Assessment (see sections V and VI of this preamble for summaries), research indicates that certain physical factors may affect the toxicologic potency of crystalline silica. These factors include particle surface characteristics, the age of fractured surfaces of the crystal particle, the presence of impurities on particle surfaces, and coating of the particle. These factors may vary among different workplace settings, suggesting that the risk to workers exposed to a given level of respirable crystalline silica may not be equivalent in different work environments. The Agency's Quantitative Risk Assessment, summarized in section VI of this preamble, relies on studies involving a range of work environments; from study to study, workers' exposures to respirable crystalline silica varied in terms of particle age, surface impurities, and particle coatings. While the risk estimates that OSHA derived using data from different work environments are somewhat dissimilar, and these differences may be due in part to variations in particle toxicity, all of OSHA's risk estimates indicate significant risk above the proposed PEL of 50 μg/m³. Thus, while the available evidence is not sufficient to establish precise quantitative differences in risk based on these physical factors, the Agency's findings of significant risk are representative of a wide range of workplaces reflecting differences in the form of silica present, surface properties, and impurities. OSHA is therefore proposing a single PEL for respirable quartz, cristobalite, and tridymite.

OSHA currently has separate entries in 29 CFR 1910.1000 Table Z–1 for cristobalite, quartz, tripoli (as quartz), and tridymite. The proposal would present a single entry for crystalline silica, as respirable dust, with a cross reference to the new standard. As discussed above, the proposed PEL applies to quartz, cristobalite, and tridymite. Tripoli, which is extremely fine-grained crystalline silica, is covered under the proposed PEL as quartz. Comparable revisions would be made to 29 CFR 1915.1000 Table Z and 29 CFR 1926.55 Appendix A.

(d) Exposure Assessment

Paragraph (d) of the proposed standard sets forth requirements for assessing employee exposures to respirable crystalline silica. 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).

As a general matter, monitoring of employee exposure to toxic substances is a well-recognized and accepted risk management tool. The purposes of requiring an assessment of employee exposures to respirable crystalline silica include: determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure; 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 level 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, the availability of exposure data enables PLHCPs performing medical examinations to be informed of the extent of occupational exposures.

Paragraph (d)(1) contains proposed general requirements for exposure assessment. The general requirements for assessing exposure to respirable

crystalline silica in the proposed standard are similar to the requirements contained in previous OSHA substance-specific health standards. Except as provided for in the construction standard under paragraph (d)(8), paragraph (d)(1)(i) requires each employer to assess the exposure of any employees who are exposed, or may reasonably be expected to be exposed, to respirable crystalline silica at or above the action level. Under paragraph (d)(1)(ii), monitoring to determine employee exposures must represent the employee's time-weighted average exposure to airborne respirable crystalline silica over an 8-hour workday. Samples must be taken within the employee's breathing zone (*i.e.,* ''personal breathing zone samples'' or ''personal samples''), and must represent the employee's exposure without regard to the use of respiratory protection.

Employers must accurately characterize the exposure of each employee to respirable crystalline silica. In some cases, this will entail monitoring all exposed employees. In other cases, as set out in proposed paragraph (d)(1)(iii), monitoring of ''representative'' employees is sufficient. Representative exposure sampling is permitted when a number of employees perform essentially the same job on the same shift and under the same conditions. For employees engaged in similar work, it may be sufficient to monitor a fraction of these employees in order to obtain data that are ''representative'' of the remaining employees. Under the proposed standard, a representative sample must include employee(s) reasonably expected to have the highest exposures. For example, this may involve monitoring the exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Representative exposure monitoring must include at least one full-shift sample taken for each job function in each job classification, in each work area, for each shift. These samples must consist of either a single sample characteristic of the entire shift or consecutive samples taken over the length of the shift. In many cases, full-shift samples on two or more days may be necessary to adequately characterize exposure and obtain results that are representative of employees with the highest exposure for each job classification. Where employees are not performing the same job under the same conditions, representative sampling will not adequately characterize actual exposures, and individual monitoring is necessary.

Paragraph (d)(2)(i) of the proposed standard requires employers to conduct an initial exposure assessment by performing initial monitoring of any employees who are exposed, or may reasonably be expected to be exposed, to respirable crystalline silica at or above the action level. Further obligations under the standard are based on the results of this initial assessment. These may include obligations for periodic monitoring, establishment of regulated areas, implementation of control measures, and provision of medical surveillance.

The proposed standard, paragraph (d)(2)(ii), provides two exceptions to the requirement to conduct initial exposure monitoring. First, under paragraph (d)(2)(ii)(A), employers may rely on existing monitoring data to satisfy the requirement for an initial exposure assessment if employee exposures have been monitored within 12 months prior to the effective date of the standard under conditions that closely resemble those currently prevailing, and if that monitoring was conducted using one of the sampling and analytical methods specified in paragraph (d)(5)(i). This provision is intended to make it clear that employers who have recently performed appropriate employee monitoring will not be required to conduct additional monitoring to satisfy the requirement for ''initial'' monitoring. OSHA anticipates that this provision will reduce the compliance burden on employers who have already assessed exposure levels, since ''initial'' monitoring would not be required. The Agency believes the use of data obtained no more than 12 months prior to the effective date is appropriate, since samples taken more than 12 months before the effective date may not adequately represent current workplace conditions. The 12 month limit is consistent with the methylene chloride standard, 29 CFR 1910.1052.

Second, to meet the requirement for an initial exposure assessment, the employer may, under paragraph (d)(2)(ii)(B), use objective data that demonstrate that respirable crystalline silica will not be released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling. Objective data must demonstrate that the work operation or the product may not reasonably be foreseen to release respirable crystalline silica in concentrations at or above the action level under any expected conditions of use. OSHA has allowed employers to use objective data in lieu of initial monitoring in other standards, such as formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001). Any existing air monitoring data or objective data used in lieu of conducting initial monitoring must be maintained in accordance with the recordkeeping requirements in paragraph (j) of this standard.

Paragraph (d)(3) of the proposed standard requires the employer to assess employee exposure to respirable crystalline silica on a periodic basis for employees exposed at or above the action level. If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If the initial monitoring indicates employee exposure are at or above the action level, then the employer has the choice of following either a fixed schedule option or a performance option for periodic exposure assessments.

The fixed schedule option in paragraph (d)(3)(i) specifies the frequency of monitoring based on the results of the initial and subsequent monitoring. If the initial monitoring indicates employee exposures to be at or above the action level but at or below the PEL, the employer must perform periodic monitoring at least every six months. If the initial or subsequent monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring at least every three months. If periodic monitoring results indicate that employee exposures have fallen below the action level, and those results are confirmed by a second measurement taken consecutively at least seven days afterwards, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring unless, under paragraph (d)(4), changes in the workplace result in new or additional exposures.

OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring provides the employer with assurance that employees are not experiencing exposures that are higher than expected and require the use of additional control measures. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to respirable crystalline silica.

Because of the fluctuation in exposures, OSHA believes that when initial monitoring results equal or exceed the action level, but are at or below the PEL, employers should continue to monitor employees to

ensure that exposures remain at or below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an accurate profile of employee exposures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA believes that the proposed frequencies of six months for subsequent periodic monitoring for exposures at or above the action level but at or below the PEL, and three months for exposures above the PEL, provide intervals that are both practical for employers and protective for employees. This belief is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048).

OSHA recognizes that monitoring can be a time-consuming, expensive endeavor and therefore offers employers the incentive of discontinuing monitoring for employees whose sampling results indicate exposures are below the action level. Periodic monitoring for a specific worker or representative group of workers can be discontinued when at least two consecutive measurements taken at least seven days apart are below the action level, because this indicates a low probability that under the prevailing conditions exposure levels exceed the PEL. Therefore the final rule provides an incentive for employers to control their employees' exposures to respirable crystalline silica to below the action level to minimize their exposure monitoring obligations while maximizing the protection of employees' health.

The performance option described in paragraph (d)(3)(ii) of the proposed standard provides employers flexibility to assess 8-hour TWA exposures on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica. OSHA recognizes that exposure monitoring may present challenges in certain instances, particularly when operations are of short duration or performed under varying environmental conditions. The performance option is intended to allow employers flexibility in performing periodic exposure assessments. Where the employer elects this option, the employer must conduct the exposure assessment prior to the time the work operation commences, and must demonstrate that employee exposures have been accurately characterized.

Previous OSHA substance-specific health standards have usually allowed employers to use objective data to characterize employee exposures, but have generally limited its use to demonstrating that exposures would be below the action level (*e.g.,* cadmium, 29 CFR 1910.1027(d)(2)(iii)). In this instance, OSHA proposes to allow reliance on the use of objective data for periodic exposure assessments, even where exposures may exceed the action level or PEL. However, the burden is on the employer to show that the exposure assessment is sufficient to accurately characterize employee exposures to respirable crystalline silica. For example, where an employer has a substantial body of data (from previous monitoring, industry-wide surveys, or other sources) indicating that worker exposures in a given operation exceed the PEL, but do not exceed 10 times the PEL under any expected conditions, the employer may choose to rely on that data to determine his or her compliance obligations (*e.g.,* implementation of feasible engineering and work practice controls, respiratory protection, medical surveillance). OSHA's intent is to allow employers flexibility in methods used to assess employee exposures to respirable crystalline silica, but to ensure that the methods used are accurate in characterizing employee exposures. Any objective data relied upon must be maintained and made available in accordance with the recordkeeping requirements in paragraph (j)(2) of the proposed standard.

Under paragraph (d)(4), the employer is required to reevaluate employee exposures whenever there has been a change in the production, process, control equipment, personnel, or work practices that may reasonably be expected to result in new or additional exposures to respirable crystalline silica at or above the action level. For example, if an employer has conducted monitoring during an operation while using local exhaust ventilation, and the flow rate of the ventilation system is decreased, then additional monitoring would be necessary to assess employee exposures under the modified conditions. In addition, there may be other situations which can result in new or additional exposures to respirable crystalline silica which are unique to an employee's work situation. For instance, a worker may move from an open, outdoor location to an enclosed or confined space. Even though the task performed and materials used may remain constant, the changed environment could reasonably be expected to result in higher exposures to respirable crystalline silica. In order to cover those special situations, OSHA requires the employer to conduct an additional exposure assessment whenever a change may result in new or additional exposures at or above the action level. This reevaluation is necessary to ensure that the exposure assessment accurately represents existing exposure conditions. The exposure information gained from such assessments will enable the employer to take appropriate action to protect exposed employees, such as instituting additional engineering controls or providing appropriate respiratory protection. On the other hand, additional monitoring is not required simply because a change has been made, if the change is not reasonably expected to result in new or additional exposures to respirable crystalline silica at or above the action level.

Paragraph (d)(5) of the proposed standard contains specifications for the methods to be used for sampling and analysis of respirable crystalline silica samples. OSHA has typically included specifications for the accuracy of exposure monitoring methods in substance specific standards, but not the specific analytical methods to be used or the qualifications of the laboratory that analyzes the samples. The proposed standard includes details regarding the specific sampling and analytical methods to be used, as well as the qualifications of the laboratories at which the samples are analyzed. As discussed in greater detail in the Technological Feasibility section of the Preliminary Economic Analysis, the Agency has preliminarily determined that these provisions are needed to ensure that monitoring can be relied upon to accurately measure employee exposures.

Under proposed paragraph (d)(5)(i), all samples taken to satisfy the monitoring requirements of this section must be evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7. OSHA has determined based on inter-laboratory comparisons that laboratory analysis by either X-ray diffraction (XRD) or infrared (IR) spectroscopy is

required to ensure the accuracy of the monitoring results in environments subject to the Agency's jurisdiction. The specified analytical methods are the XRD or IR methods for analysis of respirable crystalline silica that have been established by OSHA, NIOSH, or MSHA.

To ensure the accuracy of air sampling data relied on by employers to achieve compliance with standard, the standard requires that air samples are to be analyzed only at accredited laboratories that meet six requirements listed in paragraphs (d)(5)(ii)(A–F). The requirements were developed based on procedures implemented at laboratories that have achieved acceptable levels of accuracy and precision during a study of inter-laboratory variability. An employer who engages an independent laboratory to analyze respirable crystalline silica samples could rely on an assurance from that laboratory that the specified requirements were met. For example, the laboratory could include a statement that it complied with the requirements of the standard along with the sampling results provided to the employer.

Paragraph (d)(5)(ii)(A) requires employers to ensure that samples taken to monitor employee exposures are analyzed by a laboratory that is accredited to ANS/ISO/IEC Standard 17025 ''General requirements for the competence of testing and calibration laboratories'' (EN ISO/IEC 17025:2005) by an accrediting organization that can demonstrate compliance with the requirements of ISO/IEC 17011 ''Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies'' (EN ISO/IEC 17011:2004). ANS/ISO/IEC 17025 is a consensus standard that was developed by the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) and approved by the American Society for Testing and Materials (ASTM). This standard establishes criteria by which laboratories can demonstrate proficiency in conducting laboratory analysis through the implementation of quality control measures. To demonstrate competence, laboratories must implement a quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error (SAE) when reporting samples. ISO/IEC 17011 establishes criteria for organizations that accredit laboratories under ISO/IEC 17025. For example, the AIHA accredits laboratories for proficiency in the analysis of crystalline silica using criteria based on the ISO 17025 and other criteria appropriate for the scope of the accreditation.

Paragraphs (d)(5)(ii)(B)–(F) contain additional requirements for laboratories that have been demonstrated to improve accuracy and reliability through inter-laboratory comparisons. The laboratory must participate in a round robin testing program with at least two other independent laboratories at least every six months. An example of a testing program that satisfies this requirement, as it is currently implemented, is the program established by AIHA Proficiency Analytical Testing Programs, LLC. The laboratory must use the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification. The laboratory must have an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error. The laboratory must characterize the sample material by identifying polymorphs of respirable crystalline silica present, identifying the presence of any interfering compounds that might affect the analysis, and making the corrections necessary in order to obtain accurate sample analysis. The laboratory must analyze quantitatively for respirable crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, and corrects for analytical interferences. The laboratory must perform routine calibration checks with standards that bracket the sample concentrations using five or more calibration standard levels to prepare calibration curves, and use instruments optimized to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL.

Under paragraph (d)(6) of the proposed rule, employers covered by the general industry standard must notify each affected employee within 15 working days of completing an exposure assessment. Notification is required whenever an exposure assessment has been conducted regardless of whether or not employee exposure exceeds the action level or PEL. In construction, employers must notify each affected employee not more than five working days after the exposure assessment has been completed. A shorter time period for notification is provided in construction in recognition of the often short duration of operations and employment in particular locations in this sector. The time allowed for notification is consistent with the harmonized notification times established for certain health standards applicable to general industry and construction in Phase II of OSHA's Standards Improvement Project. 70 FR 1112; January 5, 2005. Where the employer follows the scheduled monitoring option provided for in paragraph (d)(3)(i), the 15 (or five) day period for notification commences when monitoring results are received by the employer. For employers following the performance-oriented option under paragraph (d)(3)(ii), the period commences when the employer makes a determination of the exposure levels and the need for corresponding control measures (*i.e.,* prior to the time the work operation commences, and whenever exposures are re-evaluated).

The notification requirements in this provision apply to all employees for which an exposure assessment has been conducted, either individually or as part of a representative monitoring strategy. It includes employees who were subject to personal monitoring, as well as employees whose exposure was assessed based on other employees who were sampled, and employees whose exposures have been assessed on the basis of objective data. The employer shall either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, paragraph (d)(6)(ii) requires that whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce employee exposures to or below the PEL. The requirement to inform employees of the corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the OSH Act. 29 U.S.C. 657(c)(3).

Notifying employees of their exposures provides them with knowledge that can permit and encourage them to be more proactive in working to control their own exposures through better and safer work practices and more active participation in safety programs. As OSHA noted with respect to its Hazard Communication Standard: ''Workers provided the necessary hazard information will more fully participate in, and support, the protective measures instituted in their workplaces.'' 59 FR 6126, 6127; Feb. 9, 1994. Exposures to respirable crystalline silica below the PEL may still be hazardous, and making employees aware of such exposures may encourage them to take whatever steps

they can, as individuals, to reduce their exposures as much as possible.

Paragraph (d)(7) requires the employer to provide affected employees or their designated representatives an opportunity to observe any air monitoring of employee exposure to respirable crystalline silica, whether the employer uses the fixed schedule option or the performance option. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, and assure that the observer uses such clothing or equipment.

The requirement for employers to provide employees or their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the OSH Act mandates that regulations developed under section 6 of the Act provide employees or their representatives with the opportunity to observe monitoring or measurements. 29 U.S.C. 657(c)(3). Also, section 6(b)(7) of the OSH Act states that, where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. 29 U.S.C. 655(b)(7). The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

Table 1 in paragraph (f) of the proposed construction standard lists exposure control methods for selected construction operations. As discussed with regard to paragraph (f), OSHA has preliminarily determined that the engineering controls, work practices, and respiratory protection specified for each operation in Table 1 represent appropriate and effective controls for those operations. Therefore, paragraph (d)(8) of the proposed construction standard makes an exception to the general requirement for exposure assessment where employees perform operations in Table 1 and the employer has fully implemented the controls specified for that operation. This relieves the employer of the burden of performing exposure monitoring in these situations.

Where the employer elects to implement the control measures specified in Table 1 for a given construction operation, paragraph (d)(8)(ii) requires that the employer presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL, unless the employer can demonstrate otherwise in accordance with paragraph (d) of the proposed rule. So, for example, if an employer elects to implement the controls specified in Table 1 for a given construction operation that requires a respirator and does not conduct an exposure assessment to demonstrate that exposures are below the PEL, the employer would be required to provide each employee performing that operation for 30 or more days per year with medical surveillance in accordance with paragraph (h) of the proposed rule.

(e) Regulated Areas and Access Control

Under paragraph (e)(1) in the standards, employers have two options wherever an employee's exposure to airborne concentrations of respirable silica is, or can reasonably be expected to be, in excess of the PEL: (1) the establishment of regulated areas in accordance with paragraph (e)(2); or (2) the implementation of a written access control plan in accordance with paragraph (e)(3).

The purpose of a regulated area is to ensure that the employer makes employees aware of the presence of respirable crystalline silica at levels above the PEL, and to limit exposure to as few employees as possible. The establishment of a regulated area is an effective means of minimizing exposure to employees not directly involved in operations that generate respirable crystalline silica and limiting the risk of exposure to a substance known to cause adverse health effects. Because of the potentially serious results of exposure and the need for persons entering the area to be properly protected, the number of persons given access to the area should be limited to those employees needed to perform the job. Limiting access to regulated areas also has the benefit of reducing the employer's obligation to implement other provisions of this proposed standard to as few employees as possible.

Under paragraph (e)(2)(ii), regulated areas are to be demarcated from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundary of the regulated area, and minimizes the number of employees exposed to respirable crystalline silica within the regulated area. OSHA has not specified how employers are to demarcate regulated areas. Signs, barricades, lines, or textured flooring may each be effective means of demarcating the boundaries of regulated areas. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on their knowledge of the specific conditions of their workplaces. Whatever methods are chosen to establish a regulated area, the demarcation must effectively warn employees not to enter the area unless they are authorized, and then only if they are using the proper personal protective equipment. Allowing employers to demarcate and limit access to the regulated areas as they choose is consistent with recent OSHA substance-specific health standards, such as chromium (VI) (29 CFR 1910.1026) and 1,3-butadiene (29 CFR 1910.1051).

Paragraph (e)(2)(iii) describes who may enter regulated areas. In both standards, access to regulated areas is restricted to persons required by their job duties to be present in the area, as authorized by the employer. In addition, designated employee representatives exercising the right to observe monitoring procedures are allowed to enter regulated areas. For example, employees in some workplaces may designate a union representative to observe monitoring; this person would be allowed to enter the regulated area. Persons authorized under the OSH Act, such as OSHA compliance officers, are also allowed access to regulated areas.

Under paragraph (e)(2)(iv), employers must provide each employee and designated representative who enters a regulated area with an appropriate respirator in accordance with paragraph (g), and require that the employee or designated representative uses the respirator while in the regulated area. The boundary of the regulated area indicates where respirators must be donned prior to entering, and where respirators can be doffed, or removed, upon exiting the regulated area. This provision is intended to establish a clear and consistent requirement for respirator use for all employees who enter a regulated area, regardless of the duration of their presence in the regulated area. OSHA believes this proposed requirement is simple to administer and enforce, protective of employee health, and consistent with general practice in management of regulated areas.

OSHA has proposed a requirement for use of protective clothing or other measures to limit contamination of clothing for employees working in regulated areas. Paragraph (e)(2)(v) requires that, where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer must

either provide appropriate protective clothing such as coveralls or similar full-bodied clothing, or else provide a means to remove excessive silica dust from contaminated clothing when exiting the regulated area. This provision is intended to limit additional respirable crystalline exposures to employees in regulated areas that could result from disturbing the dust that has accumulated on their clothing. It is also intended to protect employees in adjacent areas from exposures that could occur if employees with grossly contaminated clothing were to carry crystalline silica dust to other areas of the workplace. The purpose of this provision is not, however, to protect employees from dermal exposure to crystalline silica, as discussed further below.

In paragraph (e)(2)(v)(A), the proposal refers to ''finely divided materials.'' When using this term, the proposed standard refers to particles with very small diameters (*i.e.,* ≤ 10 μm) such that, once airborne, the particles would be considered respirable dust. ''Gross contamination'' refers to a substantial accumulation of dust on clothing worn by an employee working in a regulated area such that movement by the individual results in the release of dust from the clothing. The provision is not intended to cover any contamination of clothing, but rather those limited circumstances where significant quantities of dust are deposited on workers' clothing. Where such conditions exist, OSHA anticipates that the dust present on workers' clothing or the release of dust from the clothing would be plainly visible.

Under paragraphs (e)(2)(v)(A)(*1*)–(*2*), the employer would have the option of providing either appropriate protective clothing, such as coveralls that can be removed upon exiting the regulated area, or any other means of removing excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica. The employer may choose the approach that works best in the circumstances found in a particular workplace. The employer may choose, for example, to provide HEPA vacuums for removal of dust from clothing. It should be noted, however, that paragraph (f)(3)(ii) (paragraph(f)(4)(ii) of the standard for construction) prohibits the use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL. Paragraph (e)(2)(v) requires contaminated clothing to be either cleaned or removed upon exiting the regulated area, in order to ensure that other areas of the workplace do not become contaminated. Cleaning or removal of contaminated clothing must take place prior to removal of respiratory protection in order to ensure that any exposure to dust released from contaminated clothing is minimized.

In other substance-specific chemical standards, OSHA has typically included requirements for provision of protective clothing, as well as associated provisions addressing removal, storage, cleaning, and replacement of protective clothing. The proposed provisions for this respirable crystalline standard are more limited than other OSHA standards, in that the requirements only apply in regulated areas, and then only when there is the potential for clothing to become grossly contaminated. The employer is also given the option of providing other means to remove dust from contaminated clothing, an alternative not generally available in other OSHA standards. OSHA has proposed these more limited provisions because the Agency has made a preliminary determination that the proposed provisions will serve to reduce employee exposures, and that additional requirements for protective clothing are not reasonably necessary and appropriate.

Most other chemicals regulated under OSHA substance-specific standards either have direct dermal effects or can contribute to overall exposures through dermal absorption. OSHA is not aware of any evidence that dermal exposure is a concern for respirable crystalline silica. Moreover, dusts containing crystalline silica are ubiquitous in many of the work environments covered by this proposed standard. Therefore, the proposed silica standard focuses on those situations where contamination of clothing has the potential to contribute significantly to employee inhalation exposures. OSHA recognizes that the ASTM standards addressing occupational exposure to respirable crystalline silica do not include requirements for protective clothing. However, the Agency believes that the proposed provisions will serve to limit employee exposures in those situations where contamination of clothing contributes to inhalation exposures. OSHA also notes that the Agency's Advisory Committee on Construction Safety and Health recommended that OSHA maintain the language on protective clothing that was included in the draft provided for review under the Small Business Regulatory Enforcement Fairness Act (SBREFA). The SBREFA draft language would have required protective clothing or a means to vacuum contaminated clothing for all employees exposed above the PEL. The Agency seeks comment on the proposed provisions for protective clothing and has included this topic in the ''Issues'' section of this preamble.

OSHA's standard addressing sanitation in general industry (29 CFR 1910.141) requires that whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing shall be provided (29 CFR 1910.141(e)). The sanitation standard also includes provisions for lavatories with running water (29 CFR 1910.141(d)(2)), and prohibits storage or consumption of food or beverages in any area exposed to a toxic material (29 CFR 1910.141(g)(2)). Similar provisions are in place for construction (29 CFR 1926.51). OSHA expects that employers will comply with the provisions of the sanitation standard when required. Thus, no additional requirements for hygiene practices are included in the proposed silica standards.

The proposed standard provides two options for employers to choose between for minimizing exposure to employees not directly involved in operations that generate respirable crystalline silica. The establishment of regulated areas under paragraph (e)(2), as described above, is the first option for exposure control in workplaces, and when fully implemented will satisfy this requirement. However, OSHA recognizes that establishing regulated areas in some workplaces can be difficult. For example, in the SBREFA review process, the question was raised as to how a regulated area could be established for a highway project, where the source of exposure could be constantly moving. Some activities covered by the general industry/maritime standard may present similar difficulties, such as hydraulic fracturing operations where exposures may occur over a large area. In recognition of the practical problems that may be encountered in such circumstances, the proposed standard includes an option in paragraph (e)(3) for establishing and implementing a written access control plan in lieu of a regulated area.

Paragraph (e)(3)(ii) in the standard sets out the requirements for a written access control plan. The plan must contain provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can

reasonably be expected to be, in excess of the PEL. It must describe how employees will be notified of the presence and location of areas where exposures are, or can reasonably be expected to be, in excess of the PEL, and how these areas will be demarcated from the rest of the workplace. For multi-employer workplaces, the plan must identify the methods that will be used to inform other employers of the presence and the location of areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL, and any precautionary measures that need to be taken to protect employees. The written plan must contain provisions for limiting access to these areas, in order to minimize the number of employees exposed and the level of employee exposure. The plan must also describe procedures for providing each employee working in areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL with an appropriate respirator in accordance with paragraph (g) of this section. Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the access control plan must include provisions for the employer to provide either appropriate protective clothing, or a means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica. The access control plan must also include provisions for removal or cleaning of such clothing.

The employer must review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary. The written access control plan must be available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

The intent of the provision for establishing written access control plans in lieu of regulated areas is to provide employers with flexibility to adapt to the particular circumstances of their worksites while maintaining equivalent protection for employees. The Agency seeks comment on this proposed approach and has included this topic in the ''Issues'' section of this preamble.

(f) Methods of Compliance

Paragraph (f)(1) of the proposed rule establishes a hierarchy of controls which employers must use to reduce and maintain exposures to respirable crystalline silica to or below the permissible exposure limit (PEL). The proposed rule requires employers to implement engineering and work practice controls as the primary means to reduce exposure to the PEL or to the lowest feasible level above the PEL. In situations where engineering and work practice controls are not sufficient to reduce exposures to or below the PEL, employers are required to supplement these controls with respiratory protection, according to the requirements of paragraph (g) of the proposed rule. OSHA proposes to require primary reliance on engineering controls and work practices 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 the Agency's traditional adherence to a hierarchy of preferred controls.

OSHA requires adherence to this hierarchy of controls in a number of current standards, including the Air Contaminants (29 CFR 1910.1000) and Respiratory Protection (29 CFR 1910.134) standards, as well as previous substance-specific standards. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (*see AFL–CIO* v. *Marshall,* 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers* v. *Marshall,* 647 F.2d 1189 (DC Cir. 1980), *cert. denied,* 453 U.S. 913 (1981) (lead standard); *ASARCO* v. *OSHA,* 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel* v. *OSHA,* 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen* v. *U.S. Dep't of Labor,* 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

The Agency understands that engineering controls: (1) Control crystalline silica-containing dust particles at the source; (2) are reliable, predictable, and provide consistent levels of protection to a large number of workers; (3) can be monitored continually and relatively easily; and (4) are not as susceptible to human error as is the use of personal protective equipment. The use of engineering controls to prevent the release of silica-containing dust particles at the source also minimizes the silica exposure of other employees in surrounding work areas, especially at construction sites, who are not directly involved in the task that is generating the dust, and may not be wearing respirators.

Respirators are another important means of protecting workers 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 worker'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 the good work practices of individual employees. 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 the workplace as a whole, 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 considers 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 odor 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 workers 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), 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.

These concerns about the burdens placed on workers by the use of respirators were acknowledged in OSHA's revision of its Respiratory Protection standard, and are the basis for the requirement 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 (63 FR 1152, Jan. 8, 1998). Although experience in industry shows that most healthy workers 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.

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 workers and can cause workers to refrain from wearing the respirator, thereby rendering it ineffective.

While OSHA acknowledges that certain types of respirators may lessen problems associated with breathing resistance and skin discomfort, OSHA does not believe that respirators provide employees with a level of protection that is equivalent to engineering controls, regardless of the type of respirator used. It is well-recognized that certain types of respirators are superior to other types of respirators with regard to the level of protection offered, or impart other advantages. OSHA has evaluated the level of protection offered by different types of respirators in the Agency's Assigned Protection Factors rulemaking (68 FR 34036, June 6, 2003). Even in situations where engineering controls are not sufficiently effective to reduce exposure levels to or below the PEL, the reduction in exposure levels benefits workers by reducing the required protection factor of the respirator, which provides a wider range of options in the type of respirators that can be used. For example, for situations in which dust concentrations are reduced through use of engineering controls to levels that are less than ten times the PEL, employers would have the option of providing approved half-mask respirators that may be lighter and easier to use when compared with full-facepiece respirators.

In summary, engineering and work practice controls are capable of reducing or eliminating a hazard from the workplace; respirators protect only the employees who are wearing them. In addition, the effectiveness of respiratory protection always depends on the actions of employees, while the efficacy of engineering controls is generally independent of the individual. OSHA believes that engineering controls offer more reliable and consistent protection to a greater number of workers, and are therefore preferable to respiratory protection. *Engineering controls.* The engineering controls presented in this proposal can be grouped into these main categories: (1) Substitution, (2) isolation, (3) ventilation, and (4) dust suppression. Depending on the sources of crystalline silica dust and the operations conducted, a combination of control methods may reduce silica exposure levels more effectively than a single method. *Substitution.* Substitution refers to the replacement of a toxic material with another material that reduces or eliminates the harmful exposure. OSHA considers substitution to be an ideal control measure if it replaces a toxic material in the work environment with a non-toxic material, thus eliminating the risk of adverse health effects.

The technological feasibility study (PEA, Chapter 4) indicates that employers use substitutes for crystalline silica in a variety of operations. For example, some employers use substitutes in abrasive blasting operations, repair and replacement of refractory materials, operations performed in foundries, and in the railroad transportation industry. If substitutes for crystalline silica are being used in any operation not considered in the feasibility study, OSHA is requesting relevant information that contains data supporting the effectiveness, in reducing exposure to crystalline silica, of substitutes currently being used.

Before replacing a toxic material with a substitute, it is important that employers evaluate the toxicity of the substitute materials relative to the toxicity of the original material. Substitute materials that pose significant new or additional risks to workers are not a desirable means of control. Additionally, employers must comply with Section 5(a)(1) of the OSH Act, which prohibits occupational exposure to ''recognized hazards that are causing or are likely to cause death or serious physical harm.'' 29 U.S.C. 654(a)(1). Employers must also comply with applicable standards. 29 U.S.C. 654(a)(2). For example, with respect to chemical hazards, OSHA's Hazard Communication standard imposes specific requirements for employee training, material safety data sheets, and labeling. 29 CFR 1910.1200.

While the Agency's technological feasibility analysis includes information about materials that some employers use as alternatives to silica or silica-containing materials, the Agency recognizes that these substitute materials may present health risks. OSHA does not intend to imply that any particular material is an appropriate or safe substitute for silica. *Isolation.* Isolation, by means of a process enclosure, is another effective engineering control employed to reduce exposures to crystalline silica. It refers to a physical barrier normally surrounding the source of exposure and installed 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 workers who are not directly involved in dust-generating operations.

Due to the shift from manually operated to automated processes, enclosures have become more practicable. For example, forming line operators in structural clay products manufacturing can use automation for transfer of materials, allowing conveyors and milling areas to be enclosed (OSHA SEP Inspection Report 300523396). Another example can be observed in automated refractory demolition and installation methods. A ''pusher'' system installed in coreless induction furnaces allows refractory linings to be automatically pressed out by push plates installed in furnace bottoms. A representative of Foundry Products Supplier B (2000a) estimated that total worker exposure using a pusher system would be roughly half that of traditional

chipping refractory removal methods and possibly as much as 80 percent less if an enclosure (tarp) was used over the end of the furnace from which the lining is extruded. At a pottery facility, the exposure for a material handler monitoring automated equipment that is adding silica-containing raw materials to a mixer was about 66 percent lower than the exposure of a material handler manually adding the material to the mixer (OSHA SEP Inspection Report 300384435). At a structural clay industry facility inspected by OSHA, an 86-percent reduction in respirable quartz exposure readings occurred after management installed an enclosed, automated sand transfer system, despite not having optimally sealed components (PEA, Chapter 4).

Workers can also be isolated from a hazardous source when they operate heavy machinery equipped with enclosed cabs. In such cases, a cab that is well sealed and equipped with ventilation and a high-efficiency particulate air (HEPA) filter can minimize the potential for exposure from the dust created outside the cab.

MSHA (1997) recommended the following controls to maximize the effectiveness of an enclosed cab: keeping the cab interior's horizontal and vertical surfaces and areas clean and free of debris; inspecting door seals and closing mechanisms to ensure they work properly; ensuring that seals around windows, power line entries, and joints in the walls and floors of the cab are tightly sealed; ensuring that air conditioners are designed so that air comes in from the outdoors to create positive pressure and passes first through a pre-filter (those with an American Society of Heating, Refrigeration and Air-Conditioning Engineers efficiency rating of 90 percent are common) and then through a HEPA filter; and ensuring that HEPA filters are changed when they reach the manufacturer's final resistance value (MSHA, 1997).

Tractors, front-end loaders, and other mobile material-handling equipment equipped with properly enclosed, sealed, and ventilated operator cabs (*i.e.,* no leaks, positive pressure, and effective air filtration) can substantially reduce silica exposures associated with the use of such equipment. Direct-reading instruments show that fine particle (0.3 micron (μm) in size) concentrations inside operator cabs can be reduced by an average of 96 percent when cabs are clean, sealed, and have a functionally adequate filtration and pressurization system. Gravimetric sampling instruments found an average cab efficiency of about 93 percent when comparing dust levels outside and inside the cab (Cecala et al., 2005). Similarly, NIOSH investigators reported respirable dust exposure reductions of 97 and 98 percent, respectively, inside the cabin of a modified railroad ballast dumper in the railroad transportation industry (NIOSH HHE 92–0311, 2001). Other researchers have reported particle reductions inside the operator cab greater than 90 percent (Hall et al., 2002).

The Agency recognizes that although enclosed cabs have been proven to be an effective control method, they do not control exposures at the source. In many circumstances, machine operators work alongside employees who are outside the enclosed cabs and are not protected by them. As such, OSHA expects employers to apply all other feasible controls to protect those employees.

In certain situations, a process enclosure can enhance the benefits of other control methods when used simultaneously, such as when an enclosure is equipped with local exhaust ventilation (LEV). When the enclosure contains the crystalline-silica-containing dust cloud, the ventilation system is able to remove that contaminant in a more effective and timely fashion, as opposed to having it dissipate out of the ventilation system's exhaust range where there is no enclosure.

In the asphalt roofing manufacturing industry, the capture of process emissions (including dust) at the coater station is best achieved by using LEV in conjunction with an enclosure. When using a full enclosure with LEV, NIOSH recommends several practices that improve the capture efficiency of the ventilation system. OSHA believes these recommendations are beneficial whenever this control method is used in a production line. The recommendations are: (1) When process enclosures are used, the number and size of openings in the enclosure must be minimized to prevent a reduction in the capture efficiency of the ventilation system; (2) all doors should be adequately sealed and closed during operation of the line; (3) the size of the opening where the product enters and leaves the process equipment should be minimized to ensure an inward flow of air by the negative pressure within the enclosure; and (4) negative pressure must be maintained inside the enclosure to prevent leakage of process emissions into the workplace.

In the foundry industry, shakeout operators are responsible for monitoring equipment that separates the casting being produced from the molding material. This process generally involves shaking the casting, which creates dust exposure associated with respirable crystalline silica levels above the PEL. OSHA has determined that employers using this process should enclose the shakeout operations, and the most effective method to reduce exposure is installing efficient ventilation (PEA, Chapter 4).

Another example occurs in the masonry industry, when stationary saws are placed inside ventilated enclosures, and the set-up permits the operator to stand outside the enclosure. A 78-percent reduction in respirable quartz exposure was observed (from 354 μg/m^3 to 78 μg/m^3) when workers used a site-built ventilated booth outdoors as opposed to cutting with no booth (ERG–C, 2008).

Ventilation. Ventilation is another engineering control method used to minimize airborne concentrations of a contaminant by supplying or exhausting air. Two types of systems are commonly used: LEV and dilution ventilation. 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. Dilution ventilation allows the contaminant to spread over the work area but dilutes it by circulating large quantities of air into and out of the area. Consistent with past recommendations such as those included in the Hexavalent Chromium Rule, OSHA prefers the use of LEV systems to control airborne toxics because, if designed properly, they efficiently remove contaminants and provide for cleaner and safer work environments.

The use of effective exhaust ventilation in controlling worker exposures to crystalline silica can be illustrated by an example in the mineral processing industry. Here, the highest exposure levels obtained by OSHA were associated with bag dumping and disposal operations at a pottery clay manufacturing company (OSHA SEP Inspection Report 116178096). After the facility installed ventilated bag disposal hoppers, HEPA filters, and an enhanced LEV system, the exposure of the production workers was reduced by about 80 percent (from 221 μg/m^3 to 44 μg/m^3). A Canadian study of a rock-crushing plant also shows the effectiveness of LEV systems (Grenier, 1987); the plant, originally equipped with a general exhaust ventilation system with fabric dust collectors, processed rock containing as much as 60 percent crystalline silica. Operation of the LEV system was associated with reductions of respirable crystalline silica levels ranging from 20 to 79 percent.

LEV can be adapted to diverse sources of emissions. For workers who empty bags or mix powders that contain crystalline silica material, a portable exhaust trunk positioned near the bag-dumping hopper can capture a portion of the dust released during that activity. Additional crystalline silica exposure can occur when workers compress empty bags, an activity that can also be performed with LEV control (PEA, Chapter 4).

LEV can also be applied to operations involving portable tools. The benefits of tool-mounted LEV systems for controlling crystalline silica have been demonstrated by two NIOSH evaluations. In one evaluation, NIOSH tested two tool-mounted LEV shrouds for hand-held pneumatic chipping equipment (impact drills): one custom built, the other a commercially available model. Comparing multiple short-term exposure samples, NIOSH found that the shrouds reduced personal breathing zone (PBZ) respirable dust by 48 to 60 percent (NIOSH, 2003–EPHB 282–11a). In a separate evaluation, NIOSH collected short-term PBZ samples while workers used 25- or 30-pound jackhammers to chip concrete from inside concrete mixer truck drums. During 90- to 120-minute periods of active chipping, mean respirable silica levels decreased by 69 percent when the workers used a tool-mounted LEV shroud in these enclosed spaces (NIOSH, 2001–EPHB 247–19).

In the railroad transportation industry, dust control kits that incorporate LEV are designed to reduce the amount of ballast dust released by activities of heavy equipment during maintenance. These kits can be used with brooming equipment (mechanical sweepers) and present an alternative to relying on cab modification. Workers that operate brooming equipment have the greatest potential for elevated exposures among workers in this industry, and the Agency believes that kits would be a better control measure than cab modification because they reduce exposures at the source. Unfortunately, information regarding the effectiveness of these kits in reducing worker exposure to crystalline silica is not available from the manufacturer. OSHA is therefore requesting any relevant information that would aid the Agency in determining the potential impact of dust control kits in the railroad transportation industry (HTT, 2003; ERG–GI, 2008).

Based on the information presented in OSHA's technological feasibility analysis, many exposures in the workplace have occurred, in part, due to faulty ventilation systems and improper work practices that minimize their efficiency. In many cases, exposures can be reduced with the proper use and maintenance of ventilation systems (PEA, Chapter 4).

Dust suppression. Dust suppression methods are generally effective in controlling respirable crystalline silica dust, and they can be applied to many different operations such as material handling, rock crushing, abrasive blasting, and operation of heavy equipment (Smandych et al., 1998). Dust suppression can be accomplished by one of three systems: (1) wet dust suppression, in which a liquid or foam is applied to the surface of the dust-generating material; (2) airborne capture, in which moisture is dispensed into a dust cloud, collides with particles, and causes them to drop from the air; and (3) stabilization, which holds down dust particles by physical or chemical means (lignosulfonate, calcium chloride, and magnesium chloride are examples of stabilizers).

The most common dust suppression controls encountered during the technological feasibility review correspond to wet methods (PEA, Chapter 4). Water is generally an inexpensive and readily available resource and has been proven an efficient engineering control method to reduce exposures to airborne crystalline silica-containing dust. Dust, when wet, is less able to become or remain airborne.

In its analysis of technological feasibility, OSHA demonstrated that wet methods are effective in a wide variety of operations. For example, respirable quartz exposures for masonry cutters using stationary saws were substantially lower when wet cutting was performed instead of dry cutting (mean levels of 42 $\mu g/m^3$ versus 345 $\mu g/m^3$). Also, the exposure level for fabricators in the stone and stone products industry, who produce finished stone products from slabs, can be reduced substantially by applying wet method controls. Simcox et al. (1999) shows that exposures of fabricators at granite-handling facilities were reduced by 88 percent (490 $\mu g/m^3$ to 60 $\mu g/m^3$) when all dry-grinding tools used on granite were either replaced or modified to be water-fed.

Regarding the application of wet methods to operations involving portable equipment, recent studies show that using wet methods to control respirable dust released during chipping with hand-held equipment can reduce worker exposure substantially. NIOSH (2003–EPHB 282–11a) investigated a water-spray dust control used by construction workers breaking concrete with 60- and 90-pound jackhammers. A spray nozzle was fitted to the body of the chipping tool, and a fine mist was directed at the breaking point. Compared with uncontrolled pavement breaking, PBZ respirable dust concentrations were between 72 and 90 percent lower when the water spray was used. Williams and Sam (1999) also reported that a water-spray nozzle mounted on a hand-held pneumatic chipper decreased respirable dust by approximately 70 percent in the worker's breathing zone.

Washing aggregate also reduces the amount of fine particulate matter generated during subsequent use or handling. Burgess (1995) reports that the use of washed sand, from which a substantial portion of the fine particles have been removed, results in respirable crystalline silica exposures that are generally lower than when sand is not pre-washed. Plinke et al. (1992) also report that increasing moisture content decreases the amount of dust generated and state that it is often most efficient to apply water sprays to material before it reaches a transfer point so that the dust has time to absorb water before being disturbed.

For the railroad transportation industry, OSHA is recommending that ballast be washed before it is loaded into hopper cars. Ballast wetted at the supplier's site might dry prior to reaching the dumping site (NIOSH HETA–92–0311, 2001). In this circumstance, applying an additional layer of blanketing foam or other sealing chemical suppressant on top of the rail car can reduce water evaporation and provide an additional type of dust suppression (ECS, 2007). *Work practice controls.* Work practice controls systematically modify how workers perform an operation, and often involve workers' use of engineering controls. For crystalline silica exposures, OSHA's technological feasibility analysis shows that work practice controls are generally applied complementary to engineering controls, to adjust the way a task is performed. For work practice controls to be most effective, it is essential that workers and supervisors are fully aware of the exposures generated by relevant workplace activities and the impact of the engineering controls installed. Work practice controls are preferred over the use of personal protective equipment since work practice controls can address the exposure of silica at the source of emissions, thus protecting nearby workers.

Work practice controls can enhance the effects of engineering controls. For example, to ensure that LEV is working effectively, a worker would position it so that it captures the full range of dust

created, thus minimizing silica exposures.

A good example of adequate work practice controls can be found in ready-mixed concrete operations. Exposure data available to OSHA indicate that all truck drivers or other workers who remove residual concrete inside ready-mixed truck mixer drums have silica exposures greater than the proposed PEL, with some exposures approaching 10,000 μg/m³. The Agency recommends wet methods and ventilation as appropriate engineering controls and also gives priority to performing a particular work practice that can reduce exposures. Specifically, this work practice involves the timely rinsing of drum mixers. One report (Williams and Sam, 1999) concluded that heavy build-up of concrete inside truck mixer drums results in higher concentrations of worker exposure to crystalline silica during cleaning because a greater amount of time is required to remove the build-up. Rinsing the drum with water immediately after each load helps minimize build-up and the resulting dust exposure. The same cleaning methods are used, such as water pressure and scraping, independently of how often rinsing is performed. However, by rinsing the tanks with more frequency, the employer is modifying the nature of the cleaning operation because less concrete will be present, and thus less respirable dust created, during each cleaning.

Another example of good work practices can be observed in the porcelain enameling industry. One facility stated that porcelain applicators can ensure that they are making optimal use of LEV by avoiding positioning themselves between the enamel spray and the ventilation system. For large items, workers can use a turntable support to rotate the item so that it can be sprayed on all sides while the worker maintains the spray direction pointing into the ventilated booth (Porcelain Industries, 2004a).

Combined control methods. Exposure documentation obtained by the Agency demonstrates that for many operations, a combination of engineering and work practice controls reduces silica exposure levels more effectively than a single control method. The following examples represent preliminary feasibility conclusions for several industries.

In the dental equipment and supplies industry, OSHA has found that employers can limit the exposure of most workers to 50 μg/m³ or less by implementing a combination of engineering controls, including improving ventilation systems (at bag-dumping stations, weighing and mixing equipment, and packaging machinery) and designing workstations to minimize spills, and encouraging work practices that maximize the effect of engineering controls. One facility that implemented these controls reduced median exposure levels by 80 percent, from 160 μg/m³ to 32 μg/m³ (OSHA SEP Inspection Report 122252281).

Based on the exposure profile for the rock and concrete drilling industry, construction sites have already achieved compliance with the proposed PEL for about half of the workers operating drilling rigs through a combination of controls, including wet dust suppression methods, shrouds, and hoods connected to dust extraction equipment, and management of dust collection dump points (PEA, Chapter 4).

An example from a routine cupola relining in the ferrous foundry industry also demonstrates the benefit of a combination of controls. Samples taken before and after additional controls were installed reflect a 90-percent reduction of the median worker exposures (OSHA SEP Inspection Report 122209679). The modifications included using refractory material with reduced silica and greater moisture content, improving equipment and materials to reduce malfunction and task duration, wetting refractory material before removal, and assigning a consistent team of trained workers to the task.

Burmeister (2001) also reported on the benefits of multiple controls on another refractory relining activity. Initially, a full-shift crystalline silica result of 2.74 times the current calculated PEL was obtained while a worker chipped away the old refractory lining and then mixed the replacement refractory material. The foundry responded by holding a training meeting and seeking worker input on abatement actions, implementing a water control system to reduce dust generated during the pneumatic chipping process, purchasing chisel retainers that eliminated the need for workers to reach into the ladle during chipping, and purchasing a vacuum to remove dust and chipped material from the ladle. With these changes in place, a consultant found that exposure was reduced to 87 percent of the calculated PEL, representing a 70-percent reduction in worker exposure.

These examples illustrate the importance and value of maintaining an effective set of engineering controls alongside work practice controls to optimize silica exposure reduction. The proposed requirements are consistent with ASTM E 1132–06 and ASTM E 2625–09, the national consensus standards for controlling occupational exposure to respirable crystalline silica in general industry and in construction, respectively. Each of these standards has explicit requirements for methods of compliance. These requirements include use of properly designed engineering controls such as ventilation or other dust suppression methods and enclosed workstations such as control booths and equipment cabs; requirements for maintenance and evaluation of engineering controls; and implementation of certain work practices such as not working in areas where visible dust is generated from respirable crystalline silica containing materials without use of respiratory protection. OSHA has elected to propose a performance standard for general industry in which particular engineering and work practice controls are not specified. Instead, the standard requires that employers use engineering and work practice controls to achieve the PEL. In this case the use of properly designed, maintained, and regularly inspected engineering controls is implied by the ongoing ability of the employer to achieve the PEL. The national consensus standard for construction (ASTM E 2625–09) includes task-based control strategies for situations where exposures are known from empirical data. This approach is consistent with the alternative approach for construction operations in paragraph (f)(2) described below.

Paragraph (f)(2) of the proposed rule provides an alternative approach to achieve compliance with paragraph (f), Methods of Compliance, for construction operations. Under this paragraph, employers that implement the specific engineering controls, work practices, and, if required, respiratory protection described in Table 1 (please refer to paragraph (f) of the proposed rule) are considered to be in compliance with the requirements for engineering and work practice controls in paragraph (f)(1) of the proposed rule. An advantage of complying with Table 1 is that the employer need not make a determination of the hierarchy of controls, because the table incorporates that determination for each job operation listed. Furthermore, proposed paragraph (d)(8)(i) specifies that if an employer chooses to follow Table 1, the employer need not conduct exposure assessments required by paragraph (d) of the proposed rule. Rather, for those operations in Table 1 where respirator use is required, proposed paragraph (d)(8)(ii) requires employers to presume that workers engaged in those operations are exposed above the PEL; in those cases, the employer would be

required to comply with all provisions of the standard that apply to exposures above the PEL except for monitoring. For instance, when Table 1 requires workers to use respirators, the employer relying on Table 1 must: establish a regulated area or access control plan pursuant to proposed paragraph (e); comply with the cleaning methods provisions in proposed paragraph (f)(4); comply with the prohibition of employee rotation as specified in proposed paragraph (f)(5); establish a respiratory protection program pursuant to proposed paragraph (g)(2); and provide medical surveillance pursuant to paragraph (h) if workers are exposed for 30 or more days per year.

Table 1 was developed using recommendations made by small entity representatives through the Small Business Regulatory Enforcement Fairness Act (SBREFA) process. The SBREFA panel asked OSHA to develop a provision that detailed what specific controls to use for each construction operation covered by the rule in order to achieve compliance with paragraph (f)(1). Additionally, the Advisory Committee for Construction Safety and Health (ACCSH) has recommended that OSHA proceed with the development of Table 1. The table provides a list of 13 construction operations that expose workers to respirable crystalline silica as well as control strategies (engineering controls, work practices, and respirators) that reduce those exposures.

In developing control strategies for each of the 13 construction operations in Table 1, OSHA relied upon information from a variety of sources including scientific literature, NIOSH reports, OSHA site visits, and compliance case files (SEP reports). For several of the listed operations and controls, the Agency requests additional information from the public that will allow the Agency to determine whether the operations, corresponding control strategies, and conditions of use should be modified or removed from Table 1. OSHA also requests comment on the degree of specificity used for engineering and work practice controls for tasks identified in Table 1, including maintenance requirements.

Table 1 implements a novel approach for OSHA. The Agency believes that the table will provide significant benefits to workers and employers by ensuring that workers are adequately protected, providing specific approaches for complying with paragraph (f) requirements, and reducing the monitoring and sampling burden.

The table divides operations according to duration into ''less than or equal to'' four-hours-per-day tasks and ''greater than'' four-hours-per-day tasks. The Agency recognizes that some activities do not last a full work shift, and often some activities are performed for half-shifts or less. The duration of a task influences the extent of worker exposure and the selection of appropriate control strategies. OSHA followed its hierarchy of controls to develop these control strategies. Respiratory protection has been included in Table 1 for operations in which the specified engineering and work practice controls may not maintain worker exposures at or below the proposed PEL for all workers and at all times. Employers who comply with Table 1 need not assess employee exposures as otherwise required under paragraph (f), and workers in these circumstances will not have the benefit of conventional exposure data to characterize their exposures. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the Agency is proposing to require respiratory protection in situations where overexposures may occur even with the implementation of engineering and work practice controls. The Agency is requesting comments regarding the appropriateness of the use and selection of respirators in several operations.

If an employer anticipates that a worker will perform a single operation listed in Table 1 for four hours or less during a single shift, then the employer must ensure that the worker uses whichever respirator is specified in the ''≤4 hr/day'' column in the table. For example, if an employer anticipates that a worker will operate a stationary masonry saw for four hours or less, and the worker does not perform any other operation listed in Table 1, the worker would not be required to use respiratory protection because there is no respirator requirement for that entry in the table.

If an employer anticipates that a worker will perform a single operation listed in Table 1 for more than four hours, then the employer must ensure that the worker uses the respirator specified in the ''>4 hr/day'' column in Table 1 for the entire duration of the operation. For example, if an employer anticipates that a worker will operate a stationary masonry saw for more than four hours, and the worker does not perform any other operation listed in Table 1, the worker would be required to wear a half-mask respirator for the entire duration of the operation (refer to Table 1).

Additionally, for workers who engage in two or more discrete operations from Table 1 for a total of more than four hours during a single work shift, employers that rely on Table 1 must provide, for the entire duration of each operation performed, the respirator specified in the ''>4 hr/day'' column for that operation, even if the duration of that operation is less than four hours. If no respirator is specified for an operation in the ''>4 hr/day'' column, then respirator use would not be required for that part of a worker's shift.

For example, if a worker is using a stationary masonry saw for three hours and engages in tuckpointing for two hours in the same the shift, the employer would be required to ensure that the worker uses a half-mask respirator for the three hours engaged in sawing, and a tight-fitting, full-face PAPR for the two hours engaged in tuckpointing work. In other words, if a worker uses a stationary saw and engages in a tuckpointing operation for a total of more than four hours in a single work shift, the worker would be required to use a half-mask respirator for the entire time he or she operates the stationary saw and a tight-fitting, full-face PAPR for the tuckpointing work, regardless of how long each task is performed.

The following paragraphs describe the engineering controls, work practices and respirators selected for each of the operations listed in Table 1. In addition, the Agency describes the information that it has relied upon to develop the control strategies.

For most control strategies in the table, OSHA is proposing to require additional specifications to ensure that the strategies are effective. The most frequently required additional specifications are:

- Changing water frequently when using water delivery systems, to avoid silt build-up in the water and prevent wet slurry from accumulating and drying. This prevents silica from becoming airborne when the water becomes aerosolized by the rotation of equipment or when the water dries and leaves residual respirable silica-containing dust.
- Operating equipment such that no visible dust is emitted from the process. Visible dust may be an indication that the controls are not operating effectively. The absence of visible dust does not necessarily indicate that workers are protected, but visible dust is a clear indication of a potential problem.
- Providing sufficient ventilation to prevent build-up of visible airborne dust when working indoors or in enclosed spaces. Stagnant air in an enclosed

environment may increase worker exposures.

• Ensuring that saw blades and abrasive discs are not excessively worn. Excessive wear tends to increase respirable silica emissions and worker exposures.

• Using dust collectors according to manufacturers' specifications. Manufacturer specifications are often based on operation-specific designs.

Use of stationary masonry saws. For workers operating stationary masonry saws, OSHA is proposing to require that the saws be equipped with an integrated water delivery system that is operated and maintained to minimize dust emissions. The exposure profile created for this operation shows that cutting with wet methods offers a clear reduction to exposures, as opposed to dry cutting with no controls or with a mix of administrative or other engineering controls. The Agency obtained 12 samples for workers dry cutting with no engineering controls, 9 samples for workers dry cutting with a mix of controls, and 7 samples for workers operating the saws with water at the point of operation. The mean, median, and range values were all lower for workers using wet methods:

• Median of 33 μg/m³ (a 34-percent reduction from dry cutting and 63-percent reduction from dry cutting with some controls).

• Mean of 42 μg/m³ (an 88-percent reduction from dry cutting and 80-percent reduction from dry cutting with some controls).

• A maximum value of 93 μg/m³, as opposed to a maximum value of 2,005 μg/m³ for dry cutting, and 824 μg/m³ for dry cutting with some controls.

The Agency concludes, based on this information and the analysis discussed in the exposure profile for this operation (PEA, Chapter 4), that the water delivery system specified in Table 1 consistently reduces worker exposures to or below the proposed PEL when the saws are used for four hours or less. As a result, respiratory protection is not included in the control strategy for these operations. OSHA believes that, even when workers operate stationary masonry saws for eight hours, wet methods will reduce 8-hour exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, the maximum TWA value measured for a stationary masonry saw operator is 93 μg/m³, equivalent to a 4-hr exposure of 47 μg/m³ (*see* Chapter 4 of the PEA). Thus, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who use stationary masonry saws for more than four hours.

Use of hand-operated grinders. The table provides employers with two different control strategies.

Option 1: Use water-fed grinders that continuously feed water to the cutting surface, operated and maintained to minimize dust emissions. For operations lasting less than four hours, OSHA is proposing that respirators will not be required. For operations lasting four hours or more, OSHA is proposing the use of half-mask respirators to ensure workers are protected.

For its technological feasibility analysis, OSHA did not obtain any sample results where wet grinding occurred. Information available to the Agency suggests that overexposures still occur when using wet methods and that there are additional challenges such as limited applications. OSHA has decided to include this control strategy based on the use of water systems on similar tools used in the cut stone and stone products manufacturing industry that have shown a reduction of exposures to well below 100 μg/m³ (OSHA 3362–05). The Agency believes that similar reductions can be achieved for grinding operations because the amount of respirable dust produced in these operations is comparable. Based on this inference, OSHA believes that wet methods alone will provide sufficient protection for shifts lasting four hours or less, and is proposing to require the use of half-mask respirators with an APF of 10 for shifts lasting more than four hours.

The Agency requests comments and additional information regarding wet grinding and the adequacy of this control strategy.

Option 2: Use hand-operated grinders with commercially available shrouds and dust collection systems operated and maintained to minimize dust emission. The dust collector must be equipped with a HEPA filter and must operate at 25 cubic feet per minute (cfm) or greater airflow per inch of blade diameter. OSHA is proposing to require the use of half-mask respirators at all times, for outdoor and indoor operations alike, to ensure workers are protected.

OSHA's exposure profile for this operation contains 13 samples associated with the use of LEV. Two of these samples are associated with outdoor activities (40 μg/m³ and 53 μg/m³), and 11 samples are associated with indoor work (a range of 12 μg/m³ to 208 μg/m³). Overall, exposure samples show that outdoor exposures are lower than indoor exposures. The mean, median, and range values for these operations are:

• Median of 47 μg/m³ for outdoor operations with LEV, and 107 μg/m³ for indoor operations with LEV.

• Mean of 46 μg/m³ for outdoor operations with LEV, and 96 μg/m³ for indoor operations with LEV.

• A maximum value of 53 μg/m³ for outdoor operations with LEV, and 208 μg/m³ for indoor operations with LEV.

These values suggest that workers would sometimes achieve levels below the proposed PEL with LEV. However, the Agency recognizes that elevated exposures occur even with the use of LEV in these operations based on the fact that 8 out of 13 samples collected exceed the proposed PEL, with 6 samples ranging from 100 μg/m³ to 250 μg/m³. Based on this information, OSHA is proposing that employers apply the engineering control specified and equip workers with half-mask respirators at all times. It is important to note that OSHA has preliminarily concluded that the LEV control outlined in the table will not reduce and maintain exposures to the proposed PEL for all workers. However, these controls will reduce exposures within the APF of 10 offered by half-mask respirators. The Agency seeks additional information to confirm that the control strategy (including the use of half-mask respirators) listed in the table will reduce workers' exposure to or below the PEL.

Tuckpointing. OSHA is proposing to require employers to equip grinding tools with commercially available shrouds and dust collection systems, operated and maintained to minimize dust emissions. The grinder must be operated flush against the working surface, with grinding operations performed against the natural rotation of the blade (*i.e.,* mortar debris must be directed into the exhaust). Employers would be required to use vacuums that provide at least 80 cubic feet per minute (cfm) to 85 cfm airflow through the shroud and include filters that are at least 99 percent efficient.

Recent dust control efforts for tuckpointing have focused on using a dust collection hood, or shroud, which encloses most of the grinding blade. It is used with a vacuum cleaner system that exhausts air from these hood systems and collects dust and debris. These shroud and vacuum combinations capture substantial amounts of debris, but air monitoring results summarized in OSHA's exposure profile for this

operation show that even with this control in place, silica exposures often continue to exceed 100 μg/m³, with many of the results exceeding 250 μg/m³.

The highest exposure obtained for outdoor work with LEV (6,196 μg/m³), and many other exposures, suggest that there are circumstances in which the protection factor offered by a PAPR will be needed to reduce worker exposure to below 50 μg/m³. OSHA is aware that some exposures may be effectively controlled with the LEV system and a respirator with an APF of 10, but is proposing to require the use of the LEV system with respirators that provide an APF of 50 to ensure that the control strategy protects those workers with extremely elevated exposures. Based on this information, OSHA estimates that a substantial percentage of the worker population will need respiratory protection in the form of a powered air-purifying respirator (PAPR) with a loose-fitting helmet or a negative-pressure full-facepiece respirator regardless of task duration.

Furthermore, OSHA is stressing the importance of sufficient air circulation in enclosed or indoor environments to maximize the effect of the control strategy outlined. Elevated results are reported for tuckpointers in operations performed in areas with limited air circulation (including indoors). As such, the Agency is proposing to require employers to provide for ventilation to prevent the accumulation of airborne dust during operations performed in enclosed spaces, in addition to requiring equipment to be operated so that no visible dust is emitted from the process.

Use of jackhammers and other impact drillers. The table provides employers with two different control strategies.

Option 1: Apply a continuous stream or spray of water at the point of operation.

Results in OSHA's exposure profile show that the wet methods attempted in the five samples obtained were not effective at all in reducing exposures; in fact, the statistical values are higher than those under baseline conditions. Based on the best available information, OSHA believes that no single wet method was applied effectively and consistently throughout these operations, and the data obtained for wet methods is reflective of that inconsistency (ERG–C, 2008; PEA, Chapter 4). The three highest results for the samples corresponding to wet methods show respirable dust levels higher than the mean respirable dust value for comparable uncontrolled operations, indicating that the wet method control was not applied effectively, as it was not reducing total respirable dust levels.

Conversely, however, OSHA has obtained information from individual employers, NIOSH, and an informal consortium of New Jersey organizations interested in controlling silica during road construction activities that have all tested wet dust suppression methods with chipping and breaking equipment. The results of these tests indicate that wet dust suppression is effective in reducing respirable crystalline silica exposures.

The Agency obtained a reading for a jackhammer operator breaking concrete outdoors, where a continuous stream of water was directed at the breaking point. When compared with the median value in the exposure profile for outdoor and uncontrolled operations, the result represents a 77-percent exposure reduction in respirable quartz (OSHA SEP Inspection Report 106719750).

NIOSH provided similar findings when it completed several studies evaluating water spray devices to suppress dust created while workers used chipping and breaking equipment. Compared with concentrations during uncontrolled pavement breaking, respirable dust results were between 72 and 90 percent lower when the water spray was used (NIOSH EPHB–282–11a, 2003). A follow-up NIOSH study reported a similar 77-percent reduction in silica concentration during 60-minute trials with a solid cone nozzle producing water mist (NIOSH EPHB–282–11c–2, 2004).

Two other findings also show that water spray systems are effective in reducing respirable dust concentrations. Williams and Sam (1999) evaluated a shop-built water spray system attached to a hand-held pneumatic chipper used by a worker removing hardened concrete from inside a mixing truck drum. Although this task is not typically performed by construction workers, it represents a worst-case environment (in a confined space or indoors) for construction concrete chipping and breaking jobs. Water spray decreased respirable dust by about 70 percent in the worker's breathing zone, again showing that a water spray system offers substantial reduction in silica-containing dust generated.

Additionally, the New Jersey Laborers Health and Safety Fund, NIOSH, and the New Jersey Department of Health and Senior Services have collaborated in publishing simple instructions for developing spray equipment for jackhammers. A design tested in New Jersey involving a double water spray—one on each side of the breaker blade—reduced peak dust concentrations by approximately 90 percent compared with the peak concentration measured for uncontrolled breaking (Hoffer, 2007; NIOSH 2008–127, 2008; NJDHSS, no date).

OSHA believes that, even when workers perform impact drilling for eight hours, wet methods will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who perform impact drilling for more than four hours.

OSHA notes that applying the lowest exposure reduction of the values reported in the studies would reduce the highest range of exposures to within an APF of 10 provided by a half-mask respirator and, thus, consistently and adequately protect workers for a full shift. Additionally, for impact drilling operations lasting four hours or less, OSHA is proposing to allow workers to use water delivery systems without the use of respiratory protection, as the Agency believes that this dust suppression method alone will provide consistent, sufficient protection. OSHA is requesting comments and additional information that address the appropriateness of this control strategy.

It is important to mention that the highest exposures in the profile were obtained during indoor work, with a maximum value of 3,059 μg/m³. OSHA believes that these elevated results are in part due to poor air circulation in enclosed environments. The Agency believes that it is particularly important to ensure adequate air circulation during indoor work, so that airborne dust does not accumulate and contribute to higher exposures. As such, the proposed Table 1 includes a specification that directs employers to provide adequate ventilation during indoor work so as to prevent build-up of visible airborne dust.

Option 2: Use tool-mounted shroud and HEPA-filtered dust collection system, operated and maintained to minimize dust emissions.

Based on available information, LEV systems are also able to effectively reduce respirable airborne silica dust. NIOSH tested two tool-mounted LEV shrouds during work with chipping hammers intended for chipping vertical concrete surfaces. Comparing multiple

short–term samples, NIOSH found that the shrouds reduced respirable dust by 48 to 60 percent (Echt et al., 2003; NIOSH EPHB 282–11a, 2003). In a separate evaluation, NIOSH showed that this type of LEV system controls dust equally well for smaller chipping equipment. Mean silica levels decreased 69 percent when the workers used a tool-mounted LEV shroud in enclosed spaces (NIOSH EPHB 247–19, 2001). In this study, a combination of LEV and general exhaust ventilation provided additional dust control, resulting in a 78 percent decrease in silica readings. This finding further supports OSHA's proposal to ensure that additional ventilation is provided during indoor work to prevent the accumulation of airborne dust.

OSHA believes that, even when workers perform impact drilling for eight hours, these controls will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers perform this operation for more than four hours, silica exposures may occasionally exceed the PEL. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who perform impact drilling for more than four hours. OSHA believes that that LEV systems will reduce the highest range of airborne respirable silica concentrations (in the exposure profile) to within an APF provided by a half-mask respirator for operations lasting a full shift. For operations lasting four hours or less, OSHA is proposing to allow workers to use the shroud and HEPA vacuum system without respirators, as the Agency believes that this control alone will provide consistent, sufficient protection. The highest exposure values were obtained during indoor work, and the Agency is proposing that employers provide appropriate air circulation in order to maximize the effectiveness of the proposed control strategy.

Use of rotary hammers or drills (except overhead use). Table 1 requires that drills be equipped with a hood or cowl and a HEPA-filtered dust collector, operated and maintained to minimize dust emissions. The proposed control strategy also directs employers to eliminate blowing or dry sweeping drilling debris from working surfaces.

Of the 14 respirable quartz readings summarized in the exposure profile for this operation, seven represent hole drilling indoors under uncontrolled conditions. The highest reading obtained for workers in this job category, 286 μg/m³, was recorded for a worker drilling holes with a ¾-inch bit in the floor of a concrete parking garage where air circulation was poor (Lofgren, 1993). The other seven results, most of which were collected during outdoor drilling of brick and rock, are also spread over a wide range but tend to be lower than (less than half) the indoor values, with a maximum of 130 μg/m³ (NIOSH HETA–2003–0275–2926).

Shepherd et al. (2009) found that compared with uncontrolled drilling, using dust collection cowls connected to portable vacuums reduced silica exposures by 91 to 98 percent. The researchers tested four commercially available combinations of two cowls and two vacuums indoors. Although investigators note that results might vary for different drill types and drill bit sizes, OSHA estimates that the proposed control strategy will consistently maintain exposures below the proposed PEL even during periods of intense drilling. OSHA is proposing that employers ensure that dust collectors are used according to manufacturer's specifications in order to maximize dust reduction, and that the vacuums used are appropriate for the nature of the task to provide the adequate suction rate.

Based on the percent reductions documented in the Shepherd study, using a drill equipped with a hood or cowl and a HEPA-filtered dust collector reduces the highest exposure reading in the profile to levels below the proposed PEL. As such, OSHA anticipates that this control strategy alone will reduce or maintain exposures below 50 μg/m³ for workers using rotary hammers or drills for durations up to 8 hours (excluding overhead work).

Hallin (1983) indicates a greater potential for overexposure during overhead drilling. A test run reported that drilling for 120 minutes into a concrete ceiling with a percussion drill and a hammer drill gave respirable quartz concentrations of 1,740 μg/m³ and 720 μg/m³, respectively. The percussion drill was later fitted with a dust collector, and a 180-minute test run produced a value of 80 μg/m³. This type of drilling was not addressed in the Shepherd report; therefore, OSHA cannot confirm that using the cowl and dust collector would sufficiently protect workers. The Agency has no additional information that would indicate that exposures resulting from overhead work might be consistently reduced below the proposed PEL. Based on these factors, OSHA is proposing to exclude this particular task from Table 1. Furthermore, the Agency concurs with the recommendation made by Hallin (1983) that overhead drilling is ergonomically stressful and should not be performed consistently for a full shift.

Use of vehicle-mounted earth-drilling rigs for rock and concrete. Although the equipment used for each type of drilling varies, OSHA has addressed workers using drilling rigs of all types for rock, earth, and concrete together in the same section of the technological feasibility analysis. This is because the worker activities have much in common and the general methods of silica control are also similar. Specifically, these workers control the vehicle-mounted or rig-based drills from more than an arm's length from the drill bit(s). They also perform certain intermittent tasks near the drilling point, such as fine-tuning the bit position, moving debris away from the drill hole, and working directly or indirectly with compressed air to blow debris from deep within the holes.

When drilling rock, workers typically use rigs that are vertically oriented and equipped to produce a deep hole through the addition of bit extensions. This operation generally involves the drilling of one hole for an extended period of time, with minimal interruption. In contrast, when drilling concrete, workers often use rigs that consist of an array of one or many drills fixed to the maneuverable arm of a construction vehicle or purpose-built mobile machine, which permits the operator to produce a series of precisely spaced mid-size holes. This process requires operators to frequently start and stop the drilling process.

Based on these differences, OSHA is proposing to require separate additional specifications for rock drilling and concrete drilling, with both types of drilling using LEV at the point of operation and water to suppress dust from the dust collector exhaust. The Agency estimates that these control strategies will protect workers from overexposures, as consistent use of dust extraction shrouds or hoods reduces worker exposures at both rock and concrete drilling sites. The control strategies for rock drilling and concrete drilling are discussed below.

OHSA recognizes that enclosed cabs are available for concrete and rock drilling rigs, and operators who work in enclosed cabs will experience exposure reductions (ERG–C, 2008). OSHA is proposing that respirators will not be required for these operators, regardless of length of shift. Although cabs benefit operators while in the cab, they do not affect workers' exposure during positioning or hole-tending activities. To effectively control exposures of all

workers involved in the operation, employers must apply the engineering controls outlined in Table 1 to manage exposure sources.

In order for the cabs to work optimally, OSHA is proposing that cabs have the following characteristics: (1) Air conditioning and positive pressure is maintained at all times, (2) incoming air is filtered through a pre-filter and a HEPA filter, (3) the cab interior is maintained as free as practicable from settled dust, and (4) door seals and closing mechanisms are working properly. Cecala et al. (2005) studied modifications designed to lower respirable dust levels in an enclosed cab on a 20-year-old surface drill at a silica sand operation. The study found that effective filtration and cab integrity (*e.g.,* new gaskets, sealed cracks to maintain a positive-pressure environment) are the two key components necessary for dust control in an enclosed cab. OSHA believes that the cab specifications outlined will promote proper air filtration and cab integrity. *Rock drilling.* The control strategy for this operation specifies the use of a dust collection system around the drill bits as well as a water spray to wet the exhaust, operated and maintained to minimize dust emissions. Respiratory protection will not be required unless work is being performed under the shroud at the point of operation.

Modern shroud designs, which are commercially available, have been shown to consistently achieve respirable dust reductions (Reed et al., 2008; Drilling Rig Manufacturer A, 2009). Moreover, NIOSH has quantified reductions in dust emissions associated with LEV used with a dowel drilling machine. For these concrete drilling rigs, NIOSH found that close-capture dust collection hoods reduced respirable dust concentrations by 89 percent compared with drilling without the hoods. OSHA believes that similar reductions are achievable on rock drilling machines equipped with dust collection systems, as the quantity of airborne dust generated is comparable for both types of drilling.

Additionally, OSHA believes it is important for employers to use dust collectors in accordance with manufacturer specifications. NIOSH has shown that dust collector efficiency is improved when workers use an appropriate suction rate, maintain the shroud in good condition, and keep the shroud positioned to fully enclose the bit as it enters the hole. The Agency is also proposing to include a visible dust specification, which employers can use as a tool to identify potential problems with controls.

Due to the nature of rock drilling, workers often have to work under the shroud to clear tailings and dust from in or around the hole. When this work is performed, workers do not receive the same amount of protection from the control system, and they have to work closer to the point of dust generation. As such, OSHA believes that workers will experience higher exposures. In order to ensure that workers are adequately protected, OSHA is proposing that employers ensure that workers use half-mask respirators when working under shrouds at the point of operation. The Agency is seeking comments and additional information that address the appropriateness of this specification.

The Agency is also proposing to require employers to use a water delivery system to suppress dust emanating from the dust collector exhaust. Research shows that in the vicinity of a rock-drilling rig, dust collector dumping operations are the largest single contributor of airborne respirable particulates. Maksimovic and Page has shown that in rock-drilling rigs, this source contributed 38 percent of the respirable dust emissions, while the deck shroud contributed 24 percent (reported in Reed et al., 2008). NIOSH reports that modifications (involving water delivery systems) to dust collector discharge areas have reduced exposures from this source by 63 to 89 percent, which means that overall airborne particles can be reduced by at least 24 percent.

For example, a result of 54 $\mu g/m^3$ was obtained for a worker who operated a rig equipped with a vacuum dust collection system. This overexposure resulted from the lack of dust suppression while dust was being dumped from the second filter of the collector—not from the actual drilling operation. Information from the inspection shows that the collector had two filters, and water was used to suppress dust from dumping operations from the first filter only (OSHA SEP Inspection Report 300340908). OSHA believes that adding a water delivery system to suppress dust from the discharge at the second filter would have resulted in a lower exposure. This result indicates that the control strategy outlined, when applied effectively, will adequately protect workers during a full work shift without requiring respirators.

Concrete drilling. The control strategy for this operation specifies the use of a dust collection system around the drill bits as well as a low-flow water spray to wet the exhaust, operated and maintained to minimize dust emissions.

NIOSH has recommended several modifications to typical concrete drilling rig dust collection equipment (NIOSH EPHB 334–11a, 2008). OSHA anticipates that these upgrades will help ensure that optimal dust collection efficiency is maintained over time. As such, the Agency is proposing to require these additional specifications:

- Using smooth ducts and maintaining a duct transport velocity of 4,000 feet per minute to prevent duct clogging
- Providing duct clean-out points to aid in duct maintenance and prevent clogging, and
- Installing pressure gauges across dust collection filters so the operator can clean or change the filter at an appropriate time

Furthermore, Minnich 2009 demonstrated that a dust plume originated from the point of operation after a worker activated a drill and LEV system simultaneously. OSHA believes that the overall collection efficiency would be improved by activating the exhaust suction prior to initiating drilling and deactivating it after the drill bit stops rotating, and is proposing to require that employers operate their LEV systems in this manner.

Similar to rock drilling, OSHA believes it is important for employers to use dust collectors in accordance with manufacturer specifications based on the NIOSH findings described in the rock drilling section. The Agency is also proposing to include a visible dust specification for concrete drilling, as it will help employers identify potential problems with controls.

While the available data do not specifically characterize the effects of controls for concrete drilling rigs in all circumstances, the Agency has substantial data on the effectiveness of controls in rock drilling, and based on the similarities of these operations (refer to PEA, Chapter 4). OSHA estimates that these controls provide similar protection in concrete drilling and are able to reduce and maintain exposures to the proposed PEL most of the time. Implementing the additional specifications listed in Table 1 will also provide protection. However, OSHA cannot rule out the possibility that silica exposures will occasionally exceed the PEL, when workers perform this operation outside of an enclosed cab for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who perform concrete drilling outside of

an enclosed cab for more than four hours.

OSHA seeks additional data to describe the efficacy of the controls described above in reducing exposures for workers who operate concrete drilling rigs. Additionally, the Agency is requesting comments and additional information regarding the adequacy of the control strategy described in Table 1.

Use of drivable milling machines. Table 1 proposes that employers use water-fed systems that deliver water continuously at the cut point to suppress dust, operated and maintained to minimize dust emissions. The table also includes a visible dust provision, which helps employers identify potential problems with the control strategy. The Agency is proposing that no respiratory protection will be required for shifts lasting four hours or less, and that half-mask respirators be used for operations lasting more than four hours.

Some machines are equipped with water delivery systems that are specifically designed to suppress dust. However, water is more generally applied to the cutting drum of milling machines to prevent mechanical overheating. OSHA believes that improved water delivery systems will help reduce exposures for the worker population that remains overexposed. For example, a study conducted in the Netherlands with a novel dust emission suppression system shows the potential impact of a water-delivery system (combined with an additive) as a control strategy. Compared with a standard milling machine that uses cooling water only on the blade, the use of an aerosolized water and foam dust suppression system reduced the mean exposure for drivers and tenders by about 95 and 98 percent, respectively (Van Rooij and Klaasse, 2007). The same study also reported results for the use of aerosolized water without the additive. Aerosolized water alone provided a substantial benefit, reducing the mean exposure for drivers and tenders by about 88 and 84 percent, respectively.

Based on the exposure profile, OSHA anticipates that the vast majority of workers already experience exposure levels below the proposed PEL for operations lasting four hours or less. With water delivery systems designed specifically to suppress dust, the Agency expects that workers will be consistently protected against respirable crystalline silica exposures. With this control strategy in place, OSHA believes that respirators will not be necessary for operations lasting four hours or less.

OSHA believes that, even when workers operate drivable milling machines for eight hours, water delivery systems will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, OSHA cannot rule out the possibility that silica exposures will occasionally exceed the PEL under certain circumstances, when workers operate these machines for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who operate drivable milling machines for more than four hours.

Based on the range of exposures in the exposure profile (*see* Chapter 4 of the PEA), OSHA anticipates that properly designed water delivery systems to suppress dust and half-mask respirators will provide sufficient protection (the highest exposure measured for any worker is 340 μg/m^3, with no dust suppression controls in place). As such, the Agency believes that using wet methods and half-mask respirators is a control strategy that consistently protects workers for operations lasting more than four hours.

Walking behind milling machines. For walk-behind milling machines, Table 1 provides workers with two options for controlling exposures to crystalline silica.

The first option directs employers to use water-fed equipment that continuously feeds water to the cutting surface to suppress dust, operated and maintained to minimize dust emissions.

The exposure profile for this operation contains six samples, with the highest exposure being the only one above the proposed PEL. The two lowest exposures in the profile (both are 12 μg/m^3) were obtained for workers that used water-fed machines (ERG–C, 2008), indicating that the wet method effectively controls silica exposure.

If the highest exposure in the profile is weighted for four hours, the adjusted exposure is less than the proposed PEL. Thus, OSHA anticipates that for operations lasting four hours or less, workers will be consistently protected by wet methods.

OSHA believes that, even when workers operate walk-behind milling machines for eight hours, water delivery systems will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, when workers operate these machines for more than four hours, silica exposures may occasionally exceed the PEL under certain circumstances. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide respiratory protection to workers who operate walk-behind milling machines for more than four hours. The Agency believes the use of a half-mask respirator will ensure consistent worker protection.

The second option is to use tools equipped with commercially available shrouds and dust collection systems, which are operated and maintained to minimize dust emissions. The dust collector must be equipped with a HEPA filter and must operate at an adequate airflow to minimize airborne visible dust. Additionally, the dust collector must be used in accordance with manufacturer specifications including the airflow rate.

To date OSHA has not been able to quantify the effectiveness of currently available LEV in controlling respirable quartz levels associated with walk-behind milling operations; however, OSHA believes that evidence from similar construction tasks supports its value for workers performing milling. OSHA believes that the LEV dust control option will work at least as effectively for milling machines as for tuckpointing grinders. Although the tuckpointers using LEV still experienced a geometric mean result of 60 μg/m^3, walk-behind milling machine operators have the advantages of lower uncontrolled exposure levels, greater distance between the tool and their breathing zone, and equipment that is self-supporting (the milling drum enclosure more easily kept sealed against the floor), rather than hand-held. Therefore, an LEV system with an appropriately sized vacuum will similarly reduce most walk-behind milling machine operator exposures.

Based on the exposure samples analyzed, OSHA estimates that most workers already have exposures under the proposed PEL for operations lasting four hours or less, and is not proposing to require respirator use.

For operations lasting more than four hours, the Agency believes that at most the workers will be protected by using LEV alone, as described Chapter 4 of the PEA. However, the Agency cannot rule out the possibility that workers who operate these machines for more than four hours will occasionally receive exposures that exceed the PEL, under certain circumstances. Because, in the

absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who operate drivable milling machines for more than four hours.

Use of hand-held masonry saws. Table 1 provides employers with two different control strategies. Along with the engineering controls listed in Table 1, OSHA is proposing the additional specifications that will aid employers in using the engineering controls optimally.

- Prevent wet slurry from accumulating and drying. The accumulation and drying of wet slurry can lead to settled dust that is easily resuspended and can contribute to worker exposures.
- Ensure that the equipment is operated such that no visible dust is emitted from the process. When controls are functioning properly, visible dust should not be observed. This specification will help employers identify potential problems with the control strategy.
- When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. Proper airflow prevents air from becoming stagnant and dilutes the levels of respirable crystalline silica.
- Use dust collectors in accordance with manufacturer specifications. Selecting the correct system and flow rates will consistently reduce exposure.

Option 1: Employers use a water-fed system that delivers water continuously at the cut point, operated and maintained to minimize dust emissions.

The exposure profile for outdoor cutting with wet methods shows that for shift lasting four hours or less, workers consistently experience exposure below the proposed PEL. The Agency believes that wet methods alone will provide protection and is proposing to require that employers apply the wet method control without the use of respiratory protection.

OSHA believes that, even when workers operate hand-held masonry saws outdoors for eight hours, wet methods will reduce TWA exposures to or below the proposed PEL most of time, as described in Chapter 4 of the PEA. However, on the basis of the two highest sample results in the exposure profile (*see* Chapter 4 of the PEA), the Agency believes that silica exposures may occasionally exceed the PEL under certain circumstances, when workers perform these operations outdoors for more than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who operate hand-held masonry saws outdoors for more than four hours.

Similarly, the highest readings in the exposure profile for operations using wet methods indoors suggest that silica exposures may sometimes exceed the PEL even for workers who perform these activities for less than four hours. Therefore, the Agency is proposing to require the use of a half-mask respirator with an APF of 10 for workers who operate hand-held masonry saws indoors or within a partially sheltered area, regardless of task duration.

Option 2: Use a saw equipped with a local exhaust dust collection system, operated and maintained to minimize dust emissions.

While the exposure profile does not contain any samples for work involving hand-held masonry saws conducted with LEV in place, several studies have shown the general effectiveness of LEV to reduce silica concentrations. Meeker et al. (2009) shows that LEV can reduce respirable silica exposures to levels near 100 μg/m^3 during short-term periods of active cutting outdoors. Since most workers cut intermittently even during times of active cutting (*e.g.,* 10 or 20 seconds using the saw followed by a longer period—up to several minutes—of measuring and moving materials or equipment), 8-hour TWA values are likely to be considerably lower (Flanagan et al., 2001). However, OSHA has not been able to confirm that LEV methods offer the same degree of exposure reduction to workers currently experiencing more modest, but still elevated, exposures.

Thus, the Agency cannot rule out the possibility that silica exposures will sometimes exceed the PEL, even when workers perform these operations for less than four hours. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide half-mask respirators to workers who use LEV to control exposures while operating hand-held masonry saws outdoors.

While OSHA does not have exposure data to specifically describe indoor operations using LEV controls, Thorpe et al. (1999) and Meeker et al. (2009) reported exposure reductions by 88 to 93 percent for outdoor operation. OSHA believes that these exposure reductions would be similar in indoor operations because there is no added general ventilation in these environments such as natural air circulation outdoors and airborne dust tends to become more stagnant indoors. Given the very high uncontrolled exposures documented in the Chapter 4 of the PEA, even the projected exposure reduction from LEV does not rule out the possibility that exposures above 500 μg/m^3 will occasionally occur under certain circumstances. Because, in the absence of an exposure assessment, employers will not be able to confirm that exposures are below the PEL, or identify circumstances in which exposures may exceed the PEL, the proposed rule requires that employers provide full face-piece respirators to workers who operate hand-held masonry saws indoors or in partially enclosed areas, regardless of task duration.

Use of portable walk-behind or drivable masonry saws. Table 1 directs employers to use a water-fed system that delivers water continuously at the cut point, operated and maintained to minimize dust emissions with the following specifications:

- Prevent wet slurry from accumulating and drying. The accumulation and drying of wet slurry can lead to settled dust that is easily resuspended and can contribute to worker exposures.
- Ensure that the equipment is operated such that no visible dust is emitted from the process. When controls are functioning properly, visible dust should not be observed. This specification will help employers identify potential problems with the control strategy.
- When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. Proper airflow prevents air from becoming stagnant and dilutes the levels of respirable crystalline silica.

The exposure profile for this operation shows that of the 12 respirable silica results associated with wet-cutting concrete outdoors using walk-behind saws, only 1 measurement exceeded the proposed PEL, while 8 were less than the LOD. These results suggest that for outdoor operations, water-fed walk-behind saws provide adequate protection for workers.

Based on this information, OSHA believes that by using the wet method controls as specified, workers will be provided with consistent, adequate protection and is proposing to not require the use of a respirator when working outdoors.

Flanagan et al. (2001) reported higher 8-hour TWA respirable silica levels for operators and their assistants who used water-fed walk-behind saws indoors for most of their shift (the worst-case conditions resulted in four 8-hour TWA values between 130 μg/m³ and 710 μg/m³). The author noted that factors such as inadequate ventilation or poor wet vacuum capture efficiency contributed to the higher indoor respirable silica levels.

By applying the additional specifications and engineering controls outlined in Table 1, OSHA believes that indoor exposures will be reduced to levels where respiratory protection with an APF of 10 will provide adequate protection. OSHA is proposing to require the use of a half-mask respirator for tasks of all duration when working indoors or in partially shielded areas.

Rock crushing. Table 1 provides employers with two control strategies to protect employees not working in enclosed cabs. Both options (described below) require the use of half-mask respirators regardless of task duration.

For equipment operators working within an enclosed cab, OSHA is proposing that cabs have the following characteristics: (1) air conditioning and positive pressure is maintained at all times, (2) incoming air is filtered through a pre-filter and a HEPA filter, (3) the cab is maintained as free as practicable from settled dust, and (4) door seals and closing mechanisms are working properly. Cecala et al. (2005) studied modifications designed to lower respirable dust levels in an enclosed cab on a 20-year-old surface drill at a silica sand operation. The study found that effective filtration and cab integrity (*e.g.,* new gaskets, sealed cracks to maintain a positive-pressure environment) are the two key components necessary for dust control in an enclosed cab. OSHA believes that the cab specifications outlined will promote proper air filtration and cab integrity. OSHA is proposing that operators who work in enclosed cabs meeting these specifications will not be required to wear respirators.

OSHA is also proposing an additional specification, which requires that dust control equipment be operated such that no visible dust is emitted from the process. When controls are functioning properly visible dust should not be observed, and this specification will help employers identify potential problems with the control strategy.

Option 1: Use wet methods or dust suppressants.

Based on available information, OSHA believes that water or other dust suppression is used during rock crushing activities but that the application may be either inconsistent or inefficient (ERG–C, 2008). However, the Agency has obtained other information that shows that dust suppression systems have been effective in reducing exposures. For example, a silica result of 54 μg/m³ was obtained for the operator of a stationary crusher at a concrete recycling facility using fine mist water spray (ERG-concr-crush-A, 2001). It is important to note that this machine operator spent much of the shift in a poorly sealed booth directly over the crusher, but left the booth frequently to tend to other activities. Due to the lack of information regarding the workshift, OSHA cannot asses the full extent of the impact that water dust control had on the worker exposure.

Gottesfeld et al. (2008) summarized a study conducted in India at several rock crushing facilities. The study demonstrates that after water spray installation, 70 percent of the breathing zone and area results were less than 50 μg/m³, and just one result exceeded 250 μg/m³. In contrast, before the water mist system was added, all results exceeded 50 μg/m³, and 60 percent were greater than 250 μg/m³, a condition similar to those in OSHA's exposure profile for workers associated with rock crushing machines. OSHA acknowledges that worksites may different in the United States, but believes that similar exposure reductions can be achieved with rock crushers in the U.S.

Wet dust suppression options that can offer a substantial benefit include water expanded into foam, steam, compressed water fog, and wetting agents (surfactants added to water to reduce surface tension) (ERG–C, 2008). OSHA believes that when used properly and consistently, these dust suppressants could reduce silica concentrations at least as effectively as and more consistently than directional water mist spray alone, achieving exposure reductions of 70- to 90-percent.

OSHA acknowledges that available data is inadequate to indicate whether water mist or other dust suppressants alone are sufficient to reduce these workers' silica exposures below 50 μg/m³. However, based on the best available information, OSHA estimates that by consistently using properly directed water mist spray (or other dust suppression methods), the vast majority of rock crushers can achieve consistent results in a range that is compatible with use of a half-mask respirator with an APF of 10.

Option 2: Use local exhaust ventilation systems at feed hoppers and along conveyor belts, operated and maintained to minimize dust emissions.

Information available to OSHA indicates that LEV is capable of reducing silica concentrations. For example, Ellis Drewitt (1997) reported a reading of 300 μg/m³ for a worker in Australia using a dust extraction system (when compared to the uncontrolled mean of 798 μg/m³ in the exposure profile).

Another international report from Iran describes a site where workers used rock crushers with LEV (Bahrami et al., 2008). The report demonstrated that LEV systems were associated with a marked decrease in respirable dust. Among 20 personal silica samples for process workers and hopper-filling workers associated with rock crushers after LEV was installed, the mean PBZ respirable quartz results were 190 μg/m³ to 400 μg/m³, respectively. It is important to note that the bulk samples of this rock contained 85 to 97 percent quartz. The Agency believes that these levels would likely have been lower if the rock had not been nearly pure silica. If the respirable dust sample had contained the more typical 12 percent silica on the filter, OSHA estimates that the corresponding airborne silica concentrations would have been 92 μg/m³ to 178 μg/m³. The Agency recognizes that exposures may be higher than this estimate, but does not possess additional information that more clearly characterizes worker exposures with the implementation of LEV controls.

As such, OSHA believes that a fully functioning LEV system can control exposures for most workers to within the protection factor offered by a half-mask respirator. OSHA is aware of the difficulties present in applying LEV to rock crushing operations, and is requesting additional information addressing the appropriateness and practicability of this control strategy.

Drywall finishing (with silica-containing material). The main source of exposure for drywall finishing operations occurs when dust is generated while sanding dried, silica-containing joint compound (ERG–C, 2008). Fourteen of the 15 samples collected for the exposure profile for this operation show exposures below the proposed PEL, with 7 samples below the LOD. The one overexposure, 72 μg/m³, was obtained for a worker performing overhead sanding (NIOSH HETA 94–0078–2660, 1997). Table 1 provides employers with two control strategies; neither option requires the use of respirators.

Option 1: Use pole sander or hand sander equipped with a dust collection system, operated and maintained to minimize dust emissions. Use dust

collectors according to manufacturer specifications.

NIOSH tested the effectiveness of five off-the-shelf ventilated sanding systems during drywall finishing: three designed to control dust during pole sanding, and two to control dust during hand sanding. Total dust area sample results revealed that all five systems were effective for reducing total airborne dust by at least 80 percent, ranging up to 97 percent (NIOSH ECTB–208–11a, 1995). This effectiveness was confirmed in a study by Young-Corbett and Nussbaum (2009a), which found that using a ventilated sander during drywall sanding reduced respirable dust in the PBZ by 88 percent compared with a block sander (no controls).

Silica exposures were not measured explicitly in these studies, but OSHA estimates that based on the reported total dust reductions, even the highest exposure in the profile can be reduced to levels below the proposed PEL. The Agency reasonably estimates that this control strategy will adequately protect workers without the need for respirators.

Although ventilated sanders are the most effective exposure control option for silica-containing joint compound, and they offer indirect benefits to workers and managers (NIOSH Appl. Occup. Environ. Hyg. 15, 2000), there are many perceived barriers to their adoption in the workplace (NIOSH ECTB–208–11a, 1995; Young-Corbett and Nussbaum, 2009b). Hence, Option 2 is provided to employers as a way to comply with paragraph (f)(1) of the proposed rule.

Option 2: Use wet methods to smooth or sand the drywall seam.

Young-Corbett and Nussbaum (2009a) found that a wet sponge sander reduces respirable dust in the PBZ by 60 percent compared with a block sander (no controls). Other wet methods include wiping a clean, damp sponge over the still-damp joint compound to smooth the seam and rinsing the sponge in a bucket of water as it becomes loaded with compound, or wetting dried joint compound with a spray bottle and sanding with sandpaper (NIOSH ECTB–208–11a, 1995).

Again, silica exposures were not explicitly measured in the Young-Corbett and Nussbaum study. Based on the reported respirable dust reduction, however, OSHA estimates that even the highest exposure in the profile can be reduced and maintained below the proposed PEL. As such, the Agency believes that using wet methods will offer adequate protection without requiring respirators.

Use of heavy equipment during earthmoving. The exposure profile for this operation ranges from 11 μg/m³ to 170 μg/m³, with about 13 percent of the values exceeding the proposed PEL. Table 1 provides for the option of operating equipment from enclosed cabs to control exposures. It specifies that workers operate equipment from within enclosed cabs that have the following characteristics:

- Air conditioning with positive pressure maintained at all times;
- Incoming air filtered through a pre-filter and a HEPA filter;
- Having the cab be as free as practicable from settled dust; and
- Door seals and closing mechanisms that are working properly.

Based on published research, ERG–C (2008) found that effective enclosed cabs generally have these four characteristics, and extensive literature suggests that the exposure reductions can range from 80 to more than 90 percent in this industry (Rappaport et al., 2003; Pannel and Grogin, 2000; Cecala et al., 2005; NIOSH 528, 2007).

The exposure profile shows that of the 19 results for which the status of the cab was established, 17 were for unenclosed cabs. Both of the operations involving enclosed cabs had exposures of about 12 μg/m³, while operations involving several of the unenclosed cabs were associated with worker exposures greater than 50 μg/m³ and up to 87 μg/m³. This information allows OSHA to determine that operators using enclosed cabs as proposed by this option will effectively protect workers. Respiratory protection will not be needed.

Concerning abrasive blasting operations, paragraph (f)(2) of the general industry/maritime proposed rule and paragraph (f)(3) of the construction proposed rule direct employers to comply with the requirements of 29 CFR 1910.94 (Ventilation), and for shipyard employment 29 CFR 1915.34 (Mechanical Paint Removers) and 29 CFR part 1915, subpart I (Personal protective equipment). These standards apply to abrasive blasting operations that involve crystalline silica-containing blasting agents or substrates. Employers should consult these other standards to ensure that they comply with personal protective equipment, ventilation, and other operation-specific safety requirements.

OSHA is aware of current and past efforts of domestic and international entities to ban silica sand as an abrasive blasting agent. Given the best available information to date, the Agency does not believe that banning silica sand is the most appropriate course of action, as OSHA has concerns about potential harmful exposures to other substances that the alternatives might introduce in a workplace. Further toxicity data are necessary before the Agency can reach any conclusions about the hazards of these substitutes relative to the hazards of silica. The following paragraphs provide further information regarding abrasive blasting agents.

The annual use of silica sand for abrasive blasting operations has decreased from about 1.5 million tons in 1996 to 0.5 million tons in 2007, which roughly represents a 67-percent reduction (Greskevitch and Symlal, 2009)). This reduction might reflect the use of alternative blasting media, the increased use of high-pressure water-jetting techniques, and the use of cleaning techniques that do not require open sand blasting. Several substitutes for silica sand are available for abrasive blasting operations, and current data indicate that the abrasive products with the highest U.S consumptions are: coal slag, copper slag, nickel slag, garnet, staurolite, olivine, steel grit, and crushed glass.

A NIOSH study compared the short-term pulmonary toxicity of several abrasive blasting agents (NIOSH, Blasting Abrasives: Health Hazard Comparison, 2001). This study reported that specular hematite and steel grit presented less short-term in vivo toxicity and respirable dust exposure in comparison to blast sand. Overall, crushed glass, nickel glass, staurolite, garnet, and copper slag were similar to blast sand in both categories. Coal slag and olivine showed more short-term in vivo toxicity than blast sand and were reported as similar to blast sand regarding respirable dust exposure. This study did not examine long-term hazards or non-lung effects.

Hubbs et al. (2005) mention that of the nine alternatives to silica sand, NIOSH has identified five of them–coal slag, steel grit, specular hematite, garnet, and crushed glass–for further testing to determine the relative potential of these agents to induce lung fibrosis in rats exposed to whole-body inhalation. These abrasive materials were selected for study based on high production, number of workers exposed, short-term intratracheal instillation [39] relative toxicity studies, and inadequacy of available current data (Hubbs et al., 2005). The National Toxicology Program is performing long-term (39 weeks), in

[39] Intratracheal instillation is an alternative to inhalation exposure studies. Test material is delivered in a bolus aqueous solution to the lung through a syringe and ball-tipped needle into the tracheal (Phalen, 1984).

vivo, toxicity studies of these abrasive blasting agents.

Additionally, another NIOSH study (KTA-Tator, 1998) monitored exposures to several OSHA-regulated toxic substances that were created by the use of silica sand and substitute abrasive blasting materials. The study showed that several substitutes create exposures or potential exposures to various OSHA-regulated substances. The study showed exposures or potential exposures to: (1) Arsenic, when using steel grit, nickel slag, copper slag and coal slag; (2) beryllium, when using garnet, copper slag, and coal slag; (3) cadmium, when using nickel slag and copper slag; (4) chromium, when using steel grit, nickel slag, and copper slag; and (5) lead, when using copper slag.

Since these studies were performed, the Agency has learned that specular hematite is not being manufactured in the United States due to patent-owner specification. In addition, the elevated cost of steel has a substantial impact on the availability to some employers to use substitutes like steel grit and steel shot.

Elevated silica exposures have been found during the use of low-silica abrasives as well, even when blasting on non-silica substrates. For example, the use of the blasting media Starblast XL (staurolite), which contains less than 1 percent quartz according to its manufacturer, resulted in a respirable quartz level of 1,580 $\mu g/m^3$. The area sample (369-minute) was taken inside a containment structure erected around two steel tanks. The elevated exposure occurred because the high levels of abrasive generated during blasting in containment overwhelmed the ventilation system (NIOSH, 1993b). This example emphasizes the impact of control methods in specific working environments. In order to reduce elevated exposures closer to the PEL in situations like these, employers should examine the full spectrum of available controls, and how these controls perform in specific working conditions. Employers may find, for example, that they would have to provide supplementary respiratory protection to adequately protect workers that perform abrasive blasting in areas where the accumulation of dust remains stagnant (*e.g.* confined spaces) in a worker's personal breathing zone and overwhelms exhaust ventilation systems. Other engineering controls the same employer may consider would be wet and/or automated blasting.

Paragraph (f)(4) of the construction proposed rule, and Paragraph (f)(3) of the general industry/maritime proposed rule specify that accumulations of crystalline silica in the work place are to be cleaned by HEPA-filter vacuums or wet methods. This section also prohibits the use of compressed air, dry sweeping, and dry brushing to clean clothing or surfaces contaminated with crystalline silica. These requirements are being proposed to help regulate the amount of crystalline silica that becomes airborne, thus providing effective control of worker exposure. The requirements of paragraph (f)(4) are consistent with general industry standards for hazardous substances, such as cadmium and asbestos, which specify that work surfaces be cleaned wherever possible by vacuuming with a HEPA-filtered vacuum. Much documentation shows that moving from compressed air blowing and dry sweeping to HEPA-filtered vacuums and the application of wet methods effectively reduces worker exposures during cleaning activities (PEA, Chapter 4).

A study of Finnish construction workers compared the respirable crystalline silica levels during dry sweeping or when using alternative cleaning methods. Compared with dry sweeping, estimated worker exposures were about three times lower when workers used wet sweeping and five times lower when they used vacuums. In the asphalt roofing industry, NIOSH and OSHA both recommended vacuuming with HEPA-filtered vacuums as a method to minimize exposure. In five Health Hazard Evaluations at asphalt roofing manufacturing facilities, NIOSH recommended vacuuming as opposed to compressed air for cleaning dust out of equipment (ERG–GI, 2008).

OSHA's technological feasibility analysis points to numerous other instances where cleaning methods are of particular importance in reducing worker exposures. In the rock and concrete drilling industry, OSHA recommends that workers use HEPA-filtered vacuums instead of compressed air to clean holes in order to reduce–or even eliminate–substantial exposure during hole-tending activities. In the porcelain enameling industry, a facility has used a vacuum fitted with a HEPA filter for all cleaning. To minimize generating airborne dust, workers avoid dry sweeping and only shovel or scrape materials that are damp (Porcelain Industries, 2004a; 2004b).

For millers using portable or mobile equipment, Echt et al. (2002) reported that cleanup is critical for engineering controls to work most effectively for walk-behind milling machines. The study reported that airborne dust increased when a scabbler passed over previously milled areas. It was recommended that debris be cleaned using a HEPA-filtered vacuum prior to making a second pass over an area. This step enhanced LEV capability and prevented debris from being re-suspended.

Several facilities have adopted the recommended cleaning methods as part as an overall effort to reduce exposures. For example, in the jewelry and dental laboratories industries, additional controls to reduce exposures below the proposed PEL include LEV, wet methods, substitution, isolation, work practices, and improved housekeeping such as the use of a HEPA-filtered vacuum for cleaning operations. These examples again also show the value of applying a combination of controls to reduce exposures below the PEL.

Paragraph (f)(5) of the construction proposed rule, and Paragraph (f)(4) of the general industry/maritime proposed rule specify that the employer must not rotate workers to different jobs to achieve compliance with the PEL. OSHA proposes this prohibition because silica is a carcinogen, and the Agency assumes that any level of exposure to a carcinogen places a worker at risk. With worker rotation, the population of exposed workers increases.

This provision is not a general prohibition of worker rotation wherever workers are exposed to crystalline silica. It is only intended to restrict its use as a compliance method for the proposed PEL; worker rotation may be used as deemed appropriate by the employer in activities such as to provide cross-training and to allow workers to alternate physically demanding operations with less arduous ones. This same provision was used for the asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101), hexavalent chromium (29 CR 1910.1026), butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1926.60) OSHA standards.

(g) Respiratory Protection

During situations where employee exposure to respirable crystalline silica is expected to be above the PEL, paragraph (g) requires the employer to protect employees' health through the use of respirators. Specifically, in areas where exposures exceed the PEL, respirators are required during the installation and implementation of engineering and work practice controls; during work operations where engineering and work practice controls are not feasible; when all feasible engineering and work practice controls have been implemented but are not

sufficient to reduce exposure to or below the PEL; and during periods when any employee is in a regulated area or an area for which an access control plan indicates that use of respirators is necessary.

These limitations on the required use of respirators are generally consistent with other OSHA health standards, such as methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). They reflect the Agency's determination, discussed above in section (f) (Methods of compliance), that respirators are inherently less reliable than engineering and work practice controls in reducing employee exposure to respirable crystalline silica. OSHA has therefore proposed to allow reliance on respirators only in certain designated situations.

Proposed paragraph (g)(1)(i) requires the use of respirators in areas where exposures exceed the PEL during periods when engineering and/or work practice controls are being installed or implemented. OSHA recognizes that respirators may be essential to achieve the PEL under these circumstances. During these times, employees would have to use respirators for temporary protection until the hierarchy of controls has been implemented.

OSHA anticipates that engineering controls will be in place by the start-up date specified in paragraph (k)(2)(ii) of the construction and the general industry/maritime proposed standards. The Agency realizes that in some cases employers may commence operations, install new or modified equipment, or make other workplace changes that result in new or additional exposures to crystalline silica after the effective date as defined by paragraph (k)(1). In these cases, a reasonable amount of time may be needed before appropriate engineering controls can be installed and proper work practices implemented. When employee exposures exceed the PEL in these situations, employers must provide their employees with respiratory protection and require its use.

Proposed paragraph (g)(1)(ii) requires respiratory protection in areas where exposures exceed the PEL during work operations in which engineering and work practice controls are not feasible. OSHA anticipates that there will be few situations where no feasible engineering or work practice controls are available to limit employee exposure to respirable crystalline silica. In situations where respirators are used as the sole form of protection to achieve compliance with the PEL, the employer will be required to demonstrate that engineering and work practice controls are not feasible.

Proposed paragraph (g)(1)(iii) requires the use of respirators for supplemental protection in circumstances where feasible engineering and work practice controls alone cannot reduce exposure levels to or below the PEL. Examples include some tuckpointing, jackhammering, and abrasive blasting operations. The employer must always install and implement engineering and work practice controls whenever they are feasible, even if these controls alone cannot reduce employee exposures to or below the PEL. Whenever respirators are used as supplemental protection to achieve compliance with the PEL, the burden is on the employer to demonstrate that engineering and work practice controls alone are insufficient to achieve the PEL.

Under proposed paragraph (g)(1)(iv), employers have to provide respiratory protection during periods when any employee is in a regulated area. Proposed paragraph (e) in the general industry/maritime standard and proposed paragraph (e)(2) in the construction standard would require employers to establish a regulated area wherever an unprotected employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL. OSHA has included the provision requiring respirator use in regulated areas in the proposed rule to make it clear that each employee is required to wear a respirator when present in a regulated area, regardless of the duration of time spent in the area. Because of the potentially serious results of exposure, OSHA believes that this provision is necessary and appropriate because it would have the effect of limiting unnecessary exposures to employees who enter regulated areas, even if they are only in a regulated area for a short period of time.

Proposed paragraph (e)(3) gives the employer the option of developing an access control plan as a means of minimizing exposures to employees not directly involved in operations that generate respirable crystalline silica. This written access control plan would serve as an alternative to setting up regulated areas under paragraph (e)(2). An access control plan must include procedures for providing and requiring the use of respiratory protection in areas where exposures can reasonably be expected to exceed the PEL. Proposed paragraph (g)(1)(v) of the construction standard requires the use of respiratory protection when specified by the access control plan.

Proposed paragraph (g)(2) requires the employer to implement a comprehensive respiratory protection program in accordance with the Agency's respiratory protection standard (29 CFR 1910.134) whenever respirators are used to comply with the requirements of the respirable crystalline silica standard. The respiratory protection program is designed to ensure that respirators are properly used in the workplace and are effective in protecting workers. The program must include: procedures for selecting respirators for use in the workplace; medical evaluation of employees required to use respirators; fit-testing procedures for tight-fitting respirators; procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; procedures and schedules for maintaining respirators; procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of employees in respiratory hazards to which they might be exposed and the proper use of respirators; and procedures for evaluating the effectiveness of the program.

In 2006, OSHA revised the respiratory protection standard (29 CFR 1910.134) to include assigned protection factors (71 FR 50122, Aug. 24, 2006). Assigned protection factor means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a respiratory protection program under 29 CFR 1910.134. The revised standard includes a table (Table 1—Assigned Protection Factors) that employers must use to select sufficiently protective respirators for employees who may be exposed to respirable crystalline silica.

Proposed paragraph (g)(3) for the construction standard indicates that, for the operations listed in Table 1 in paragraph (f) of the construction standard, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with the requirements for selection of respirators in 29 CFR 1910.134 paragraph (d). Paragraph (d) of 29 CFR 1910.134 requires the employer to evaluate respiratory hazards in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. There is no need for the employer to complete this process when following Table 1, because Table 1 specifies the type of respirator required for a particular operation.

(h) Medical Surveillance

In paragraph (h)(1)(i), OSHA proposes to require that each employer covered by this rule make medical surveillance available at no cost, and at a reasonable time and place, for all employees who are occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

There is a general consensus that medical surveillance is necessary for employees exposed to respirable crystalline silica. Medical surveillance for workers exposed to respirable crystalline silica is included in standards developed by ASTM International (ASTM, 2006; 2009) as well as in guidance or recommendations developed by the American College of Occupational and Environmental Medicine (ACOEM, 2006), the Building and Construction Trades Department, AFL–CIO (BCTD, 2001), the Industrial Minerals Association/Mine Safety and Health Administration (IMA/MSHA, 2008), National Industrial Sand Association (NISA, 2010), and the World Health Organization (WHO, 1996). Although the specific recommendations made by these organizations differ in certain respects, they are consistent in indicating that regular medical examinations are appropriate for workers with substantial exposures to respirable crystalline silica.

The purposes of medical surveillance for respirable crystalline silica include the following: to determine, where reasonably possible, if an individual can be exposed to respirable crystalline silica in his or her workplace without experiencing adverse health effects; to identify respirable crystalline silica-related adverse health effects so that appropriate intervention measures can be taken; and to determine the employee's fitness to use personal protective equipment such as respirators. The proposal 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 standards to determine whether the health of workers is adversely affected by exposure to the hazard addressed by the standard. Other OSHA health standards, such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027), also include medical surveillance requirements.

The proposed standard is intended to encourage participation by requiring that medical examinations be made available by the employer without cost to employees (also required by Section 6(b)(7) of the Act), and at a reasonable time and place. If participation requires travel away from the worksite, the employer is required to bear the cost. Employees must be paid for time spent taking medical examinations, including travel time.

OSHA is proposing that medical surveillance be made available to employees exposed to respirable crystalline silica above the PEL for 30 or more days a year. In contrast, the ASTM standards (Section 4.6.1) require medical surveillance for workers with actual or anticipated exposures to respirable crystalline silica at concentrations that exceed the occupational exposure limit for 120 or more days a year (ASTM, 2006; 2009). The OSHA proposal for medical surveillance of employees exposed to respirable crystalline silica above the PEL for 30 or more days per year is more comprehensive than the ASTM recommendation. Both the OSHA proposal and the ASTM standard use exposure above the occupational exposure limit as the trigger for medical surveillance. However, the OSHA proposal is more protective than the ASTM standard because it calls for medical surveillance of workers exposed for a shorter duration of time.

OSHA believes that the proposed cutoffs, based both on exposure level and on the number of days per year that an employee is exposed to respirable crystalline silica, are a reasonable and administratively convenient basis for providing medical surveillance benefits to respirable crystalline silica-exposed workers. With the exception of the asbestos standard (29 CFR 1910.1001), which doesn't specify an action level, medical surveillance in OSHA standards such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027) is triggered by exposure at or above action level. However, OSHA notes that employees exposed at or below the PEL, or exposed above the PEL for only a few days in a year, will be at lower risk of developing respirable crystalline silica-related disease than employees who are exposed above the PEL for 30 or more days per year. Medical surveillance triggered by exposures above the PEL covers employees who face the highest risk of developing disease related to respirable crystalline silica exposure. OSHA estimates that approximately 351,000 employees would be exposed above the proposed PEL for more than 30 days per year, and therefore require medical surveillance under the proposed standard. For comparison, OSHA estimates approximately 1,026,000 employees would be exposed above the proposed action level of 25 ug/μ^3 but at or below the proposed PEL, a difference of 675,000 employees. The total number of medical exams required, which takes into account turnover in the work force, would be similarly affected. For example, in the first year following promulgation, approximately 454,000 exams would be required under the proposed standard. If medical surveillance was triggered at the action level rather than the PEL, over 1,280,000 exams would be required. Under the proposed standard, periodic medical exams would be required on a triennial basis, increasing over time the total number of medical exams. Thus, requiring medical surveillance only for employees exposed above the proposed PEL reduces the burden on employers and focuses resources on the employees at highest risk. OSHA solicits comments on the approporate trigger for medical surveillance in the issues section of the NPRM.

Paragraph (h)(1)(ii) of the proposal requires that the medical examinations made available under the rule be performed by a physician or other licensed health care professional (PLHCP). The term ''PLHCP,'' as discussed further in section (b) (Definitions), above, refers to individuals whose legal scope of practice allows them to provide, or be delegated responsibility to provide, some or all of the health care services required by the medical surveillance provisions. The determination of who qualifies as a PLHCP is thus determined on a state-by-state basis. OSHA considers it appropriate to allow any professional to perform medical examinations and procedures made available under the standard when they are licensed by state law to do so. This provision provides flexibility to the employer, and reduces cost and compliance burdens. The proposed requirement is consistent with the approach of other recent OSHA standards, such as chromium (VI) (29 CFR 1910.1026), methylene chloride (29 CFR 1910.1052), and respiratory protection (29 CFR 1910.134).

The proposed standard also specifies how frequently medical examinations are to be offered to those employees covered by the medical surveillance program. Under paragraph (h)(2), employers are required to make available to covered employees an initial (baseline) examination within 30 days after initial assignment unless the employee has received a medical examination provided in accordance with the standard within the past three years. The proposed requirement that a

medical examination be offered at the time of initial assignment is intended to determine if an individual will be able to work in the job involving respirable crystalline silica exposure without adverse effects. It also serves the useful function of establishing a health baseline for future reference. Where an examination that complies with the requirements of the standard has been provided in the past three years, that previous examination would serve these purposes, and an additional examination would not be needed. For example, some employees may work short-term jobs associated with construction projects and other activities of limited duration. In these circumstances, an employee may work for several different employers over the course of a three-year period. In such cases, each employer who hires the employee within three years of the employee's last medical examination would not have to make available an initial medical examination, but could rely on a written medical opinion from an examination provided in the past three years, if the examination complied with the requirements of the standard.

Proposed paragraphs (h)(2)(i)-(vi) specify that the baseline medical examination provided by the PLHCP must consist of: medical and work history; physical examination with special emphasis on the respiratory system; chest X-ray or equivalent diagnostic study; pulmonary function test; latent tuberculosis test; and other tests deemed appropriate by the PLHCP. Special emphasis is placed on the portions of the medical and work history focusing on exposure to respirable-crystalline silica or other agents affecting the respiratory system, history of respiratory system dysfunction (including signs and symptoms such as shortness of breath, coughing, and wheezing), history of tuberculosis, and smoking.

Medical and work histories are required because they are an efficient and inexpensive means for collecting information that can aid in identifying individuals who are at risk because of hazardous exposures (ACOEM, 2006; WHO, 1996). Information on present and past work exposures, medical illnesses, and symptoms can lead to the detection of diseases at early stages when preventive measures can be taken. Recording of symptoms is important because, in some cases, symptoms indicating onset of disease can occur in the absence of abnormal laboratory test findings.

The physical exam focuses on the respiratory system, which is known to be susceptible to respirable crystalline silica toxicity. Aspects of the physical exam, such as visual inspection, palpation, tapping, and listening with a stethoscope, would allow the PLHCP to detect abnormalities in chest shape or lung sounds that are associated with compromised lung function (WHO, 1996; IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006). The ASTM standards do not specifically address a physical exam as part of medical surveillance, but physical exams are included in other recommendations (IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006; BCTD, 2001). OSHA's proposal for a physical exam provides for a more comprehensive medical evaluation than that required by the ASTM standards.

OSHA proposes that an X-ray or an equivalent diagnostic study be made available at the first medical examination. An initial chest X-ray, although not useful for preventing silicosis, can be useful for diagnosing silicosis, for detecting mycobacterial disease, and for detecting large opacities associated with cancer (IMA/MSHA 2008). It also provides baseline data upon which to assess any subsequent changes. X-rays are the standard medical test to diagnose respirable crystalline silica-related lung diseases. However, the proposal allows for an equivalent diagnostic study in place of the chest X-ray. This is intended to allow for use of technologically advanced imaging techniques in place of conventional X-rays.

An example of a diagnostic study that is equivalent to an X-ray is a digital chest radiograph. Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Digital imaging systems offer a number of advantages over conventional film-based X-rays, including more consistent image quality, faster results, increased ability to share images with multiple readers, simplified storage of images, and reduced risk for technicians and the environment due to the elimination of chemicals for developing film (Attfield and Weissman, 2009).

The proposed standard calls for an X-ray size of no less than 14 x 17 inches and no more than 16 x17 inches at full inspiration, which is consistent with the X-ray film size required in NIOSH specifications for medical examination of underground coal miners (42 CFR part 37). The proposed standard also specifies interpretation and classification of X-rays according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader. The ILO recently made standard digital radiographic images available and has published guidelines on the interpretation and classification of digital radiographic images (ILO 2011). Therefore, digital radiographic images can now be evaluated according to the same ILO guidelines as X-ray films and are considered equivalent diagnostic tests. The ILO guidelines require that digital images be displayed on a medical-grade flat-panel monitor designed for diagnostic radiology. ILO specifications for those monitors include a minimal diagonal display of 21 inches per image, a maximum to minimum luminance ratio of at least 50, a maximum luminance of no less than 250 candelas per square meter, a pixel pitch not to exceed 210 μm, and a resolution no less than 2.5 line-pairs per millimeter. NIOSH (2011) has published guidelines for conducting digital radiography and displaying digital radiographic images in a manner that will allow for classification according to ILO guidelines. Hard copies printed from digital images are not recommended for classification because they give the appearance of more opacities compared to films or digital images (Franzblau et al., 2009).

The ILO system was designed to assess X-ray and digital radiographic image quality and to describe radiographic findings of pneumoconiosis in a simple and reproducible way (NISA, 2010; WHO, 1996; IMA/MSHA, 2008). The procedure involves scoring opacities according to shape, size, location, and profusion. Opacities are first classified as either small or large, with small opacities representing simple silicosis and large opacities representing complicated silicosis. The best indicator of silicosis severity is profusion, which is the B reader's assessment of the amount of small opacities seen in the lung fields (NISA, 2010; IMA/MSHA, 2008). Using a standard set of ILO X-ray films or digital radiographic images, the B reader compares the workers' X-rays or digital radiographic images with the ILO films or digital radiographic images and rates the profusion of small opacities. The numbers 0, 1, 2, or 3 are used to indicate increasing amounts of small opacities. A 12-point profusion scale is employed, in which the B reader gives a first choice and then a second choice profusion rating.

A NIOSH-certified B reader is a physician who has demonstrated competency in the ILO classification system by passing proficiency and periodic recertification examinations (NIOSH, 2011a). The NIOSH certification procedures were designed to improve the proficiency of X-ray and

digital radiographic image readers and minimize variability of readings. Standardized procedures for the evaluation of X-ray films and digital images by certified, qualified individuals is warranted by the prevalence and seriousness of silicosis. As of February 12, 2013, there were 242 certified B readers in the United States.

Other radiological test methods that may be useful are computed tomography (CT) or high resolution computed tomography (HRCT) scans. Two older studies reported that CT or HRCT scans were not more sensitive than X-rays for detecting silicosis but were more sensitive than X-rays at distinguishing between early and advanced stages of silicosis (Bégin *et al.,* 1987a; Talini *et al.,* 1995). More recent studies and reviews reported that CT or HRCT may be superior to chest X-ray in the early detection of silicosis and the identification of progressive massive fibrosis (PMF) (Sun *et al.,* 2008; Lopes *et al.,* 2008; Blum *et al.,* 2008). However, the value of CT or HRCT scans should be balanced with risks and disadvantages of those methods, which include higher radiation doses (WHO, 1996).

CT or HRCT scans could be considered ''equivalent diagnostic studies'' under paragraph (h)(2)(iii) of the proposed standard. However, standardized methods for interpreting and reporting the results of CT or HRCT scans are not currently available. The Agency seeks comment on whether CT and HRCT scans should be considered ''equivalent diagnostic studies'' under the standard, and has included this topic in the ''Issues'' section of this preamble.

Paragraph (h)(2)(iv) of the proposed OSHA standard calls for spirometry testing (forced vital capacity [FVC], forced expiratory volume at one second [FEV_1], and FEV_1/FVC ratio) by a spirometry technician with current certification from a NIOSH-approved spirometry course as part of the baseline medical examination. Pulmonary function tests, such as spirometry, are optional under the ASTM standards (ASTM, 2006; 2009). ASTM (2006, 2009) and others point to a lack of evidence that routine spirometry testing is useful for detecting early stages of respirable crystalline silica-related disease. They indicate that most abnormalities detected by spirometry screening are not related to respirable crystalline silica-related diseases but rather to factors such as smoking and non-occupationally related diseases. There are also a number of obstacles to widespread use of spirometry including inadequate training of medical personnel, technical problems with some spirometers, and lack of standardization for testing methodologies and procedures (ACOEM, 2011; IMA/MSHA, 2008; ATS/ERS, 2005; NISA, 2010). However, ACOEM, (2011), IMA/MSHA (2008), American Thoracic Society/European Respiratory Society (ATS/ERS, 2005), and NISA (2010) go on to note that properly conducted spirometry is considered a useful part of respiratory medical surveillance programs.

Because quality lung function tests are useful for obtaining information about the employee's lung capacity and respiratory flow rate, OSHA proposes to require spirometry as part of the baseline medical examination. Information provided by spirometry is useful for determining baseline lung function status upon which to assess any subsequent lung function changes and for evaluating any loss of lung function. This information may also be useful in assessing the health of employees who wear respirators. The proposed requirement is consistent with the approach of other OSHA standards, such as those for asbestos (29 CFR 1910.1001) and cadmium (29 CFR 1910.1027).

Because it is imperative that spirometry be conducted according to strict standards for quality control and for results to be consistently interpreted, OSHA proposes that spirometry be administered by a spirometry technician with current certification from a NIOSH-approved spirometry course. The NIOSH-approved spirometry training is based upon procedures and interpretation standards developed by the ATS/ERS and European Respiratory Society and addresses topics such as instrument calibration, testing performance, data quality, and interpretation of results (NIOSH, 2011b). Requiring spirometry technicians to have current certification from a NIOSH-approved spirometry course will improve their proficiency in generating quality results that are consistently interpreted. Similar recommendations are included in the ASTM standards (Section 4.6.5.4) (ASTM 2006; 2009).

In paragraph (h)(2)(v), OSHA proposes testing for latent tuberculosis infection at the baseline medical examination. In contrast, the ASTM standards (Section 4.6.5.3) recommend tuberculosis testing only when an X-ray shows evidence of silicosis (ASTM, 2006; 2009). NISA (2010) recommends baseline tuberculosis testing and periodic testing in workers who have chest X-ray readings of 1/0 or higher or more than 25 years of exposure to respirable crystalline silica. OSHA believes that a general requirement for testing during the initial medical examination will serve to protect workers exposed to respirable crystalline silica by identifying latent tuberculosis infection so it can be treated before active (infectious) tuberculosis develops.

In 2008, there were almost 13,000 new cases of active tuberculosis in the U.S. Although incidence of tuberculosis continues to decrease in the U.S., the ultimate goal of tuberculosis control and prevention in the U.S. is the elimination of tuberculosis (CDC, 2009). Active tuberculosis cases are prevented by identifying and treating those with latent tuberculosis disease.

As described in OSHA's Health Effects analysis and summarized in Section V of this preamble, the risk of developing active tuberculosis infection is higher in individuals with silicosis than those without silicosis (Balmes, 1990; Cowie, 1994; Hnizdo and Murray, 1998; Kleinschmidt and Churchyard, 1997; Murray et al., 1996). Moreover, there is evidence that exposure to silica increases the risk for pulmonary tuberculosis, independent of the presence of silicosis (Cowie, 1994; Hnizdo and Murray, 1998; teWaterNaude et al., 2006). OSHA therefore preliminarily concludes that it is in the best interest of both the employer and the affected worker to identify latent tuberculosis prior to silica exposure. The increased risk of developing active pulmonary tuberculosis places not only the worker, but also his or her co-workers and family members at increased risk of acquiring this potentially fatal infectious disease. Early treatment of latent disease would eliminate this risk. Testing for latent tuberculosis infection will identify cases of this disease and alert affected workers, so that the necessary treatment can be obtained from their local public health department or other health care provider. OSHA's proposed requirement is consistent with the recommendations of ACOEM (2006), which recommends tuberculosis screening for all silica-exposed workers. The Centers for Disease Control and Prevention recommends that tuberculosis testing target populations who are at the highest risk of developing the disease, including those with silicosis (CDC, 2000). The Agency seeks comment on its preliminary determination that all workers receiving an initial medical exam should receive testing for latent tuberculosis infection, and has included this topic in the ''Issues'' section of this preamble.

Paragraph (h)(2)(vi) of the proposal gives the examining PLHCP the flexibility to determine additional tests deemed to be appropriate. While the tests conducted under this section are for screening purposes, diagnostic tests may be necessary to address a specific medical complaint or finding (IMA/MSHA, 2008). For example, the PLHCP may decide that additional tests are needed to address abnormal findings in a pulmonary function test. OSHA believes that the PLHCP is in the best position to decide if any additional medical tests are necessary for each individual examined. Where additional tests are deemed appropriate by the PLHCP, the proposed standard would require that they be made available.

In paragraph (h)(3)(i), OSHA proposes periodic examinations including medical and work history, physical examination emphasizing the respiratory system, chest X-rays and pulmonary function tests, and other tests deemed to be appropriate by the PLHCP. The examinations would be required every three years under paragraph (h)(3) of this proposal, unless the PLHCP recommends that they be made available more frequently. The specific requirements for the examinations and the value of the examinations for screening workers exposed to respirable crystalline silica were addressed above. The proposed requirement for examinations every three years is consistent with the ASTM standards (Section 4.6.5), which recommend that medical surveillance be conducted no less than every three years (ASTM, 2006; 2009). Other standards recommend periodic evaluations at intervals ranging from two to five years, depending on duration of exposure (IMA/MSHA, 2008; NISA, 2010; ACOEM, 2006; BCTD, 2001).

The main goal of periodic medical surveillance for workers is to detect adverse health effects at an early and potentially reversible stage. Based on the Agency's experience, OSHA believes that surveillance every three years would strike a reasonable balance between the need to diagnose health effects at an early stage and the limited number of cases likely to be identified through surveillance.

The proposed requirement that employers offer a chest X-ray or an equivalent diagnostic test as part of the periodic medical examination conducted every three years is an important aspect of early disease detection. As indicated above, X-rays are appropriate tools for detecting and monitoring the progression of silicosis, possible complications such as mycobacterial disease, and large opacities related to cancer (IMA/MSHA 2008). Detection of simple silicosis by periodic X-ray could allow for implementation of exposure reduction methods that are likely to decrease the risk of disease progression (ACOEM, 2006). X-rays would also allow the detection of treatable conditions, such as mycobacterial infections (ACOEM, 2006).

X-rays conducted every three years as part of the triennial medical examinations are appropriate considering the long latency period of most respirable crystalline silica-related diseases. The proposed three-year frequency for chest X-rays represents a simplified approach that balances a reasonable time frame for detecting disease and administrative convenience. Under paragraph (h)(3)(ii) of the proposed standard, the PLHCP can request X-rays more frequently. The proposed frequency is consistent with the ASTM standards, as well as ACOEM recommendations (ASTM, 2006; 2009; ACOEM, 2006). Other groups recommend X-rays at intervals ranging from every two to five years, depending on exposure duration (IMA/MSHA, 2008; NISA, 2010; WHO, 1996). OSHA is interested in comments on the proposed X-ray frequency and has raised this topic in the ''Issues'' section of this preamble.

Proposed paragraph (h)(3) also requires that spirometry (FVC, FEV_1, and FEV_1/FVC ratio) be offered by a spirometry technician with current certification from a NIOSH-approved spirometry course, as part of the medical examination conducted every three years. As noted above, spirometry is optional in the ASTM standards (ASTM, 2006; 2009). However, OSHA believes that periodic spirometry is a potentially valuable tool for detecting respirable crystalline silica-related disease and monitoring the health of exposed workers.

Periodic spirometry that adheres to strict quality standards is useful for monitoring progressive lung function changes to identify individual workers or groups of workers with abnormal lung function changes. Quality longitudinal spirometry testing that compares workers' lung function to their baseline levels is useful for detecting excessive declines in lung function that could lead to severe impairment over time. For example, recent studies have shown that excessive decline in lung function can be an early warning sign for risk of COPD development (Wang et al., 2009). Identifying workers who are at risk of developing severe decrements in lung function would allow for interventions to prevent further progression of disease. OSHA is proposing a medical examination including a lung function test every three years because exposure to respirable crystalline silica does not usually cause severe declines in lung function over short time periods. The proposed frequency is consistent with ACOEM (2006) and BCTD (2001), which recommend lung function testing every two to three years. WHO (1996) and NISA (2010) recommend annual pulmonary function testing, but WHO (1996) states that if this is not feasible, it can be conducted at the same frequency as chest X-rays (every two to five years). Paragraph (h)(3) of the proposed standard gives the PLHCP the authority to request lung function testing more frequently. The PLHCP might recommend such a test because of age, tenure, exposure level, or abnormal results. The Agency seeks comment on the proposed frequency of pulmonary function testing and has raised this topic in the ''Issues'' section of this preamble.

Paragraph (h)(4) of the proposed standard would require the employer to ensure the examining PLHCP has a copy of the standard, and to provide the following information to the PLHCP: a description of the affected employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer. Making this information available to the PLHCP will aid in the evaluation of the employee's health in relation to assigned duties and fitness to use personal protective equipment, when necessary. The results of exposure monitoring are part of the information that would be supplied to the PLHCP responsible for medical surveillance. These results contribute valuable information to assist the PLHCP in determining if an employee is likely to be at risk of harmful effects from respirable crystalline silica exposure. A well-documented exposure history also assists the PLHCP in determining if a condition (*e.g.,* compromised pulmonary function) may be related to respirable crystalline silica exposure. Where the employer does not have information directly indicating an employee's exposure (*e.g.,* where the employer uses Table 1 in the proposed

construction standard and does not perform exposure monitoring), an indication of the presumed exposure associated with the operation (*i.e.,* at or above the action level, above the PEL) would fulfill this requirement.

Proposed paragraph (h)(5)(i) requires that the employer obtain a written medical opinion from the PLHCP within 30 days of each medical examination. The purpose of this requirement is to provide the employer with a medical basis to aid in the determination of placement of employees and to assess the employee's ability to use protective clothing and equipment. OSHA believes the 30-day period will provide the PLHCP sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The proposed requirement that the opinion be in written form is intended to ensure that employers and employees receive the benefit of this information.

Paragraphs (h)(5)(i)(A)–(D) of the proposal specify what must be included in the PLHCP's opinion. The standard first proposes that the PLHCP's written medical opinion describe the employee's health condition as it relates to exposure to respirable crystalline silica, including any conditions that would put the employee at increased risk of material impairment of health from further exposure to respirable crystalline silica. The standard also proposes that the PLHCP's written medical opinion include recommended limitations for the employee's exposure to respirable crystalline silica or use of personal protective equipment such as respirators. These proposed requirements are consistent with the overall goals of medical surveillance: to determine if an individual can be exposed to respirable crystalline silica present in his or her workplace without experiencing adverse health effects, to identify respirable crystalline silica-related adverse health effects so that appropriate intervention measures can be taken, and to determine the employee's fitness to use personal protective equipment such as respirators.

Paragraph (h)(5)(i)(C) proposes that the PLHCP must include in the written medical opinion a statement that the employee should be examined by a pulmonary specialist if the X-ray is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP. As described above, paragraph (h)(2)(iii) of the proposed standard requires that X-rays be interpreted according to the ILO Classification of Radiographs of Pneumoconioses. The ASTM standards recommend that workers with profusion opacities greater than 1/1 (profusion similar to that shown on a standard category 1 radiograph) be evaluated at a frequency determined by a physician qualified in pulmonary disease (Section 4.7.1) and receive annual counseling by a physician or other person knowledgeable in occupational safety and health (Section 4.7.2) (ASTM, 2006; 2009). The proposed OSHA standard addresses pneumoconiosis at an earlier stage than the ASTM standards, thus allowing for intervention at an earlier indication of possibly abnormal findings.

Paragraph (h)(5)(i)(D) of the proposal would require that the PLHCP include in the written medical opinion a statement that the PLHCP has explained to the employee the medical examination results, including conditions related to respirable crystalline silica exposure that require further evaluation or treatment and any recommendations related to use of protective clothing or equipment. Under this provision, OSHA anticipates that the employee will be informed directly by the PLHCP of all results of his or her medical examination, including conditions of nonoccupational origin. Direct consultation between the PLHCP and employee ensures that the employee will receive all information about health status, including non-occupationally related conditions, that are not communicated to the employer.

Under proposed paragraph (h)(5)(ii), the employer must ensure that the PLHCP does not include findings unrelated to crystalline silica exposure in the written opinion provided to the employer or otherwise reveal such findings to the employer. OSHA has proposed this provision to ensure confidentiality of medical information and to reassure employees participating in medical surveillance that they will not be penalized or embarrassed as a result of the employer obtaining information about them not directly pertinent to occupational exposure to respirable crystalline silica. Paragraph (h)(5)(iii) of the proposed standard requires the employer to provide a copy of the PLHCP's written opinion to the employee within two weeks after the employer receives it, to ensure that the employee has been informed of the results of the examination in a timely manner.

OSHA is aware of concerns that the written medical opinion may divulge confidential information regarding an employee's medical condition, or may otherwise divulge information that may adversely affect an individual's employment status. The Building and Construction Trades Department, AFL–CIO has expressed the view that, except in limited circumstances, any decision to disclose medical information to an employer should be left to the employee (BCTD, 2009). OSHA respects concerns for medical privacy and is aware of how disclosure of medical information could potentially impact workers. The proposed requirements are intended to balance employee privacy with employers' need for information to assess possible health effects or risks related to respirable crystalline silica exposure by employees. OSHA seeks comment on the proposed requirement for the employer to obtain a written medical opinion, and has raised this topic in the ''Issues'' section of this preamble.

Proposed paragraph (h)(6)(i) requires that an examination by a pulmonary specialist be offered when indicated in the PLHCP's written opinion. This requirement is intended to ensure that individuals with abnormal findings are seen by a professional with expertise in respiratory disease who can provide not only expert medical judgment, but also counseling regarding work practices and personal habits that could affect these individuals' respiratory health. In this respect the proposed provision is conceptually consistent with the provision in the ASTM standards (4.7.2) for counseling by a physician or other person qualified in occupational safety and health. Data presented by the American Board of Internal Medicine (ABIM) indicate that as of February 5, 2013, 13,138 physicians in the United States had valid certificates in pulmonary disease (ABIM, 2013). ABIM does not report how many of these physicians are currently practicing. However, ABIM does report that 4,378 new certificates in pulmonary disease were issued in the period from 2001–20010 (ABIM, 2012). Because physicians are likely to practice in the field for some time after receiving their certification, this figure indicates that a substantial number of pulmonary specialists are available to perform examinations required under the proposed standard.

Paragraph (h)(6)(i) further proposes that these additional examinations by pulmonary specialists must be made available within 30 days following receipt of the PLHCP's recommendation that examination by such a specialist is indicated. OSHA proposes, under paragraph (h)(6)(ii), that the employer provide the pulmonary specialist with the same information that is provided to the original PLHCP (*i.e.,* a copy of the

standard; a description of the affected employee's former, current, and anticipated duties as they relate to respirable crystalline silica exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer). The reasons why the pulmonary specialist should receive this information are the same as those for the PLHCP and were addressed above.

Proposed paragraph (h)(6)(iii) requires the employer to obtain a written medical opinion from the pulmonary specialist comparable to the written opinion obtained from the original PLHCP, including a description of the employee's health condition as it relates to respirable crystalline silica exposure, the pulmonary specialist's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to respirable crystalline silica, and any recommended limitations on the employee's exposure to respirable crystalline silica or use of personal protective equipment. The pulmonary specialist would also need to state in the written opinion that these findings were explained to the employee. The reasons why the pulmonary specialist should provide this information to the employer are the same as those for the PLHCP and were addressed above.

Some OSHA health standards contain a provision for medical removal protection (MRP). MRP typically requires that the employer temporarily remove an employee from exposure when such an action is recommended in a written medical opinion. During the time of removal, the employer is required to maintain the total normal earnings, as well as all other employee rights and benefits, of the removed employee. However, MRP is not intended to serve as a workers' compensation system. The primary reason MRP was included in previous standards was to encourage employee participation in medical surveillance. By protecting employees who are removed on a temporary basis from economic loss, this potential disincentive to participating in medical surveillance is alleviated. Previous standards also included MRP requirements to prevent the onset of disease and to detect and minimize the extent of existing disease. For example, OSHA's cadmium standard (29 CFR 1910.1026) provides for MRP based on criteria such as biological monitoring results and evidence of cadmium-related disease. Removal from exposure can allow for biological monitoring results to return to acceptable levels, or for improvement in the employee's health condition.

OSHA has made a preliminary determination that MRP is not reasonably necessary or appropriate for respirable crystalline silica-related health effects. Thus, the proposed rule does not include a provision for MRP. The Agency believes that respirable crystalline silica-related health effects (*e.g.,* silicosis) are generally chronic conditions that are not remedied by temporary removal from exposure. Since situations where temporary removal would be appropriate are not anticipated to occur, OSHA does not believe that MRP is necessary. The Agency seeks comment on this preliminary determination, and has included this topic in the ''Issues'' section of this preamble.

(i) Communication of Respirable Crystalline Silica Hazards to Employees

The proposed standard includes requirements intended to ensure that the dangers of respirable crystalline silica exposure are communicated to employees by means of labels, safety data sheets, and employee information and training. OSHA believes that it is necessary to inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees 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 in safety data sheets. These written forms of communication will be effective and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects.

OSHA has proposed to revise its existing hazard communication standard (HCS) (29 CFR 1910.1200) to conform with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Revision 3. (*See* 74 FR 50280, Sept. 30, 2009.) The hazard communication requirements of the proposed crystalline silica rule are designed to be consistent with the revised HCS, while including additional specific requirements needed to protect employees exposed to respirable crystalline silica. OSHA intends for the requirements of the respirable crystalline silica rule to conform with the final hazard communication standard. The proposed requirements are also consistent with the worker training and education provisions of ASTM International's standards addressing control of occupational exposure to respirable crystalline silica (Section 4.8 in both E 1132–06 and E 2625–09) (ASTM, 2006; 2009).

In the HCS rulemaking, OSHA proposed to revise substance-specific health standards by referencing the HCS requirements for labels, safety data sheets, and training and by identifying the hazards that need to be addressed in the employer's written hazard communication program. Accordingly, proposed paragraph (i)(1) of the silica rule requires compliance with the HCS requirements and lists cancer, lung effects, immune system effects, and kidney effects as hazards that need to be addressed in the employer's hazard communication program. These are the health effects that OSHA has preliminarily determined to be associated with respirable crystalline silica exposure.

Proposed paragraph (i)(2)(i) requires the employer to ensure that each affected employee can demonstrate knowledge of the specified training elements (discussed below). When using the term ''affected employee'' in this context, OSHA is referring to any employee who may be exposed to respirable crystalline silica under normal conditions of use or in a foreseeable emergency. Employee knowledge of the specified training elements could be determined through methods such as discussion of the required training subjects, written tests, or oral quizzes. In order 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.

Proposed paragraphs (i)(2)(i)(A) and (B), which require training on specific operations in the workplace that could result in respirable crystalline silica exposure and specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, closely parallel the HCS. OSHA has included these

elements in the proposed respirable crystalline silica rule to ensure that both employers and employees understand the sources of potential silica exposure and control measures used to reduce exposure. Workers have a particularly important role in controlling silica exposures because work practices often play a crucial role in controlling exposures, and engineering controls frequently require action on the part of workers to function effectively. For example, stationary masonry saws using wet methods to control dust may require adjustment of the nozzle and the water flow rate to ensure that an adequate volume of water reaches the cutting area. Water filters may need to be rinsed or replaced at regular intervals, and basin water may need to be replaced on a regular basis to prevent clogging of the nozzles. Similarly, the effectiveness of local exhaust ventilation systems, another common method used to control exposures to respirable crystalline silica, is often enhanced by the use of proper work practices. When tuckpointing, for instance, workers should ensure that the shroud surrounding the grinding wheel remains flush against the working surface to minimize the amount of dust that escapes from the collection system. Operating the grinder in one direction (counter to the direction of blade rotation) is effective in directing mortar debris into the exhaust system, and backing the blade off before removing it from the slot permits the exhaust system to clear accumulated dust. Workers' implementation of work practices such as these is often necessary to ensure that they are adequately protected, and OSHA has preliminarily concluded that the importance of recognizing potential exposures and understanding appropriate work practices merits including these provisions in the proposed silica rule.

Proposed paragraph (i)(2)(i)(C) requires training on the contents of the respirable crystalline silica rule, and proposed paragraph (i)(2)(ii) requires that the employer make a copy of the standard readily available to employees without cost. OSHA believes that it is important for employees to be familiar with and have access to the proposed respirable crystalline silica standard and the employer's obligations to comply with it.

Proposed paragraph (i)(2)(i)(D) requires employers to provide training to workers on the purpose and description of the medical surveillance program found at paragraph (h) of the proposed silica rule. Such training should cover the signs and symptoms of respirable crystalline silica-related adverse health effects including cancer, lung effects, immune system effects, and kidney effects. This information will help to ensure that employees are able to effectively participate in medical surveillance, which is discussed above in section (h) (Medical surveillance).

OSHA intends for the training requirements under the proposed silica standard, like those in the hazard communication standard, to be performance-oriented. The Agency has therefore written proposed section (i) in terms of objectives, which are meant to ensure that employees are made aware of the hazards associated with respirable crystalline silica in their workplace and how they can help to protect themselves. The proposed standard also lists the subjects, which are in addition to or reiterate those covered by the HCS, that must be addressed in training, but not the specific ways in which the training is to be accomplished. OSHA believes that the employer is in the best position to determine how the training can most effectively be accomplished. Hands-on training, videotapes, slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. 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 in each specific workplace.

In order for the training to be effective, the employer must ensure that it is provided in a manner that the employee is able to understand. OSHA has consistently required that employee training required by OSHA standards be presented in a manner that employees can understand. This position was recently reiterated in a memorandum to OSHA Regional Administrators from Assistant Secretary David Michaels (OSHA, 2010). Employees have varying educational levels, literacy, and language skills, and the training must be presented in a language, or languages, and at a level of understanding that accounts for these differences in order to meet the proposed requirement in paragraph (i)(2) that individuals being trained understand the specified elements. This may mean, for example, providing materials, instruction, or assistance in Spanish rather than English if the workers being trained are Spanish-speaking and do not understand English. The employer is not required to provide training in the employee's preferred language if the employee understands both languages; as long as the employee is able to understand the material in the language used, the intent of the proposed standard would be met.

The frequency of training under the proposed standard is determined by the needs of the workplace. At the time of initial assignment to a position involving exposure to respirable crystalline silica, each employee needs to be trained sufficiently to understand the specified training elements. Additional training may be needed periodically to refresh and reinforce the memories of employees who have previously been trained or to ensure that employees are informed of new developments in the workplace that may result in new or additional exposures to respirable crystalline silica. Additional training might also be necessary after new engineering controls are installed to ensure that employees are able to properly use the new controls and implement work practices relating to those controls. Further, employees might need additional training in the use of new personal protective equipment. Such training would ensure that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

(j) Recordkeeping

Paragraph (j) of the proposed standard requires employers to maintain air monitoring data, objective data, and medical surveillance records. The recordkeeping requirements are proposed 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 accidents and illnesses.

Proposed paragraph (j)(1)(i) requires employers to keep accurate records of all air monitoring results used or relied on to assess employee exposure to respirable crystalline silica. Paragraph (j)(1)(ii) requires that such records include the following information: the date of measurement for each sample taken; the operation monitored; sampling and analytical methods used; the number, duration, and results of samples taken; the identity of the laboratory that performed the analysis; the type of personal protective equipment, such as respirators, worn by the employees monitored; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored. These requirements

are generally consistent with those found in other OSHA standards, such as methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). OSHA has proposed an additional requirement in this rulemaking—recording the identity of the laboratory that performed the analysis of exposure measurements—because of the importance of ensuring that laboratories performing analyses of respirable crystalline silica samples conform with the requirements specified in paragraph (d)(5) of the proposed rule.

Proposed paragraph (j)(2)(i) requires employers who rely on objective data, pursuant to proposed paragraph (d)(2)(ii)(B) or (d)(3)(ii), to keep accurate records of the objective data. Objective data means information, such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance, demonstrating employee exposure to respirable crystalline silica associated with a particular product, material, process, operation, or activity.

Proposed paragraph (j)(2)(ii) requires the record to include: the crystalline silica-containing material in question; the source of the objective data; the testing protocol and results of testing; a description of the process, operation, or activity involved and how the data support the assessment; and other data relevant to the process, operation, activity, material, or employee exposures. Since objective data may be used to exempt the employer from provisions of the proposal or provide a basis for selection of respirators, it is critical that the use of objective data be carefully documented. Reliance on objective data is intended to provide the same degree of assurance that employee exposures have been correctly characterized as air monitoring would. The records should demonstrate a reasonable basis for the conclusions drawn from the objective data.

Proposed paragraph (j)(3)(i) requires the employer to establish and maintain an accurate record for each employee subject to medical surveillance under paragraph (h) of the proposed standard. Paragraph (j)(3)(ii) lists the categories of information that an employer would be required to record: the name and social security number of the employee; a copy of the PLHCP's and pulmonary specialist's written opinions about the employee; and a copy of the information provided to the PLHCPs and pulmonary specialists as required by proposed paragraph (h)(4). The information provided to the PLHCPs and pulmonary specialists includes the employee's duties as they relate to crystalline silica exposure, crystalline silica exposure levels, descriptions of personal protective equipment used by the employee, and information from employment-related medical examinations previously provided to the employee (*see* paragraph (h)(4)).

OSHA believes that medical surveillance records, like exposure records, are necessary and appropriate for protection of employee health, enforcement of the standard, and development of information regarding the causes and prevention of occupational illnesses. Employee access to medical surveillance records helps protect employees because such records contribute to the evaluation of employees' health and enable employees and their health care providers to make informed health care decisions. These records are especially important when an employee's medical conditions place him or her at increased risk of health impairment from further exposure to respirable crystalline silica. Furthermore, the employer could evaluate medical surveillance data for indications that workplace conditions are associated with increased risk of illness and take corrective actions. Finally, the records can be used by the Agency and others to identify illnesses and deaths that may be attributable to respirable crystalline silica exposure, evaluate compliance programs, and assess the efficacy of the standard.

Proposed paragraphs (j)(1)(iii), (j)(2)(iii), and (j)(3)(iii) require employers to maintain and provide access to air monitoring, objective data, and medical surveillance records, respectively, in accordance with OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020). That standard, specifically 29 CFR 1910.1020(d), requires employers to ensure the preservation and retention of exposure and medical records. Air monitoring data and objective data are considered employee exposure records that must be maintained for at least 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii). Medical records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i).

The maintenance and access provisions incorporated from 29 CFR 1910.1020 ensure that records are available to employees so that they may examine the employer's exposure assessments and assure themselves that they are being adequately protected. Moreover, compliance with the requirement to maintain records of exposure data will enable the employer to show, at least for the duration of the retention-of-records period, that the exposure assessment was accurate and conducted in an appropriate manner. The lengthy record retention period is necessitated in this case by the long latency period commonly associated with silica-related diseases. Furthermore, determining causality of disease in employees is assisted by, and in some cases requires, examining present and past exposure data as well as the results of present and past medical examinations.

(k) Dates

Under paragraph (k)(1) of the proposed standard, the final crystalline silica rule becomes effective 60 days after its publication in the **Federal Register**. This period is intended to allow affected employers the opportunity to familiarize themselves with the standard. Under paragraph (k)(2)(i), employer obligations to comply with most requirements of the final rule begin 180 days after the effective date (240 days after publication of the final rule). This additional time period after the effective date is designed to allow employers to complete initial exposure assessments, establish regulated areas or access control plans, provide initial medical examinations, and comply with other provisions of the rule.

Paragraph (k)(2)(ii) allows additional time for employers to implement the engineering controls required under paragraph (f) of the proposed rule. Engineering controls need to be in place within one year after the effective date. This is to allow affected employers sufficient time to design, obtain, and install the necessary control equipment. During the period before engineering controls are implemented, employers must provide respiratory protection to employees under proposed paragraph (g)(1)(i).

Paragraph (k)(2)(iii) specifies that the laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date. OSHA recognizes that the requirements for monitoring in the proposed rule will increase the demand for analysis of respirable crystalline silica samples. A two year start-up period is proposed to allow time for laboratories to achieve compliance with the proposed requirements, particularly with regard to requirements for accreditation and round robin testing.

OSHA solicits comment on the adequacy of these proposed start-up dates. OSHA would like to ensure that engineering controls and medical surveillance are implemented as quickly as possible, while also ensuring that

employers have sufficient time to complete these processes. OSHA is also interested in ensuring that laboratories comply with the requirements of the standard as quickly as possible, while also ensuring that sufficient laboratory capacity is available to meet the needs of employers. In addition, the Agency is interested in mitigating impacts on firms complying with the rule, and seeks comment on approaches that would phase in requirements of the rule based on industry, employer size, or other factors. The Agency has included these topics in the ''Issues'' section of this preamble.

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List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Cancer, Chemicals, Cristobalite, Crystalline silica, Hazardous substances, Health, Occupational safety and health, Quartz, Reporting and recordkeeping requirements, Silica, Tridymite.

XVIII. 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 proposed sections under the following authorities: sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 4–2010 (75 FR 55355, September 10, 2010); and 29 CFR part 1911.

Signed at Washington, DC, on August 23, 2013.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons set forth in the preamble, OSHA proposes to amend chapter XVII of title 29, parts 1910, 1915, and 1926, of the Code of Federal Regulations 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: Secs. 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 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 31159), or 4–2010 (75 FR 55355), as applicable; and 29 CFR part 1911. All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653. Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

■ 2. In § 1910.1000, Table Z–1—Limits for Air Contaminants, remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust''; and add ''Silica, crystalline, respirable dust; see 1910.1053'' in alphabetical order, to read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–1—LIMITS FOR AIR CONTAMINANTS

Substance	CAS No. (c)	ppm [(a)] [1]	mg/m^3 [(b)] [1]	Skin designation
* * *	*	*	*	*
Silica, crystalline, respirable dust; see 1910.1053.				
* * *	*	*	*	*

* * * * *

■ 3. In § 1910.1000, Table Z–3—Mineral Dusts, the entry ''Silica:'' is revised to read as follows:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–3—MINERAL DUSTS

Substance	mppcf [a]	mg/m^3
Silica:		
Amorphous, including natural diatomaceous earth	20	80 mg/m^3
		%SiO_2
* * *	*	*

■ 4. A new § 1910.1053 is added, to read as follows:

§ 1910.1053 Respirable crystalline silica.

(a) *Scope and application.* (1) This section applies to all occupational exposures to respirable crystalline silica, except:

(2) Construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926; and

(3) Agricultural operations covered under 29 CFR part 1928.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 micrograms per cubic meter of air (25 μg/m³), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Competent person means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling 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 him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Respirable crystalline silica means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

This section means this respirable crystalline silica standard, 29 CFR 1910.1053.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m³, calculated as an 8-hour TWA.

(d) *Exposure assessment.* (1) *General.* (i) Each employer covered by this section shall assess the exposure of employees who are or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level.

(ii) The employer shall determine employee exposures from breathing zone air samples that reflect the 8-hour TWA exposure of each employee.

(iii) The employer shall determine 8-hour TWA exposures on the basis of one or more air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same job 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 this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(2) *Initial exposure assessment.* (i) Except as provided for in paragraph (d)(2)(ii) of this section, each employer shall perform initial monitoring of employees who are, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level.

(ii) The employer may rely on existing data to satisfy this initial monitoring requirement where the employer:

(A) Has monitored employee exposures after [INSERT DATE 12 MONTHS PRIOR TO EFFECTIVE DATE OF FINAL RULE] under conditions that closely resemble those currently prevailing, provided that such monitoring satisfies the requirements of paragraph (d)(5)(i) of this section with respect to analytical methods employed; or

(B) Has objective data that demonstrate that respirable crystalline silica is not capable of being released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling.

(3) *Periodic exposure assessments.* If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If initial monitoring indicates that employee exposures are at or above the action level, the employer shall assess employee exposures to respirable crystalline silica either under the fixed schedule prescribed in paragraph (d)(3)(i) of this section or in accordance with the performance-based requirement prescribed in paragraph (d)(3)(ii) of this section.

(i) *Fixed schedule option.* (A) Where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months.

(B) Where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months.

(C) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring for that employee, except as otherwise provided in paragraph (d)(4) of this section.

(ii) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(4) *Additional exposure assessments.* The employer shall conduct additional exposure assessments as required under paragraph (d)(3) of this section whenever a change in the 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.

(5) *Method of sample analysis.* (i) The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7.

(ii) The employer shall ensure that samples are analyzed by a laboratory that:

(A) Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard

17011:2004 for implementation of quality assessment programs;

(B) Participates in round robin testing with at least two other independent laboratories at least every six months;

(C) Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

(D) Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

(E) Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis;

(F) Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

(*1*) Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

(*2*) Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

(*3*) Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

(6) *Employee notification of assessment results.* (i) Within 15 working days after completing an exposure assessment in accordance with paragraph (d) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever the exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(e) *Regulated areas and access control.* (1) *General.* Wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) of this section or an access control plan in accordance with paragraph (e)(3) of this section.

(2) *Regulated areas option.* (i) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(ii) *Demarcation.* The employer shall demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundaries of the area and minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(iii) *Access.* The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(iv) *Provision of respirators.* The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(v) *Protective work clothing in regulated areas.* (A) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer shall provide either of the following:

(*1*) Appropriate protective clothing such as coveralls or similar full-bodied clothing; or

(*2*) Any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica.

(B) The employer shall ensure that such clothing is removed or cleaned upon exiting the regulated area and before respiratory protection is removed.

(3) *Written access control plan option.* (i) The employer shall establish and implement a written access control plan.

(ii) The written access control plan shall contain at least the following elements:

(A) Provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL;

(B) Procedures for notifying employees of the presence and location of areas identified pursuant to paragraph (e)(3)(ii)(A) of this section, and for demarcating such areas from the rest of the workplace where appropriate;

(C) For multi-employer workplaces, the methods the employer covered by this section will use to inform other employer(s) of the presence and location of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures that need to be taken to protect employees;

(D) Provisions for limiting access to areas where respirable crystalline silica exposures may exceed the PEL to effectively minimize the number of employees exposed and the level of employee exposure;

(E) Procedures for providing each employee and their designated representative entering an area where respirable crystalline silica exposures may exceed the PEL with an appropriate respirator in accordance with paragraph (g) of this section, and requiring each employee and their designated representative to use the respirator while in the area; and

(F) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica:

(*1*) Provisions for the employer to provide either appropriate protective clothing such as coveralls or similar full-bodied clothing, or any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica; and

(*2*) Provisions for the removal or cleaning of such clothing.

(iii) The employer shall review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary.

(iv) The employer shall make the written access control plan available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Abrasive blasting.* In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply with the requirements of 29 CFR 1910.94 (Ventilation), 29 CFR 1915.34 (Mechanical paint removers), and 29 CFR part 1915, subpart I (Personal Protective Equipment), as applicable, where abrasive blasting operations are conducted using crystalline silica-containing blasting agents, or where abrasive blasting operations are conducted on substrates that contain crystalline silica.

(3) *Cleaning methods.* (i) The employer shall ensure that accumulations of crystalline silica are cleaned by HEPA-filter vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(ii) Compressed air, dry sweeping, and dry brushing shall not be used to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(4) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during work operations for which engineering and work practice controls are not feasible;

(iii) During work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL; and

(iv) During periods when the employee is in a regulated area pursuant to paragraph (e) of this section.

(v) During periods when the employee is in an area where respirator use is required under an access control plan pursuant to paragraph (e)(3) of this section.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration), interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader, or an equivalent diagnostic study;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume at one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (h)(2) (except paragraph (h)(2)(v)) of this section at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The written opinion shall contain:

(A) A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;

(B) Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators;

(C) A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) of this section if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and

(D) A statement that the PLHCP has explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

(ii) The employer shall ensure that the PLHCP does not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to respirable crystalline silica.

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(6) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a pulmonary specialist, the employer shall make available a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion.

(ii) The employer shall ensure that the examining pulmonary specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (h)(4) of this section.

(iii) The employer shall obtain a written medical opinion from the pulmonary specialist that meets the requirements of paragraph (h)(5) (except paragraph (h)(5)(i)(C)) of this section.

(i) *Communication of respirable crystalline silica hazards to employees.* (1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (i)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) *Employee information and training.* (i) The employer shall ensure that each affected employee can demonstrate knowledge of at least the following:

(A) Specific operations in the workplace that could result in exposure to respirable crystalline silica, especially operations where exposure may exceed the PEL;

(B) Specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, including appropriate work practices and use of personal protective equipment such as respirators and protective clothing;

(C) The contents of this section; and

(D) The purpose and a description of the medical surveillance program required by paragraph (h) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each affected employee.

(j) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all exposure measurement results used or relied on to characterize employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, operation, or activity and how the data support the assessment; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's and pulmonary specialist's written opinions; and

(C) A copy of the information provided to the PLHCPs and pulmonary specialists as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(k) *Dates.* (1) *Effective date.* This section shall become effective November 12, 2013

(2) *Start-up dates.* (i) All obligations of this section, except engineering controls required by paragraph (f) of this section and laboratory requirements in paragraph (d)(5)(ii) of this section, commence 180 days after the effective date.

(ii) Engineering controls required by paragraph (f) of this section shall be implemented no later than one year after the effective date.

(iii) Laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date.

Appendix A to § 1910.1053—Medical Surveillance Guidelines (Non-Mandatory)

Introduction

The purpose of this non-mandatory Appendix is to provide helpful information about complying with the medical surveillance provisions of the Respirable Crystalline Silica standard, as well as to provide other helpful recommendations and information. Medical screening and surveillance allow for early identification of exposure-related health effects in individual workers and groups of workers, respectively, so that actions can be taken to both avoid further exposure and prevent adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences. Thus, medical surveillance of silica-exposed workers requires involvement of clinicians with thorough knowledge of silica-related health effects and a public health perspective.

This Appendix is divided into four sections. Section I reviews silica-related diseases, appropriate medical responses, and public health responses. Section II outlines

the components of the medical surveillance program for workers exposed to silica. Section III describes the roles and responsibilities of the clinician implementing the program and of other medical specialists and public health providers. Section IV provides additional resources.

I. Recognition of Silica-Related Diseases

Overview. Silica refers specifically to the compound silicon dioxide (SiO_2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with a number of adverse health effects. Exposure to respirable crystalline silica can occur in foundries, industries that have abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing.

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined.

A. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is as follows:

1. Symptoms—shortness of breath and cough, although workers may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as mycobacterium tuberculosis infection (TB) or lung cancer. Workers with these symptoms should immediately receive further evaluation and treatment.

2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

3. Spirometry—may be normal or may show only mild restriction or obstruction.

4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ''eggshell calcifications'' are seen.

5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease.

Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Additionally, a case of acute or accelerated silicosis indicates a significant breakdown in prevention. Urgent communication with the employer is warranted to review exposure levels and protect other workers.

B. Accelerated Silicosis. Accelerated silicosis occurs within 2–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The clinical presentation of accelerated silicosis is as follows:

1. Symptoms—shortness of breath, cough, and sometimes sputum production. Workers with accelerated silicosis are at high risk of tuberculosis, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis, and fatigue, may herald one of these infections or the onset of lung cancer.

2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe disease.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

5. Clinical Course—accelerated silicosis has a rapid, severe course. Referral to a physician who is American Board of Medical Specialties (ABMS)-Certified in Pulmonary Medicine should be made whenever the diagnosis of accelerated silicosis is being considered. Referral to the appropriate specialist should be made if signs or symptoms of tuberculosis, other silica-related infections, or lung cancer are observed. As noted above, the clinician should also alert the employer of the need for immediate review of exposure controls in the worksite in order to protect other workers.

C. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of very high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include weight loss, fatigue, productive cough, hemoptysis, and pleuritic chest pain.

2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ''ground glass'' appearance of interstitial fibrosis will appear.

5. Clinical Course—workers with acute silicosis are at high risk of tuberculosis, atypical mycobaterial infections, and fungal superinfections. Because this disease is immediately life-threatening and indicates a profoundly high level of exposure, it constitutes an immediate medical and public health emergency. The worker must be urgently referred to a physician ABMS-certified in Pulmonary Medicine. As noted above, the clinician should also alert the employer of the need for immediate exposure controls in the worksite in order to protect other workers.

During medical surveillance examinations, clinicians should be alert for other silica-related health outcomes as described below.

D. Chronic Obstructive Pulmonary Disease (COPD). COPD, including chronic bronchitis and emphysema, has also been documented in silica-exposed workers, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each worker for progressive changes consistent with the development of COPD. Additionally, collective spirometry data for groups of workers should be evaluated for declines in lung function, thereby providing a mechanism to detect insufficient silica control measures for groups of workers.

E. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Early studies noted an association between workers with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks, 2007).

F. Tuberculosis (TB). Silica-exposed workers with latent TB are 3–30 times more likely to develop active pulmonary TB infection (ATS, 1997; Rees, 2007). Although silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics are known to be associated with increased rates of latent TB infection. The clinician should review the latest CDC information on TB incidence rates and high risk populations. Additionally, silica-exposed workers are at increased risk for contracting atypical mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii.*

G. Lung Cancer. The International Agency for Research on Cancer (IARC, 1997) classified silica as Group I (*carcinogenic to humans*). Additionally, several studies have indicated that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive (Brown, 2009).

II. Medical Surveillance

Clinicians who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section I of this Appendix. At each clinical encounter, the clinician should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. The following guidance includes components of the medical surveillance examination that are required under the Respirable Crystalline Silica standard, noted below in *italics.*

A. History. A complete work and medical history must be performed on the initial examination and every three years thereafter. Some of the information for this history must also be provided by the employer to the clinician. A detailed history is particularly important in the initial evaluation. Include the following components in this history:

1. Previous and Current Employment
   a. *Past, current, and anticipated exposures to respirable crystalline silica or other toxic substances*
   b. *Exposure to dust and other agents affecting the respiratory system*
   c. *Past, current, and anticipated work duties relating to exposures to respirable crystalline silica*
   d. *Personal protective equipment used, including respirators*
   e. *Previous medical surveillance*
2. Medical History
   a. All past and current medical conditions
   b. *Review of symptoms, with particular attention to respiratory symptoms*
   c. *History of TB infection and/or positive test for latent TB*
   d. *History of other respiratory system dysfunction such as obstructive pulmonary disease or lung cancer*
   e. History of kidney disease, connective tissue disease, and other immune disease/suppression
   f. Medications and allergies
   g. *Smoking status and history*
   f. Previous surgeries and hospitalizations

B. Physical Examination. A physical examination must be performed on the initial examination and every three years thereafter. The physical examination must emphasize the respiratory system and should include an examination of the cardiac system and an extremity examination for clubbing, cyanosis, or edema.

C. Tuberculosis (TB) Testing. Baseline testing for latent or active tuberculosis must be done on initial examination. Current CDC guidelines (*www.cdc.gov*) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained clinicians. Individuals with a positive TST result and those with uncertain test results should be referred to a local public health specialist. Clinicians may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek et al, 2010). Current CDC guidelines for acceptable tests for latent TB infection should be reviewed. Clinicians may perform periodic (*e.g.,* annual) TB testing as appropriate, based on individual risk factors. The diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS, 1997). Current CDC guidance on risk factors for TB should be reviewed periodically (*www.cdc.gov*). Workers who develop active pulmonary TB should be referred to the local public health department. Workers who have evidence of latent TB infection may be referred to the local public health department for evaluation and treatment.

D. Spirometry. Spirometry must be performed on the initial examination and every three years thereafter. Spirometry provides information about individual respiratory status, tracks an individual's respiratory status over time, and is a valuable surveillance tool to track individual and group respiratory function. However, attention should be paid to quality control (ACOEM 2011; ATS/ERS Task Force 2005). Abnormal spirometry results warrant further clinical evaluation and possible work restrictions and/or treatment.

E. Radiography. A chest roentgenogram, or an equivalent diagnostic study, must be performed on the initial examination and every three years thereafter. Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. *An International Labor Organization (ILO) reading must be performed by a NIOSH-certified ''B'' reader. If the B reading indicates small opacities in a profusion of 1/0 or higher, the worker must be referred to a physician who is certified by ABMS in pulmonary medicine.* Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Until the ILO endorses the use of digital standards, conventional chest radiographs are needed for classification using the ILO system. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed periodically on the ILO (*www.ilo.org*) or NIOSH (*www.cdc.gov/NIOSH*) Web sites.

F. Other Testing. It may be appropriate to include additional testing in a medical surveillance program such as baseline renal function tests (*e.g.,* serum creatinine and urinalysis) and annual TST testing for silica-exposed workers.

III. Roles and Responsibilities

A. The Physician or other Licensed Health Care Professional (PLHCP). The PLHCP designation refers to 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 care services required by the Respirable Crystalline Silica standard. The legally permitted scope of practice is determined by each State. Those licensed for independent practice may include physicians, nurse practitioners, or physician assistants, depending on the State. A medical surveillance program for workers exposed to silica should be directed by a health care professional licensed for independent practice. Health care professionals who provide clinical services for a silica medical surveillance program should have a thorough knowledge of the many silica-related diseases and health effects. Primary care practitioners who suspect a diagnosis of silicosis, advanced COPD, or other respiratory conditions causing impairment should promptly refer the affected individuals to a physician who is certified by ABMS in pulmonary medicine.

1. The PLHCP is responsible for providing the employer with a written medical opinion within 30 days of an employee medical examination. The written opinion must include the following information:

a. *A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to respirable crystalline silica.* The employer should be notified if a health condition likely to have been caused by recent occupational exposure has been detected. *Medical diagnoses and conditions that are not related to silica exposure must not be disclosed to the employer. Latent TB infection is not caused by silica exposure and must not be disclosed to the employer.* All cases of active pulmonary TB should be referred to the Public Health Department.

b. *Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators. Again, medical diagnoses not directly related to silica exposure must not be disclosed to the employer.* Guidelines regarding ethics and confidentiality are available from professional practice organizations such as the American College of Occupational and Environmental Medicine.

c. *A statement that the employee should be examined by a physician who is certified by ABMS in pulmonary medicine, where such a referral is necessary. Referral to a pulmonary specialist is required for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate.* A referral to the Public Health Department should not be disclosed to the employer. If necessary, a public health professional will contact the employer to discuss work-related conditions and/or to perform additional medical evaluations.

d. *A statement that the clinician has explained the results of the medical examination to the employee, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.*

2. State Reporting Requirements. Health care providers should be aware that some States require them to report cases of silicosis to the State Department of Health or to the State Department of the Environment.

B. Medical Specialists. *The Silica standard requires that all workers with chest X-ray B readings of 1/0 or higher be referred to an American Board Certified Specialist in Pulmonary Disease. The employer must obtain a written opinion from the specialist that includes the same required information as outlined above under IIIA1a, b, and d.* Employers should receive any information concerning evidence of silica-related risk in their workplace (*e.g.,* evidence of accelerated or acute silicosis tied to recent exposures), so that the employer can investigate and implement corrective measures if necessary. *The employer must receive any information about an examined employee concerning work restrictions, including restrictions related to use of protective clothing or equipment. Employers must not receive other medical diagnoses or confidential health information.*

C. Public Health Providers. Clinicians should refer latent and active TB cases to their local Public Health Department. In addition to diagnosis and treatment of individual cases, public health providers promptly evaluate other potentially affected persons, including coworkers. Because silica-exposed workers are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel findings. In addition to the local and state health departments, the National Institute of Occupational Safety and Health (NIOSH) can provide assistance upon request through their Health Hazard Evaluation program.

IV. Resources and References

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Miller MR et al. Standardisation of spirometry from SERIES ''ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING'' Edited by V. Brusasco, R. Crapo and G. Viegi. Eur Respir J 2005; 26:319–338.

National Institute of Occupational Safety and Health (NIOSH) B reader Program. Access online for more information on interpretation of X-rays for silicosis and a list of certified B-readers. *http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html.*

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Screening and Surveillance of workers exposed to mineral dust; Gregory R. Wagner, Director, Division of Respiratory Diseases, NIOSH, Morgantown, WV, U.S.A.; WHO, Geneva 1996.

PART 1915—OCCUPATIONAL SAFETY AND HEALTH FOR SHIPYARD EMPLOYMENT

■ 5. The authority citation for 29 CFR part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 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), or 4–2010 (75 FR 55355), as applicable; 29 CFR part 1911.

Section 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

■ 6. In § 1915.1000, Table Z—Shipyards:

■ a. remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';

■ b. add ''Silica, crystalline, respirable dust; see 1910.1053'' in alphabetical order; and

■ c. revise the entry ''SILICA:'' under ''Mineral Dusts'', to read as follows:

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.[d]	ppm[a]*	mg/m[3][b]*	Skin designation
* * *	*	*	*	*
Silica, crystalline, respirable dust; See 1910.1053				
* * *	*	*	*	*

MINERAL DUSTS

Substance	mppcf[(j)]
SILICA:	
Amorphous, including natural diatomaceous earth	20

* * * * *

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

■ 7. The authority citation for 29 CFR part 1926 is revised to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 et seq.); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 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 31159), or 4–2010 (75 FR 55355), as applicable; and 29 CFR part 1911.

■ 8. In Appendix A to § 1926.55:

■ a. Remove ''Silica, crystalline cristobalite, respirable dust'', ''Silica, crystalline quartz, respirable dust'', ''Silica, crystalline tripoli (as quartz), respirable dust'', and ''Silica, crystalline tridymite, respirable dust'';

■ b. add ''Silica, crystalline, respirable dust; see 1926.1053'' in alphabetical order; and

■ c. revise the entry ''SILICA:'' under ''Mineral Dusts'', to 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/m³ [b]	Skin designation
* * *	*	*	*	*
Silica, crystalline, respirable dust; see 1926.1053				
* * *	*	*	*	*

MINERAL DUSTS

Substance	mppcf [(j)]
SILICA:	
Amorphous, including natural diatomaceous earth	20

* * * * *

■ 9. Add a new § 1926.1053, to read as follows:

§ 1926.1053 Respirable crystalline silica.

(a) *Scope and application.* (1) This section applies to all occupational exposures to respirable crystalline silica in construction work as defined in 29 CFR 1910.12(b) and covered under 29 CFR part 1926.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne respirable crystalline silica of 25 micrograms per cubic meter of air (25 μg/m³), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Competent person means one who is capable of identifying existing and predictable respirable crystalline silica hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Employee exposure means the exposure to airborne respirable crystalline silica that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter.

Objective data means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating employee exposure to respirable crystalline silica associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling 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 him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of respirable crystalline silica exceeds, or can reasonably be expected to exceed, the PEL.

Respirable crystalline silica means airborne particles that contain quartz, cristobalite, and/or tridymite and whose measurement is determined by a sampling device designed to meet the characteristics for respirable-particle-size-selective samplers specified in the International Organization for Standardization (ISO) 7708:1995: Air Quality—Particle Size Fraction Definitions for Health-Related Sampling.

This section means this respirable crystalline silica standard, 29 CFR 1926.1053.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of respirable crystalline silica in excess of 50 μg/m³, calculated as an 8-hour TWA.

(d) *Exposure assessment.* (1) *General.* (i) Except as provided for in paragraph (d)(8) of this section, each employer covered by this section shall assess the exposure of employees who are or may reasonably be expected to be exposed to respirable crystalline silica at or above the action level.

(ii) The employer shall determine employee exposures from breathing zone air samples that reflect the 8-hour TWA exposure of each employee.

(iii) The employer shall determine 8-hour TWA exposures on the basis of one or more air samples that reflect the exposures of employees on each shift, for each job classification, in each work area. Where several employees perform the same job 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 this requirement. In representative sampling, the employer shall sample the employee(s) who are expected to have the highest exposure to respirable crystalline silica.

(2) *Initial exposure assessment.* (i) Except as provided for in paragraph (d)(2)(ii) of this section, each employer shall perform initial monitoring of employees who are, or may reasonably be expected to be, exposed to airborne concentrations of respirable crystalline silica at or above the action level.

(ii) The employer may rely on existing data to satisfy this initial monitoring requirement where the employer:

(A) Has monitored employee exposures after [INSERT DATE 12 MONTHS PRIOR TO EFFECTIVE DATE OF FINAL RULE] under conditions that closely resemble those currently prevailing, provided that such monitoring satisfies the requirements of paragraph (d)(5)(i) of this section with respect to analytical methods employed; or

(B) Has objective data that demonstrate that respirable crystalline silica is not capable of being released in airborne concentrations at or above the action level under any expected conditions of processing, use, or handling.

(3) *Periodic exposure assessments.* If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. If initial monitoring indicates that employee exposures are at or above the action level, the employer shall repeat air monitoring to assess employee exposures to respirable crystalline silica either under the fixed schedule prescribed in paragraph (d)(3)(i) of this section or in accordance with the performance-based requirement prescribed in paragraph (d)(3)(ii) of this section.

(i) *Fixed schedule option.* (A) Where initial or subsequent exposure monitoring reveals that employee exposures are at or above the action level but at or below the PEL, the employer shall repeat such monitoring at least every six months.

(B) Where initial or subsequent exposure monitoring reveals that employee exposures are above the PEL, the employer shall repeat such monitoring at least every three months.

(C) The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level, at which time the employer may discontinue monitoring for that employee, except as otherwise provided in paragraph (d)(4) of this section.

(ii) *Performance option.* The employer shall assess the 8-hour TWA exposure for each employee on the basis of any combination of air monitoring data or objective data sufficient to accurately characterize employee exposures to respirable crystalline silica.

(4) *Additional exposure assessments.* The employer shall conduct additional exposure assessments as required under paragraph (d)(3) of this section whenever a change in the 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.

(5) *Method of sample analysis.* (i) The employer shall ensure that all samples taken to satisfy the monitoring requirements of paragraph (d) of this section are evaluated using the procedures specified in one of the following analytical methods: OSHA ID–142; NMAM 7500, NMAM 7602; NMAM 7603; MSHA P–2; or MSHA P–7.

(ii) The employer shall ensure that samples are analyzed by a laboratory that:

(A) Is accredited to ANS/ISO/IEC Standard 17025:2005 with respect to crystalline silica analyses by a body that is compliant with ISO/IEC Standard 17011:2004 for implementation of quality assessment programs;

(B) Participates in round robin testing with at least two other independent laboratories at least every six months;

(C) Uses the most current National Institute of Standards and Technology (NIST) or NIST traceable standards for instrument calibration or instrument calibration verification;

(D) Implements an internal quality control (QC) program that evaluates analytical uncertainty and provides employers with estimates of sampling and analytical error;

(E) Characterizes the sample material by identifying polymorphs of respirable crystalline silica present, identifies the presence of any interfering compounds that might affect the analysis, and makes any corrections necessary in order to obtain accurate sample analysis;

(F) Analyzes quantitatively for crystalline silica only after confirming that the sample matrix is free of uncorrectable analytical interferences, corrects for analytical interferences, and uses a method that meets the following performance specifications:

(*1*) Each day that samples are analyzed, performs instrument calibration checks with standards that bracket the sample concentrations;

(*2*) Uses five or more calibration standard levels to prepare calibration curves and ensures that standards are distributed through the calibration range in a manner that accurately reflects the underlying calibration curve; and

(*3*) Optimizes methods and instruments to obtain a quantitative limit of detection that represents a value no higher than 25 percent of the PEL based on sample air volume.

(6) *Employee notification of assessment results.* (i) Within five working days after completing an exposure assessment in accordance with paragraph (d) of this section, the employer shall individually notify each affected employee in writing of the results of that assessment or post the results in an appropriate location accessible to all affected employees.

(ii) Whenever the exposure assessment indicates that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(7) *Observation of monitoring.* (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to respirable crystalline silica.

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with protective clothing and equipment at no cost and shall ensure that the observer uses such clothing and equipment.

(8) *Specific operations.* (i) Where employees perform operations listed in Table 1 in paragraph (f) of this section and the employer has fully implemented the engineering controls, work practices, and respiratory protection specified in Table 1 for that operation, the employer is not required to assess the exposure of employees performing such operations.

(ii) For the purposes of complying with all other requirements of this section, the employer must presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL, unless the employer can demonstrate otherwise in accordance with the exposure assessment requirements of paragraph (d) of this section.

(e) *Regulated areas and access control.* (1) *General.* Wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL, each employer shall establish and implement either a regulated area in accordance with paragraph (e)(2) of this section or an access control plan in accordance with paragraph (e)(3) of this section.

(2) *Regulated areas option.* (i) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of respirable crystalline silica is, or can reasonably be expected to be, in excess of the PEL.

(ii) *Demarcation.* The employer shall demarcate regulated areas from the rest of the workplace in any manner that

adequately establishes and alerts employees to the boundaries of the area and minimizes the number of employees exposed to respirable crystalline silica within the regulated area.

(iii) *Access.* The employer shall limit access to regulated areas to:

(A) Persons authorized by the employer and required by work duties to be present in the regulated area;

(B) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; and

(C) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(iv) *Provision of respirators.* The employer shall provide each employee and the employee's designated representative entering a regulated area with an appropriate respirator in accordance with paragraph (g) of this section and shall require each employee and the employee's designated representative to use the respirator while in a regulated area.

(v) *Protective work clothing in regulated areas.* (A) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica, the employer shall provide either of the following:

(*1*) Appropriate protective clothing such as coveralls or similar full-bodied clothing; or

(*2*) Any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica.

(B) The employer shall ensure that such clothing is removed or cleaned upon exiting the regulated area and before respiratory protection is removed.

(3) *Written access control plan option.* (i) The employer shall establish and implement a written access control plan.

(ii) The written access control plan shall contain at least the following elements:

(A) Provisions for a competent person to identify the presence and location of any areas where respirable crystalline silica exposures are, or can reasonably be expected to be, in excess of the PEL;

(B) Procedures for notifying employees of the presence and location of areas identified pursuant to paragraph (e)(3)(ii)(A) of this section, and for demarcating such areas from the rest of the workplace where appropriate;

(C) For multi-employer workplaces, the methods the employer covered by this section will use to inform other employer(s) of the presence and location of areas where respirable crystalline silica exposures may exceed the PEL, and any precautionary measures that need to be taken to protect employees;

(D) Provisions for limiting access to areas where respirable crystalline silica exposures may exceed the PEL to effectively minimize the number of employees exposed and the level of employee exposure;

(E) Procedures for providing each employee and their designated representative entering an area where respirable crystalline silica exposures may exceed the PEL with an appropriate respirator in accordance with paragraph (g) of this section, and requiring each employee and their designated representative to use the respirator while in the area; and

(F) Where there is the potential for employees' work clothing to become grossly contaminated with finely divided material containing crystalline silica:

(*1*) Provisions for the employer to provide either appropriate protective clothing such as coveralls or similar full-bodied clothing, or any other means to remove excessive silica dust from contaminated clothing that minimizes employee exposure to respirable crystalline silica; and

(*2*) Provisions for the removal or cleaning of such clothing.

(iii) The employer shall review and evaluate the effectiveness of the written access control plan at least annually and update it as necessary.

(iv) The employer shall make the written access control plan available for examination and copying, upon request, to employees, their designated representatives, the Assistant Secretary and the Director.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* The employer shall use engineering and work practice controls to reduce and maintain employee exposure to respirable crystalline silica to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever such feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them with the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) *Specific operations.* For the operations listed in Table 1, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with paragraph (f)(1) of this section. (NOTE: The employer must comply with all other obligations of this section, including the PEL specified in paragraph (c) of this section.)

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
Using Stationary Masonry Saws.	Use saw equipped with integrated water delivery system. **Note:** Additional specifications: • Change water frequently to avoid silt build-up in water. • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Ensure saw blade is not excessively worn.	None	Half-Mask (10).

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
Using Hand-Operated Grinders.	Use water-fed grinder that continuously feeds water to the cutting surface.	None	Half-Mask (10).
	OR		
	Use grinder equipped with commercially available shroud and dust collection system, operated and maintained to minimize dust emissions. Collector must be equipped with a HEPA filter and must operate at 25 cubic feet per minute (cfm) or greater airflow per inch of blade diameter. **Note:** Additional specifications (wherever applicable): • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.	Half-Mask (10)	Half-Mask (10).
Tuckpointing	Use grinder equipped with commercially available shroud and dust collection system. Grinder must be operated flush against the working surface and work must be performed against the natural rotation of the blade (*i.e.,* mortar debris must be directed into the exhaust). Use vacuums that provide at least 80 cfm airflow through the shroud and include filters at least 99 percent efficient. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working in enclosed spaces, provide sufficient ventilation to prevent build-up of visible airborne dust.	Powered air-purifying respirator (PAPR) with loose-fitting helmet or negative pressure full facepiece (25).	Powered air-purifying respirator (PAPR) with loose-fitting helmet or negative pressure full facepiece (25).
Using Jackhammers and Other Impact Drillers.	Apply a continuous stream or spray of water at the point of impact.	None	Half-Mask (10).
	OR		
	Use tool-mounted shroud and HEPA-filtered dust collection system. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.	None	Half-Mask (10).
Using Rotary Hammers or Drills (except overhead).	Use drill equipped with hood or cowl and HEPA-filtered dust collector. Eliminate blowing or dry sweeping drilling debris from working surface. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Use dust collector in accordance with manufacturer specifications.	None	None.
Operating Vehicle-Mounted Drilling Rigs for Rock.	Use dust collection system around drill bit and provide a low-flow water spray to wet the dust discharged from the dust collector. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the process. • Half-mask respirator is to be used when working under the shroud. • Use dust collector in accordance with manufacturer specifications.	None	None.
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained. • Incoming air is filtered through a prefilter and HEPA filter.	None	None.

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
	• Cab is maintained as free as practicable from settled dust. • Door seals and closing mechanisms are working properly.		
Operating Vehicle-Mounted Drilling Rigs for Concrete.	Use dust collection system around drill bit and provide a low-flow water spray to wet the dust discharged from the dust collector. **Note:** Additional specifications: • Use smooth ducts and maintain duct transport velocity at 4,000 feet per minute. • Provide duct clean-out points. • Install pressure gauges across dust collection filters. • Activate LEV before drilling begins and deactivate after drill bit stops rotating. • Operate equipment such that no visible dust is emitted from the process. • Use dust collector in accordance with manufacturer specifications.	None	Half-Mask (10).
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained. • Incoming air is filtered through a prefilter and HEPA filter. • Cab is maintained as free as practicable from settled dust. • Door seals and closing mechanisms are working properly.	None	None.
Milling	For drivable milling machines:. Use water-fed system that delivers water continuously at the cut point to suppress dust. **Note:** Additional specifications: • Operate equipment such that no visible dust is emitted from the drum box and conveyor areas.	None	Half-Mask (10).
	For walk-behind milling tools: Use water-fed equipment that continuously feeds water to the cutting surface.	None	Half-Mask (10).
	OR Use tool equipped with commercially available shroud and dust collection system. Collector must be equipped with a HEPA filter and must operate at an adequate airflow to minimize airborne visible dust. **Note:** Additional specifications: • Use dust collector in accordance with manufacturer specifications including airflow rate.	None	Half-Mask (10).
Using Handheld Masonry Saws.	Use water-fed system that delivers water continuously at the cut point.		
	Used outdoors	None	Half-Mask (10).
	Used indoors or within partially sheltered area	Half-Mask (10)	Half-Mask (10).
	OR Use saw equipped with local exhaust dust collection system.		
	Used outdoors	Half-Mask (10)	Half-Mask (10).
	Used indoors or within partially sheltered area	Full Facepiece (50)	Full Facepiece (50).
	Note: Additional specifications: • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust. • Use dust collector in accordance with manufacturer specifications.		
Using Portable Walk-Behind or Drivable Masonry Saws.	Use water-fed system that delivers water continuously at the cut point.		

TABLE 1—EXPOSURE CONTROL METHODS FOR SELECTED CONSTRUCTION OPERATIONS—Continued

Operation	Engineering and work practice control methods	Required air-purifying respirator (minimum assigned protection factor)	
		≤ 4 hr/day	> 4 hr/day
	Used outdoors	None	None.
	Used indoors or within partially sheltered area	Half-Mask (10)	Half-Mask (10).
	Note: Additional specifications: • Prevent wet slurry from accumulating and drying. • Operate equipment such that no visible dust is emitted from the process. • When working indoors, provide sufficient ventilation to prevent build-up of visible airborne dust.		
Rock Crushing	Use wet methods or dust suppressants	Half-Mask (10)	Half-Mask (10).
	OR		
	Use local exhaust ventilation systems at feed hoppers and along conveyor belts.	Half-Mask (10)	Half-Mask (10).
	Note: Additional specifications: • Operate equipment such that no visible dust is emitted from the process.		
	For equipment operator working within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained; • Incoming air is filtered through a prefilter and HEPA filter; • Cab is maintained as free as practicable from settled dust; and • Door seals and closing mechanisms are working properly.	None	None.
Drywall Finishing (with silica-containing material).	Use pole sander or hand sander equipped with a dust collection system. Use dust collector in accordance with manufacturer specifications.	None	None.
	OR		
	Use wet methods to smooth or sand the drywall seam	None	None.
Use of Heavy Equipment During Earthmoving.	Operate equipment from within an enclosed cab having the following characteristics: • Cab is air conditioned and positive pressure is maintained; • Incoming air is filtered through a prefilter and HEPA filter; • Cab is maintained as free as practicable from settled dust; and • Door seals and closing mechanisms are working properly.	None	None.

NOTE 1: For the purposes of complying with all other requirements of this section, the employer must presume that each employee performing an operation listed in Table 1 that requires a respirator is exposed above the PEL.

NOTE 2: Where an employee performs more than one operation during the course of a day, and the total duration of all operations combined is > 4 hr/day, the required air-purifying respirator for each operation is the respirator specified for > 4 hr/day. If the total duration of all operations combined is ≤ 4 hr/day, the required air-purifying respirator for each operation is the respirator specified for ≤ 4 hr/day.

(3) *Abrasive blasting.* In addition to the requirements of paragraph (f)(1) of this section, the employer shall comply with the requirements of 29 CFR 1926.57 (Ventilation) where abrasive blasting operations are conducted using crystalline silica-containing blasting agents, or where abrasive blasting operations are conducted on substrates that contain crystalline silica.

(4) *Cleaning methods.* (i) The employer shall ensure that accumulations of crystalline silica are cleaned by HEPA-filter vacuuming or wet methods where such accumulations could, if disturbed, contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(ii) Compressed air, dry sweeping, and dry brushing shall not be used to clean clothing or surfaces contaminated with crystalline silica where such activities could contribute to employee exposure to respirable crystalline silica that exceeds the PEL.

(5) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* Where respiratory protection is required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph and 29 CFR 1910.134. Respiratory protection is required:

(i) Where exposures exceed the PEL during periods necessary to install or implement feasible engineering and work practice controls;

(ii) Where exposures exceed the PEL during work operations for which engineering and work practice controls are not feasible;

(iii) During work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not

sufficient to reduce exposures to or below the PEL;

(iv) During periods when the employee is in a regulated area; and

(v) During periods when the employee is in an area where respirator use is required under an access control plan pursuant to paragraph (e)(3) of this section.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(3) *Specific operations.* For the operations listed in Table 1 in paragraph (f) of this section, if the employer fully implements the engineering controls, work practices, and respiratory protection described in Table 1, the employer shall be considered to be in compliance with the requirements for selection of respirators in 29 CFR 1910.134 paragraph (d).

(h) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for each employee who will be occupationally exposed to respirable crystalline silica above the PEL for 30 or more days per year.

(ii) The employer shall ensure that all medical examinations and procedures required by this section are performed by a PLHCP as defined in paragraph (b) of this section.

(2) *Initial examination.* The employer shall make available an initial (baseline) medical examination within 30 days after initial assignment, unless the employee has received a medical examination that meets the requirements of this section within the last three years. The examination shall consist of:

(i) A medical and work history, with emphasis on: past, present, and anticipated exposure to respirable crystalline silica, dust, and other agents affecting the respiratory system; any history of respiratory system dysfunction, including signs and symptoms of respiratory disease (*e.g.,* shortness of breath, cough, wheezing); history of tuberculosis; and smoking status and history;

(ii) A physical examination with special emphasis on the respiratory system;

(iii) A chest X-ray (posterior/anterior view; no less than 14 x 17 inches and no more than 16 x 17 inches at full inspiration), interpreted and classified according to the International Labour Organization (ILO) International Classification of Radiographs of Pneumoconioses by a NIOSH-certified ''B'' reader, or an equivalent diagnostic study;

(iv) A pulmonary function test to include forced vital capacity (FVC) and forced expiratory volume at one second (FEV_1) and FEV_1/FVC ratio, administered by a spirometry technician with current certification from a NIOSH-approved spirometry course;

(v) Testing for latent tuberculosis infection; and

(vi) Any other tests deemed appropriate by the PLHCP.

(3) *Periodic examinations.* The employer shall make available medical examinations that include the procedures described in paragraph (h)(2) (except paragraph (h)(2)(v)) of this section at least every three years, or more frequently if recommended by the PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the PLHCP with the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to respirable crystalline silica;

(ii) The employee's former, current, and anticipated levels of occupational exposure to respirable crystalline silica;

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee and currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP within 30 days of each medical examination performed on each employee. The written opinion shall contain:

(A) A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from exposure to respirable crystalline silica;

(B) Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators;

(C) A statement that the employee should be examined by an American Board Certified Specialist in Pulmonary Disease (''pulmonary specialist'') pursuant to paragraph (h)(6) of this section if the chest X-ray provided in accordance with this section is classified as 1/0 or higher by the ''B'' reader, or if referral to a pulmonary specialist is otherwise deemed appropriate by the PLHCP; and

(D) A statement that the PLHCP has explained to the employee the results of the medical examination, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.

(ii) The employer shall ensure that the PLHCP does not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to respirable crystalline silica.

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(6) *Additional examinations.* (i) If the PLHCP's written medical opinion indicates that an employee should be examined by a pulmonary specialist, the employer shall make available a medical examination by a pulmonary specialist within 30 days after receiving the PLHCP's written medical opinion.

(ii) The employer shall ensure that the examining pulmonary specialist is provided with all of the information that the employer is obligated to provide to the PLHCP in accordance with paragraph (h)(4) of this section.

(iii) The employer shall obtain a written medical opinion from the pulmonary specialist that meets the requirements of paragraph (h)(5) (except paragraph (h)(5)(i)(C)) of this section.

(i) *Communication of respirable crystalline silica hazards to employees.* (1) *Hazard communication.* The employer shall include respirable crystalline silica in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of crystalline silica and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (i)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, lung effects, immune system effects, and kidney effects.

(2) *Employee information and training.* (i) The employer shall ensure that each affected employee can demonstrate knowledge of at least the following:

(A) Specific operations in the workplace that could result in exposure to respirable crystalline silica,

especially operations where exposure may exceed the PEL;

(B) Specific procedures the employer has implemented to protect employees from exposure to respirable crystalline silica, including appropriate work practices and use of personal protective equipment such as respirators and protective clothing;

(C) The contents of this section; and

(D) The purpose and a description of the medical surveillance program required by paragraph (h) of this section.

(ii) The employer shall make a copy of this section readily available without cost to each affected employee.

(j) *Recordkeeping.* (1) *Air monitoring data.* (i) The employer shall maintain an accurate record of all exposure measurement results used or relied on to characterize employee exposure to respirable crystalline silica, as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation monitored;

(C) Sampling and analytical methods used;

(D) Number, duration, and results of samples taken;

(E) Identity of the laboratory that performed the analysis;

(F) Type of personal protective equipment, such as respirators, worn by the employees monitored; and

(G) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Objective data.* (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.

(ii) This record shall include at least the following information:

(A) The crystalline silica-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing;

(D) A description of the process, operation, or activity and how the data support the assessment; and

(E) Other data relevant to the process, operation, activity, material, or employee exposures.

(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's and pulmonary specialist's written opinions; and

(C) A copy of the information provided to the PLHCPs and pulmonary specialists as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(k) *Dates.* (1) *Effective date.* This section shall become effective [INSERT DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(2) *Start-up dates.* (i) All obligations of this section, except engineering controls required by paragraph (f) of this section and laboratory requirements in paragraph (d)(5)(ii) of this section, commence 180 days after the effective date.

(ii) Engineering controls required by paragraph (f) of this section shall be implemented no later than one year after the effective date.

(iii) Laboratory requirements in paragraph (d)(5)(ii) of this section commence two years after the effective date.

Appendix A to § 1926.1053—Medical Surveillance Guidelines (Non-Mandatory) Introduction

The purpose of this non-mandatory Appendix is to provide helpful information about complying with the medical surveillance provisions of the Respirable Crystalline Silica standard, as well as to provide other helpful recommendations and information. Medical screening and surveillance allow for early identification of exposure-related health effects in individual workers and groups of workers, respectively, so that actions can be taken to both avoid further exposure and prevent adverse health outcomes. Silica-related diseases can be fatal, encompass a variety of target organs, and may have public health consequences. Thus, medical surveillance of silica-exposed workers requires involvement of clinicians with thorough knowledge of silica-related health effects and a public health perspective.

This Appendix is divided into four sections. Section I reviews silica-related diseases, appropriate medical responses, and public health responses. Section II outlines the components of the medical surveillance program for workers exposed to silica. Section III describes the roles and responsibilities of the clinician implementing the program and of other medical specialists and public health providers. Section IV provides additional resources.

I. Recognition of Silica-Related Diseases

Overview. Silica refers specifically to the compound silicon dioxide (SiO_2). Silica is a major component of sand, rock, and mineral ores. Exposure to fine (respirable size) particles of crystalline forms of silica is associated with a number of adverse health effects. Exposure to respirable crystalline silica can occur in foundries, industries that have abrasive blasting operations, paint manufacturing, glass and concrete product manufacturing, brick making, china and pottery manufacturing, manufacturing of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing.

Silicosis is an irreversible, often disabling, and sometimes fatal fibrotic lung disease. Progression of silicosis can occur despite removal from further exposure. Diagnosis of silicosis requires a history of exposure to silica and radiologic findings characteristic of silica exposure. Three different presentations of silicosis (chronic, accelerated, and acute) have been defined.

A. Chronic Silicosis. Chronic silicosis is the most common presentation of silicosis and usually occurs after at least 10 years of exposure to respirable crystalline silica. The clinical presentation of chronic silicosis is as follows:

1. Symptoms—Shortness of breath and cough, although workers may not notice any symptoms early in the disease. Constitutional symptoms, such as fever, loss of appetite and fatigue, may indicate other diseases associated with silica exposure, such as mycobacterium tuberculosis infection (TB) or lung cancer. Workers with these symptoms should immediately receive further evaluation and treatment.

2. Physical Examination—may be normal or disclose dry rales or rhonchi on lung auscultation.

3. Spirometry—may be normal or may show only mild restriction or obstruction.

4. Chest X-ray—classic findings are small, rounded opacities in the upper lung fields bilaterally. However, small irregular opacities and opacities in other lung areas can also occur. Rarely, ''eggshell calcifications'' are seen.

5. Clinical Course—chronic silicosis in most cases is a slowly progressive disease.

Accelerated and acute silicosis are much less common than chronic silicosis. However, it is critical to recognize all cases of accelerated and acute silicosis because these are life-threatening illnesses and because they are caused by substantial overexposures to respirable crystalline silica. Additionally, a case of acute or accelerated silicosis indicates a significant breakdown in prevention. Urgent communication with the employer is warranted to review exposure levels and protect other workers.

B. Accelerated Silicosis. Accelerated silicosis occurs within 2–10 years of exposure and results from high levels of exposure to respirable crystalline silica. The

clinical presentation of accelerated silicosis is as follows:

1. Symptoms—shortness of breath, cough, and sometimes sputum production. Workers with accelerated silicosis are at high risk of tuberculosis, atypical mycobacterial infections, and fungal superinfections. Constitutional symptoms, such as fever, weight loss, hemoptysis, and fatigue, may herald one of these infections or the onset of lung cancer.

2. Physical Examination—rales, rhonchi, or other abnormal lung findings in relation to illnesses present. Clubbing of the digits, signs of heart failure, and cor pulmonale may be present in severe disease.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—small rounded and/or irregular opacities bilaterally. Large opacities and lung abscesses may indicate infections, lung cancer, or progression to complicated silicosis, also termed progressive massive fibrosis.

5. Clinical Course—accelerated silicosis has a rapid, severe course. Referral to a physician who is American Board of Medical Specialties (ABMS)-Certified in Pulmonary Medicine should be made whenever the diagnosis of accelerated silicosis is being considered. Referral to the appropriate specialist should be made if signs or symptoms of tuberculosis, other silica-related infections, or lung cancer are observed. As noted above, the clinician should also alert the employer of the need for immediate review of exposure controls in the worksite in order to protect other workers.

C. Acute Silicosis. Acute silicosis is a rare disease caused by inhalation of very high levels of respirable crystalline silica particles. The pathology is similar to alveolar proteinosis with lipoproteinaceous material accumulating in the alveoli. Acute silicosis develops rapidly, within a few months to less than 2 years of exposure, and is almost always fatal. The clinical presentation of acute silicosis is as follows:

1. Symptoms—sudden, progressive, and severe shortness of breath. Constitutional symptoms are frequently present and include weight loss, fatigue, productive cough, hemoptysis, and pleuritic chest pain.

2. Physical Examination—dyspnea at rest, cyanosis, decreased breath sounds, inspiratory rales, clubbing of the digits, and fever.

3. Spirometry—restriction or mixed restriction/obstruction.

4. Chest X-ray—diffuse haziness of the lungs bilaterally early in the disease. As the disease progresses, the ''ground glass'' appearance of interstitial fibrosis will appear.

5. Clinical Course—workers with acute silicosis are at high risk of tuberculosis, atypical myco-baterial infections, and fungal superinfections. Because this disease is immediately life-threatening and indicates a profoundly high level of exposure, it constitutes an immediate medical and public health emergency. The worker must be urgently referred to a physician ABMS-certified in Pulmonary Medicine. As noted above, the clinician should also alert the employer of the need for immediate exposure controls in the worksite in order to protect other workers.

During medical surveillance examinations, clinicians should be alert for other silica-related health outcomes as described below.

D. Chronic Obstructive Pulmonary Disease (COPD). COPD, including chronic bronchitis and emphysema, has also been documented in silica-exposed workers, including those who do not develop silicosis. Periodic spirometry tests are performed to evaluate each worker for progressive changes consistent with the development of COPD. Additionally, collective spirometry data for groups of workers should be evaluated for declines in lung function, thereby providing a mechanism to detect insufficient silica control measures for groups of workers.

E. Renal and Immune System. Silica exposure has been associated with several types of kidney disease, including glomerulonephritis, nephrotic syndrome, and end stage renal disease requiring dialysis. Silica exposure has also been associated with other autoimmune conditions, including progressive systemic sclerosis, systemic lupus erythematosus, and rheumatoid arthritis. Early studies noted an association between workers with silicosis and serologic markers for autoimmune diseases, including antinuclear antibodies, rheumatoid factor, and immune complexes (Jalloul and Banks, 2007).

F. Tuberculosis (TB). Silica-exposed workers with latent TB are 3–30 times more likely to develop active pulmonary TB infection (ATS, 1997; Rees, 2007). Although silica exposure does not cause TB infection, individuals with latent TB infection are at increased risk for activation of disease if they have higher levels of silica exposure, greater profusion of radiographic abnormalities, or a diagnosis of silicosis. Demographic characteristics are known to be associated with increased rates of latent TB infection. The clinician should review the latest CDC information on TB incidence rates and high risk populations. Additionally, silica-exposed workers are at increased risk for contracting atypical mycobacterial infections, including *Mycobacterium avium-intracellulare* and *Mycobacterium kansaii.*

G. Lung Cancer. The International Agency for Research on Cancer (IARC, 1997) classified silica as Group I (*carcinogenic to humans*). Additionally, several studies have indicated that the combined effect of exposure to respirable crystalline silica and smoking was greater than additive (Brown, 2009).

II. Medical Surveillance

Clinicians who manage silica medical surveillance programs should have a thorough understanding of the many silica-related diseases and health effects outlined in Section I of this Appendix. At each clinical encounter, the clinician should consider silica-related health outcomes, with particular vigilance for acute and accelerated silicosis. The following guidance includes components of the medical surveillance examination that are required under the Respirable Crystalline Silica standard, noted below in *italics.*

A. History. A complete work and medical history must be performed on the initial examination and every three years thereafter. Some of the information for this history must also be provided by the employer to the clinician. A detailed history is particularly important in the initial evaluation. Include the following components in this history:

1. Previous and Current Employment
   - *a. Past, current, and anticipated exposures to respirable crystalline silica or other toxic substances*
   - *b. Exposure to dust and other agents affecting the respiratory system*
   - *c. Past, current, and anticipated work duties relating to exposures to respirable crystalline silica*
   - *d. Personal protective equipment used, including respirators*
   - *e. Previous medical surveillance*
2. Medical History
   - a. All past and current medical conditions
   - *b. Review of symptoms, with particular attention to respiratory symptoms*
   - *c. History of TB infection and/or positive test for latent TB*
   - *d. History of other respiratory system dysfunction such as obstructive pulmonary disease or lung cancer*
   - e. History of kidney disease, connective tissue disease, and other immune disease/suppression
   - f. Medications and allergies
   - *g. Smoking status and history*
   - f. Previous surgeries and hospitalizations

B. Physical Examination. A physical examination must be performed on the initial examination and every three years thereafter. The physical examination must emphasize the respiratory system and should include an examination of the cardiac system and an extremity examination for clubbing, cyanosis, or edema.

C. Tuberculosis (TB) Testing. Baseline testing for latent or active tuberculosis must be done on initial examination. Current CDC guidelines (*www.cdc.gov*) should be followed for the application and interpretation of Tuberculin skin tests (TST). The interpretation and documentation of TST reactions should be performed within 48 to 72 hours of administration by trained clinicians. Individuals with a positive TST result and those with uncertain test results should be referred to a local public health specialist. Clinicians may use alternative TB tests, such as interferon-γ release assays (IGRAs), if sensitivity and specificity are comparable to TST (Mazurek et al, 2010). Current CDC guidelines for acceptable tests for latent TB infection should be reviewed. Clinicians may perform periodic (*e.g.,* annual) TB testing as appropriate, based on individual risk factors. The diagnosis of silicosis or exposure to silica for 25 years or more are indications for annual TB testing (ATS, 1997). Current CDC guidance on risk factors for TB should be reviewed periodically (*www.cdc.gov*). Workers who develop active pulmonary TB should be referred to the local public health department. Workers who have evidence of latent TB infection may be referred to the local public health department for evaluation and treatment.

D. Spirometry. Spirometry must be performed on the initial examination and every three years thereafter. Spirometry provides information about individual

respiratory status, tracks an individual's respiratory status over time, and is a valuable surveillance tool to track individual and group respiratory function. However, attention should be paid to quality control (ACOEM 2011; ATS/ERS Task Force 2005). Abnormal spirometry results warrant further clinical evaluation and possible work restrictions and/or treatment.

E. Radiography. A chest roentgenogram, or an equivalent diagnostic study, must be performed on the initial examination and every three years thereafter. Chest radiography is necessary to diagnose silicosis, monitor the progression of silicosis, and identify associated conditions such as TB. *An International Labor Organization (ILO) reading must be performed by a NIOSH-certified ''B'' reader. If the B reading indicates small opacities in a profusion of 1/0 or higher, the worker must be referred to a physician who is certified by ABMS in pulmonary medicine.* Medical imaging is currently in the process of transitioning from conventional film-based radiography to digital radiography systems. Until the ILO endorses the use of digital standards, conventional chest radiographs are needed for classification using the ILO system. Current ILO guidance on radiography for pneumoconioses and B-reading should be reviewed periodically on the ILO (*www.ilo.org*) or NIOSH (*www.cdc.gov/NIOSH*) Web sites.

F. Other Testing. It may be appropriate to include additional testing in a medical surveillance program such as baseline renal function tests (*e.g.,* serum creatinine and urinalysis) and annual TST testing for silica-exposed workers.

III. Roles and Responsibilities

A. The Physician or other Licensed Health Care Professional (PLHCP). The PLHCP designation refers to 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 care services required by the Respirable Crystalline Silica standard. The legally permitted scope of practice is determined by each State. Those licensed for independent practice may include physicians, nurse practitioners, or physician assistants, depending on the State. A medical surveillance program for workers exposed to silica should be directed by a health care professional licensed for independent practice. Health care professionals who provide clinical services for a silica medical surveillance program should have a thorough knowledge of the many silica-related diseases and health effects. Primary care practitioners who suspect a diagnosis of silicosis, advanced COPD, or other respiratory conditions causing impairment should promptly refer the affected individuals to a physician who is certified by ABMS in pulmonary medicine.

1. The PLHCP is responsible for providing the employer with a written medical opinion within 30 days of an employee medical examination. The written opinion must include the following information:

a. *A description of the employee's health condition as it relates to exposure to respirable crystalline silica, including the PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to respirable crystalline silica.* The employer should be notified if a health condition likely to have been caused by recent occupational exposure has been detected. *Medical diagnoses and conditions that are not related to silica exposure must not be disclosed to the employer. Latent TB infection is not caused by silica exposure and must not be disclosed to the employer.* All cases of active pulmonary TB should be referred to the Public Health Department.

b. *Any recommended limitations upon the employee's exposure to respirable crystalline silica or upon the use of personal protective equipment such as respirators. Again, medical diagnoses not directly related to silica exposure must not be disclosed to the employer.* Guidelines regarding ethics and confidentiality are available from professional practice organizations such as the American College of Occupational and Environmental Medicine.

c. *A statement that the employee should be examined by a physician who is certified by ABMS in pulmonary medicine, where such a referral is necessary. Referral to a pulmonary specialist is required for a chest X-ray B reading indicating small opacities in a profusion of 1/0 or higher, or if referral to a pulmonary specialist is otherwise deemed appropriate.* A referral to the Public Health Department should not be disclosed to the employer. If necessary, a public health professional will contact the employer to discuss work-related conditions and/or to perform additional medical evaluations.

d. *A statement that the clinician has explained the results of the medical examination to the employee, including findings of any medical conditions related to respirable crystalline silica exposure that require further evaluation or treatment, and any recommendations related to use of protective clothing or equipment.*

2. State Reporting Requirements. Health care providers should be aware that some States require them to report cases of silicosis to the State Department of Health or to the State Department of the Environment.

B. Medical Specialists. *The Silica standard requires that all workers with chest X-ray B readings of 1/0 or higher be referred to an American Board Certified Specialist in Pulmonary Disease. The employer must obtain a written opinion from the specialist that includes the same required information as outlined above under IIIA1a, b, and d.* Employers should receive any information concerning evidence of silica-related risk in their workplace (*e.g.,* evidence of accelerated or acute silicosis tied to recent exposures), so that the employer can investigate and implement corrective measures if necessary. *The employer must receive any information about an examined employee concerning work restrictions, including restrictions related to use of protective clothing or equipment. Employers must not receive other medical diagnoses or confidential health information.*

C. Public Health Providers. Clinicians should refer latent and active TB cases to their local Public Health Department. In addition to diagnosis and treatment of individual cases, public health providers promptly evaluate other potentially affected persons, including coworkers. Because silica-exposed workers are at increased risk of progression from latent to active TB, treatment of latent infection is recommended. The diagnosis of TB, acute or accelerated silicosis, or other silica-related diseases and infections should serve as sentinel findings. In addition to the local and state health departments, the National Institute of Occupational Safety and Health (NIOSH) can provide assistance upon request through their Health Hazard Evaluation program.

IV. Resources and References

American College of Occupational and Environmental Medicine (ACOEM), Position Statement. Medical Surveillance of Workers Exposed to Crystalline Silica. 06/27/2005.

ACOEM, Position Statement. Spirometry in the Occupational Health Setting. 04/05/2011.

American Thoracic Society (ATS): Medical Section of the American Lung Association. Adverse Effects of Crystalline Silica Exposure. Am J Respir Crit Care Med Vol 155. pp 761–765, 1997.

Brown T. Silica Exposure, Smoking, Silicosis and Lung Cancer—Complex Interactions. Occupational Medicine. 2009 59(2):89–95.

Center for Disease Control and Prevention (CDC). Guide for Primary Health Care Providers: Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. 2005.

Centers for Disease Control and Prevention. Screening for Tuberculosis and Tuberculosis Infection in High-Risk Populations. Recommendations of the Advisory Council for Elimination of Tuberculosis. MMWR 1995; 44(RR–11): 18–34.

International Agency for Research on Cancer (IARC) Working Group on the Evaluation of Carcinogenic Risks to Humans. Silica, Some Silicates, Coal Dust and Para-aramid Fibrils. Lyon, France. 1997.

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Mazurek GH, Jereb J, Vernon A et al. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium* tuberculosis Infection—United States, 2010. Morbidity and Mortality Weekly Report (MMWR), 6/25/10; 59(RR05):1–25.

Miller MR et al, Standardisation of spirometry from SERIES ''ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING'' Edited by V Brusasco, R Crapo and G Viegi. Eur Respir J 2005; 26:319–338.

National Institute of Occupational Safety and Health (NIOSH) B reader Program. Access online for more information on interpretation of X-rays for silicosis and

a list of certified B-readers. *http://www.cdc.gov/niosh/topics/chestradiography/breader-info.html*

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Occupational Health Program for Exposure to Crystalline Silica in the Industrial Sand Industry. National Industrial Sand Association, 2nd ed. 2010.

Rees D, Murray J. Silica, silicosis and tuberculosis. Int J Tuberc Lung Dis 11(5):474–484.

Screening and Surveillance of workers exposed to mineral dust; Gregory R Wagner, Director, Division of Respiratory Diseases, NIOSH, Morgantown, WV, U.S.A.; WHO, Geneva 1996.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Georgia Rockcress; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2013–0030; 4500030113]

RIN 1018–AZ55

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Georgia Rockcress

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to designate critical habitat for *Arabis georgiana* (Georgia rockcress) under the Endangered Species Act of 1973, as amended (Act). In total, we propose to designate as critical habitat approximately 323 hectares (786 acres) of riparian, river bluff habitat for this species. The intended effect of this rule is to conserve Georgia rockcress and its habitat under the Act. The proposed critical habitat is located in Georgia, including parts of Gordon, Floyd, Harris, Muscogee, Chattahoochee, and Clay Counties, and in Alabama, including parts of Bibb, Dallas, Elmore, Monroe, Russell, Sumter, and Wilcox Counties.

DATES: We will accept comments received or postmarked on or before November 12, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by October 28, 2013.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R4–ES–2013–0030, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2013–0030; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Information Requested section below for more information).

The coordinates or plot points or both from which the critical habitat maps are generated are included in the administrative record for this rulemaking and are available at *http://www.fws.gov/athens/, http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0030, and at the Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we may develop for this rulemaking will also be available at the Fish and Wildlife Service Web site and Field Office set out above, and may also be included in the preamble and/or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sandy Tucker, Field Supervisor, U.S. Fish and Wildlife Service, 105 Westpark Dr., Suite D, Athens, GA 30606; telephone 706–613–9493; facsimile 706–613–6059. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION: We will refer to *Arabis georgiana* by its common name, Georgia rockcress, in this proposed rule.

Executive Summary

Why we need to publish a rule. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Designations and revisions of critical habitat can only be completed by issuing a rule in the **Federal Register**. Elsewhere in today's **Federal Register**, we propose to list Georgia rockcress as threatened under the Act.

This rule proposes to designate critical habitat for Georgia rockcress. In total, we propose to designate as critical habitat approximately 323 hectares (786 acres) of riparian, river bluff habitat for the species. The proposed critical habitat is located in Georgia, including parts of Gordon, Floyd, Harris, Muscogee, Chattahoochee, and Clay Counties, and in Alabama, including parts of Bibb, Dallas, Elmore, Monroe, Russell, Sumter, and Wilcox Counties.

The basis for our action. Under the Act, if we intend to list a species as endangered or threatened throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** to list the species as endangered or threatened and make a determination on our proposal within 1 year. We are also required under the Act to designate critical habitat, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act concurrently with listing.

We will seek peer review. We are seeking comments from knowledgeable individuals with scientific expertise to review our analysis of the best available science and application of that science and to provide any additional scientific information to improve this proposed rule. Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act, including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat is not prudent.

(2) Specific information on:

(a) The amount and distribution of Georgia rockcress and its habitat;

(b) What areas, that are occupied at the time of listing (i.e., currently occupied) and that contain features essential to the conservation of the species, should be included in the designation and why; and

(c) What areas not occupied at the time of listing (i.e., currently not occupied) are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the areas occupied by the species or proposed to be designated as critical habitat, and

possible impacts of these activities on this species and proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the Georgia rockcress and proposed critical habitat.

(5) Any foreseeable economic, national security, or other relevant impacts that may result from designating any area that may be included in the final designation. We are particularly interested in any impacts on small entities, and the benefits of including or excluding areas from the proposed designation that are subject to these impacts.

(6) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(7) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Ecological Services Office in Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**).

Previous Federal Actions

For information on previous Federal actions concerning Georgia rockcress, refer to the proposal to list Georgia rockcress as a threatened species under the Act, which appears elsewhere in today's **Federal Register**.

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographic area occupied by the species at the time it is listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical and biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are the elements of physical or biological features that, when laid out in the appropriate quantity and spatial arrangement to provide for a species' life-history processes, are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographic area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation. We designate critical habitat in areas outside the geographic area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data

available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of a listed species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions of section 9 of the Act if actions occurring in these areas may affect the species. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools continue to contribute to recovery of the listed species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist:

(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species; or

(2) Such designation of critical habitat would not be beneficial to the species.

There is currently no imminent threat of take attributed to collection or vandalism for this species (see the proposed listing rule, which appears elsewhere in today's **Federal Register**), and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, then a prudent finding is warranted. Here, the potential benefits of designation include: (1) Triggering consultation under section 7 of the Act, in new areas for actions in which there may be a Federal nexus where it would not otherwise occur because, for example, it is or has become unoccupied or the occupancy is in question; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or to private entities; and (4) preventing people from causing inadvertent harm to the species. Therefore, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we find that designation of critical habitat is prudent for Georgia rockcress.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act, we must find whether critical habitat for Georgia rockcress is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where the species is located. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for Georgia rockcress.

Physical or Biological Features

In accordance with sections 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographic area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographic, and ecological distributions of a species.

We derive the specific physical or biological features required for Georgia rockcress from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the proposed listing rule published elsewhere in today's **Federal Register**.

Space for Individual and Population Growth and for Normal Behavior

Georgia rockcress is known from the Lower Gulf Coastal Plain, Upper Gulf Coastal Plain, Red Hills, Black Belt, Piedmont, and the Ridge and Valley Physiographic Provinces (Schotz 2010, p. 6; Allison 1995, p. 6), generally occurring within regions underlain or otherwise influenced by sandstone, granite, and limestone (Moffett 2007, p. 1; Schotz 2010, p. 6). This species occurs on soils that are circumneutral to slightly basic (or buffered) and is primarily associated with high bluffs along major river courses, with dry-mesic to mesic soils of open, rocky, woodland and forested slopes,

including shallow soil accumulations on rocky bluffs, ecotones of sloping rock outcrops, and sandy loam along eroding riverbanks (Moffett 2007, p. 1; Schotz 2010, p. 6). The habitat supports a relatively closed to open canopy of deciduous trees with a rich diversity of grasses and forbs characterizing the herb layer (Schotz 2010, p. iii). Therefore, we identify well-drained soils that are buffered or circumneutral to be a physical or biological feature for this species.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Georgia rockcress generally occurs on steep river bluffs often with shallow soils overlaying rock or with exposed rock outcroppings. These edaphic conditions result in micro-disturbances, such as sloughing soils with limited accumulation of leaf litter or canopy gap dynamics, possibly with wind-thrown trees, which provide small patches of exposed mineral soil in a patchy distribution across the river bluff (Schotz 2010, p. 6). Georgia rockcress is a poor competitor (Alison 1995, p. 8; Moffett 2007, p. 4; Schotz 2010 p. 9); therefore, small-scale disturbances are critical for this species. Exposed mineral soil provides for seed to soil contact for good germination and allows Georgia rockcress to occupy habitat with limited competition for light, mineral, and water resources. Therefore, we identify large river bluffs with steep slopes and/or shallow soils that are subject to localized disturbances to be a physical or biological feature for this species.

Cover, Shelter, and Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Georgia rockcress generally occurs at sites with a substantial, mixed-level canopy with spatial heterogeneity, which provides for mixed sunlight and shade throughout the day and impedes invasive species. The habitat supports a relatively closed to open canopy of *Juniperus virginiana* (eastern red cedar), *Ostrya virginiana* (American hophornbeam), *Quercus muehlenbergii (*chinquapin oak), *Fraxinus americana* (white ash), *Acer barbatum* (southern sugar maple), and *Cercis canadensis* (eastern redbud) with a rich diversity of grasses and forbs characterizing the herb layer (Schotz 2010, p. iii). Georgia rockcress generally occurs on sites with a mature canopy providing partial shading (Moffett 2007, p. 4). Although Georgia rockcress can survive deep shade primarily as a vegetative rosette without flowering or fruiting (Alison 1995, p. 7; Moffett 2007, p. 4; Schotz 2010, p. 10), it cannot reproduce in heavily shaded conditions. It is often the mature trees grown on shallow soils that are subject to wind throw. Therefore, we identify a mature, mixed-level canopy with spatial heterogeneity to be a physical or biological feature for this species.

Habitats Protected From Disturbance or Representative of the Historical, Geographic, and Ecological Distributions of the Species

While Georgia rockcress needs small-scale disturbances to exploit, the species is a poor competitor and is easily outcompeted by aggressive competitors. Natural large-scale disturbances, such as fire and catastrophic flooding, are unlikely to occur on the steep river bluffs occupied by Georgia rockcress. Edge effects may penetrate as far as 175 meters (m) (574 feet (ft)), resulting in changes in community composition (Gehlhausen et al. 2000, p. 21). Aspect is an important factor in determining how forest microclimate and vegetation are influenced by the external environment (Gehlhausen et al. 2000, p. 30) and likely plays an important role on bluff habitat inhabited by Georgia rockcress. Edge effects are reduced by a protective vegetative border with buffers eliminating most microhabitat edge effects (see the proposed listing rule, which appears elsewhere in today's **Federal Register**) (Honu and Gibson 2006, p. 255; Gehlhausen et al. 2000, p. 32). Management strategies for the control of invasive plants should encourage canopy closure of greater than 85 percent for forested stands (Honu and Gibson 2006, p. 255). Therefore, we identify the intact habitat that is buffered to impede the invasion of nonnatives to be a physical or biological feature for this species.

Primary Constituent Elements for Georgia Rockcress

According to 50 CFR 424.12(b), we are required to identify the physical or biological features essential to the conservation of Georgia rockcress in areas occupied at the time of listing, focusing on the features' primary constituent elements. We consider primary constituent elements to be the elements of physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

The proposed critical habitat is designed to provide sufficient habitat to maintain self-sustaining populations of Georgia rockcress. We believe the conservation of Georgia rockcress is dependent upon the protection and management of sites where existing populations grow, and the maintenance of normal ecological functions within these sites. Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the primary constituent elements specific to Georgia rockcress are:

(1) Large river bluffs with steep and/or shallow soils that are subject to localized disturbances that limit the accumulation of leaf litter and competition within the Lower Gulf Coastal Plain, Upper Gulf Coastal Plain, Red Hills, Black Belt, Piedmont, and Ridge and Valley Physiographic Provinces of Georgia and Alabama.

(2) Well-drained soils that are buffered or circumneutral generally within regions underlain or otherwise influenced by granite, sandstone, or limestone.

(3) A mature, mixed-level canopy with spatial heterogeneity, providing mottled shade and often including species such as eastern red cedar, America hophornbeam, chinquapin oak, white ash, southern sugar maple, and redbud with a rich diversity of grasses and forbs characterizing the herb layer.

(4) Intact habitat with mature canopy and discrete disturbances, buffered by surrounding habitat to impede the invasion of competitors.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographic area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. A fully functioning bluff habitat (i.e., with mature canopy and discrete disturbances) is required to provide the features essential to the conservation of this species and may require special management considerations or protection to reduce the following threats: Land-clearing activities that alter the canopy, including silvicultural management, building of utility lines, structures, roads or bridges; construction of reservoirs that inundate habitat; mining activities; or introduction of invasive species that compete directly with Georgia rockcress. Large-scale disturbances, such as fire or soil-disturbing activities, should be minimized. A mature canopy with spatial heterogeneity should be maintained to impede invasive species while providing an opportunity for localized disturbances as canopy-gap dynamics develop. Invasive species

should be eliminated from the critical habitat units. A mature canopy on the bluffs and a surrounding buffer area will help to exclude nonnatives.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b) we review available information pertaining to the habitat requirements of the species and identify occupied areas at the time of listing that contain the features essential to the conservation of the species. If after identifying currently occupied areas, a determination is made that those areas are inadequate to ensure conservation of the species, in accordance with the Act and our implementing regulations at 50 CFR 424.12(e) we then consider whether designating additional areas—outside those currently occupied—are essential for the conservation of the species. We are not currently proposing to designate any areas outside the geographical area occupied by the species because occupied areas are sufficient for the conservation of the species. The 18 proposed critical habitat units capture populations across the known range of the species, providing conservation in five different physiographic provinces in three different river drainages. This effectively protects against the loss of one of the three genetic groups and provides for the expansion of all known genetic groups in each physiographic province. Therefore, we are not currently proposing to designate any areas outside the geographic area occupied by the species.

In preparing this proposed rule, we reviewed and summarized the current information available on Georgia rockcress; the information used includes known locations, our own site-specific species and habitat information, Statewide Geographic Information System (GIS) coverages (e.g., soils, geologic formations, and elevation contours), the Natural Resources Conservation Service's soil surveys, recent biological surveys and reports, peer-reviewed literature, and discussions and recommendations from Georgia rockcress experts.

As discussed below, when determining proposed critical habitat boundaries we made every effort to avoid including developed areas such as lands covered by water, buildings, pavement, and other structures because such lands lack physical or biological features for Georgia rockcress. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We propose to designate critical habitat on lands that we have determined are occupied at the time of listing and contain sufficient elements of physical or biological features to support life-history processes essential for the conservation of the species. Specifically, we are proposing 18 units for designation based on the presence of sufficient elements of physical or biological features to support Georgia rockcress's life-history processes. All of the proposed units contain all of the identified elements of physical or biological features and support all of the life-history processes, at least in the majority of the unit.

We considered several factors in the selection and proposal of specific areas as critical habitat for Georgia rockcress. This especially included the protection of populations throughout the species' range in Georgia and Alabama. Given the extremely small number of total plants (fewer than 5,000 in a given year, 12 of the 18 populations have fewer than 50 plants (Schotz 2010, p. iii; Elmore 2010, pp. 1–4; Moffett 2007, pp. 2–7; Alison 1999, pp. 1–5; Alison 1995, pp. 7–18)), distributed as disjunct populations across five physiographic provinces (Schotz 2010, pp. 9–10; Moffett 2007, pp. 2–7; Alison 1995, pp. 7–18) in three major river systems with each genetically important to the conservation of the species (Garcia 2012, pp. 30–36), we consider all of the known populations located on major river bluffs to be critical habitat for Georgia rockcress. In order to decrease the probability of loss of genetic diversity, extant populations need to be distributed across the range of the species and across all five physiographic provinces.

Our approach to delineating specific proposed critical habitat units focused first on considering all areas of suitable habitat within the geographic distribution of this species and the known locations of the extant and historical populations. We evaluated field data collected from documented occurrences, various GIS layers, soil surveys, and United States Geological Survey (USGS) quadrangle maps. These data include Georgia rockcress locations, soils, elevation, topography, geologic formations, streams, and current land uses.

In this way, we determined that 18 populations are essential to the conservation of Georgia rockcress. We then used site-specific information to determine the extent of these populations. The proposed critical habitat units were then delineated by screen-digitizing polygons (map units) using ArcView, a computer GIS program. We buffered known populations to maintain intact habitat that would be resistant to invasive species and would provide suitable habitat for expansion of the population when appropriate small-scale disturbances occur. Edges function as sources of propagules for disturbed habitats and represent complex environmental gradients with changes in light availability, temperature, humidity, wind speed, and soil moisture, with plant species responding directly to environmental changes (Meiners et al. 1999, p. 261). Edge effects, including canopy break due to timber harvest, fields, or maintained rights-of-way, may penetrate from 30 m (98 ft) to 175 m (574 ft), resulting in changes in community composition. Nonnatives may invade 30 to 120 m (394 ft), with the greatest prevalence of nonnatives occurring between 10 meters (33 feet) and 30 meters (Honu and Gibson 2006, p. 264; Forman 2002, p. 95; Gehlhausen et al. 2000, p. 21; Meiners et al. 1999, p. 266; Fraver 1994, p. 830). While Gehlhausen (2000, p. 32), suggesting that a protective vegetative buffer strip would eliminate edge effect. Honu and Gibson (2006, p. 264) suggested that a buffer of at least 50 m (164 ft) eliminates most edge effects.

In selecting an area to include as proposed critical habitat, we started from known occurrences and then selected a minimum distance needed to capture sufficient bluff habitat to provide opportunities for plants to migrate across the bluff habitat to take advantage of localized disturbances and to provide a reasonable measure of protection from nonnatives. To capture sufficient bluff habitat vertically (up and down slope) from the river edge to the top of the slope, we buffered known occurrences 76 m (250 ft) up and down slope, because we found that this distance captures most of the physical and biological features of critical habitat, as well as providing a buffer

against nonnatives that will at least exclude the high prevalence range (area most likely to result in invasion by nonnatives), as described by Honu and Gibson (2006, p. 264).

However, the vertical buffering alone does not provide sufficient habitat for plants to migrate across the bluff. Therefore, in the lateral direction along the river, we added an additional distance around occurrences of up to 305 m (1,000 ft). This buffer captures sufficient bluff habitat to provide opportunity for plants to take advantage of localized disturbances.

Based on the known plant distribution, we placed boundaries around the populations that included the plants, as well as their primary constituent elements. We used UTM zone 16N/North American Datum 1983 (NAD 83) coordinates to delineate the boundaries of the proposed critical habitat. In defining these critical habitat boundaries, we made an effort to exclude all developed areas, such as housing developments, open areas, rivers (or lakes), and other lands unlikely to contain the primary constituent elements essential for the conservation of Georgia rockcress. We then evaluated the topography, soils, geology, and canopy cover to identify intact habitat that could buffer against invasive species and provide habitat for future populations. In most cases, habitat that was lacking the primary constituent elements was deemed unsuitable and is not included in the proposed critical habitat polygon. We removed areas from the proposed designated area if they are in the water, had been clear cut, had been converted to pasture, had been converted to a road, had a structure built on them, or had been used as a quarry. We include utility line rights-of-ways because Georgia rockcress will persist in this habitat. While the removal of the canopy for a right-of-way makes the habitat receptive to nonnatives, the ongoing mowing keeps nonnatives from outcompeting Georgia rockcress and allows this species to persist. Starting from the polygon or point data of a Georgia rockcress location and moving down slope, the proposed critical habitat area generally ends at the water's edge.

The 18 units in this proposed designation include the geographic spread of the entire historical range of the species. All proposed units contain the primary constituent elements essential for the conservation of Georgia rockcress (see ''Primary Constituent Elements for Georgia Rockcress,'' above). The omission of historically occupied sites and the rest of the currently occupied sites from this proposed critical habitat designation does not diminish their individual or cumulative importance to the species. Rather, it is our determination that the habitat contained within the 18 units included in this proposed rule constitutes our best determination of areas essential for the conservation, and eventual recovery, of Georgia rockcress. The 18 units we are proposing as critical habitat encompass approximately 323 hectares (ha) (786 acres (ac)) in Georgia and Alabama.

To the extent feasible, we will continue, with the assistance of other Federal, State, and private researchers, to conduct surveys, research, and conservation actions on the species and its habitat in areas that may be designated and not designated as critical habitat. If additional information becomes available on the species' biology, distribution, and threats, we would evaluate the need to designate additional critical habitat, delete or reduce critical habitat, or refine the boundaries of critical habitat. If the species is listed (see the proposed listing rule, which appears elsewhere in today's **Federal Register**), sites that are occupied by this plant that are not being proposed for critical habitat would continue to receive protection under the Act's section 7 jeopardy standard where a Federal nexus may occur.

Proposed Critical Habitat Designation

The 18 areas we propose as critical habitat are numbered and provided in Table 1 below. All of the proposed areas are occupied. Except as noted, all of the units contain all of the PCEs and require special management consideration or protection to address the threats (see discussion above) and to ensure their contribution to the conservation of Georgia rockcress. Unit names were derived from reports generated from previous survey efforts (Schotz 2010, pp. 20–57; Moffett 2007, pp. 5–8; Allison 1999, pp. 3–8; Allison 1995, pp. 18–28), to promote continuity with monitoring efforts.

TABLE 1—PROPOSED CRITICAL HABITAT UNITS FOR GEORGIA ROCKCRESS

[Area estimates reflect all land within critical habitat unit boundaries]

Unit No.	Unit name	County/State	Ownership	Hectares	Acres
1	Fort Tombecbee	Sumter/AL	State	6	14
2	Marshalls Bluff	Monroe/AL	Private	11	27
3	Prairie Bluff	Wilcox/AL	Private	13	32
4	Portland Landing River Slopes	Dallas/AL	Private	12	31
5	Durant Bend	Dallas/AL	Private	12	28
6	Murphys Bluff Bridge Cahaba River	Bibb/AL	Private	11	26
7A	Creekside Glades	Bibb/AL	Private	12	29
7B	Little Schulz Creek	Bibb/AL	Private	12	28
8A	Cottingham Creek Bluff	Bibb/AL	Private	22	55
8B	Pratts Ferry	Bibb/AL	Private	11	28
9A	Fern Glade	Bibb/AL	Federal	14	34
9B	Sixmile Creek	Bibb/AL	Private	13	21
10A	Browns Dam Glade North	Bibb/AL	Private	14	35
10B	Browns Dam Glade South	Bibb/AL	Private	15	37
11	McGuire Ford | Limestone Park	Bibb/AL	Private	6	15
12	Fort Toulouse State Park	Elmore/AL	State	7	17
13	Fort Gaines Bluff	Clay/GA	Private	17	42
14A	Fort Benning (GA)	Chattahoochee/GA	Federal	14	35
14B	Fort Benning (AL)	Russell/AL	Federal	11	26
15A	Goat Rock North	Harris/GA	Private	7	19
15B	Goat Rock South	Harris, Muscogee/GA	Private	24	59
16	Blacks Bluff Preserve	Floyd/GA	Private	37	92
17	Whitmore Bluff	Floyd/GA	Private	17	43

TABLE 1—PROPOSED CRITICAL HABITAT UNITS FOR GEORGIA ROCKCRESS—Continued

[Area estimates reflect all land within critical habitat unit boundaries]

Unit No.	Unit name	County/State	Ownership	Hectares	Acres
18	Resaca Bluffs	Gordon/GA	Private	5	13
Total				323	786

Note: Area sizes may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for Georgia rockcress, below.

Critical Habitat Unit Descriptions

We are proposing a total of 18 critical habitat units for Georgia rockcress located in Georgia, including parts of Chattahoochee, Clay, Floyd, Gordon, Harris, and Muscogee Counties, and in Alabama, including parts of Bibb, Dallas, Elmore, Monroe, Russell, Wilcox, and Sumter Counties. Each proposed critical habitat unit contains all of the PCEs and can accommodate all of the life stages of this species. In order to provide determinable legal descriptions of the critical habitat boundaries, we drew polygons around these units, using as criteria the plant's primary constituent elements, the known extent of the populations, and the elevation contours on the map. We made an effort to avoid developed areas that are unlikely to contribute to the conservation of Georgia rockcress. Areas within the boundaries of the mapped units, such as buildings, roads, clearings, lawns, and other urban landscaped areas, do not contain one or more of the primary constituent elements. As such, Federal actions limited to these areas would not trigger consultation under section 7 of the Act, unless they affect the species or its primary constituent elements in the critical habitat.

Unit 1. Fort Tombecbee, Sumter County, Alabama

The 6 ha (14 ac) Fort Tombecbee unit is approximately 0.5 kilometers (km) (0.3 miles (mi)) northeast of the city of Epes, Alabama, and is owned by the University of West Alabama. This Georgia rockcress occurrence inhabits the crest and steep slopes of a deeply-incised stream bank overlooking a small intermittent creek approximately 91 m (300 ft) upstream from its confluence with the Tombigbee River. Livestock grazing was observed during a visit made in May 2010, in a portion of the site where the species was previously observed; it is conceivable that livestock may have further impacted the occurrence. Only four plants were found in 2010 (Schotz 2010, p. 51). The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with road crossings and development.

Unit 2. Marshalls Bluff, Monroe County, Alabama

The 11-ha (27-ac) Marshall Bluff unit is a privately owned tract 9.6 km (6 mi) southwest of Perdue Hill, Alabama, on the eastern bank of the Alabama River on a high bluff (Marshalls Bluff) overlooking the Alabama River. An abandoned quarry exists approximately 150 m (500 ft) distant to the east, and while the quarry may have destroyed bluff habitat, the quarry currently poses no threat to the occurrence, and there are no plans to expand the quarry (Schotz 2010, p. 22). More than 400 plants were found in 2010. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with mining.

Unit 3. Prairie Bluff, Wilcox County, Alabama

Privately owned, the 13-ha (32-ac) Prairie Bluff unit is located along the banks of the Millers Ferry (William ''Bill'' Dannelly) Reservoir, approximately 1.6 km (1 mi) north of the Lee Long Bridge on State Route 28. Georgia rockcress is scattered along the bluffs and ravines associated with the Alabama River. Nonnative species, most notably *Ligustrum sinense* (Chinese privet) and *Lonicera japonica* (Japanese honeysuckle), threaten this site (Alison 1999, p. 2; Schotz 2010, pp. 54–55). More than 500 plants were found in this unit in 2010; however, some habitat was likely inundated by the reservoir. This site is slated for residential development with lakeside lots, and the infestation of nonnatives will likely become worse. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with roads, development, hydropower, and nonnative species.

Unit 4. Portland Landing River Slopes, Dallas County, Alabama

Privately owned, the 12-ha (31-ac) Portland Landing River Slopes unit is located 18 km (11.5 mi) south of Orrville, Alabama, on the south side of the Alabama River at Portland Landing. This occurrence of Georgia rockcress is restricted to the unstable, highly erodible, sandy soils along the bank of the Alabama River. Nonnatives most notably *Melia azedarach* (Chinaberry or bead-tree), Japanese honeysuckle, and *Pueraria montana* var. *lobata* (kudzu) are present, and although not severe, these nonnatives will persist without active management (Schotz 2010, p. 40). In 2010, 498 Georgia rockcress plants were recorded (Schotz 2010, p. 40). The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with timber harvest, hydropower, and nonnative species.

Unit 5. Durant Bend, Dallas County, Alabama

Privately owned, the 12-ha (28-ac) Durant Bend unit occurs 16 km (10 mi.) east of Selma in a sharp bend on the Alabama River. Fewer than 50 plants were reported in sandy alluvium along the Alabama River under a partially open to filtered canopy in 2010 (Schotz 2010, p. 37). While the majority of plants occur in forested conditions, a small number of plants were observed in relatively open and exposed soils of actively eroding sections of the riverbank. Nonnatives, including Chinese privet and Japanese honeysuckle, are present but not severe. Timber harvesting has recently taken place approximately 46 m (150 ft) north of the site, but it currently has not impacted species' viability or habitat integrity (Schotz 2010, p. 37). The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with timber harvest and nonnative species.

Unit 6. Murphys Bluff Bridge Cahaba River, Bibb County, Alabama

Privately owned, the 11-ha (26-ac) Murphys Bluff Bridge Cahaba River unit is 11.4 km (7 mi) southwest of Centreville, Alabama, and located along the west bank of the Cahaba River downstream (southwest) of the Murphy Road Bridge. Chinese privet, Japanese honeysuckle, and other nonnatives are present, but are relatively sparse. Infestation of nonnative plants could worsen. Timber harvesting has been observed nearby and may pose a potential concern (Schotz 2010, p. 22). Sixteen Georgia rockcress plants were found at this location during the 2010 survey. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with road crossings and nonnative species.

Unit 7A. Creekside Glades, Bibb County, Alabama

Privately owned, the 12-ha (29-ac) Creekside Glades subunit is located 9.6 km (6 mi) north-northeast of Centreville, Alabama, along the banks of Little Schultz Creek. Georgia rockcress occurs in association with a small dolomite glades complex on either side of Little Schultz Creek. The plants (mostly rosettes, i.e., non-reproductive) predominantly occur in the ecotone of the glades and the encompassing woodland, in association with a mix of shrubs and low-growing trees. A smaller number of individuals (mostly mature) can be found in the glades and surrounding woodlands (Alison 1999, p. 2; Schotz 2010, p. 30). This subunit contained 42 plants in 2010. A utility line right-of-way passes through this subunit, and while there is no canopy on the right-of-way, it provides essential supporting habitat such that the right-of-way has not been excluded from critical habitat. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with development and utility right-of-way maintenance.

Unit 7B. Little Schulz Creek, Bibb County, Alabama

Privately owned, the 12-ha (28-ac) Little Schulz Creek subunit is located 8.9 km (5.5 mi) north-northeast of Centreville, Alabama. In 2010, 29 plants occurred on limestone outcrops along the west bank of the Cahaba River. The site is characterized as a bouldery limestone woodland situated along a low bluff overlooking the Cahaba River. Georgia rockcress inhabits shallow soils associated with the bluff, occurring under an open to lightly shaded canopy (Schotz 2010, p. 32). This subunit consisted of 29 plants in 2010. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with development and utility right-of-way maintenance.

Unit 8A. Cottingham Creek Bluff and Unit 8B. Pratts Ferry, Bibb County, Alabama

Privately owned, the Cottingham Creek Bluff subunit is located on the east side of the Cahaba River, upstream of Pratts Ferry Bridge, 10 km (6.2 mi) northeast of Centreville, Alabama. The Pratts Ferry subunit is located on the west side of the Cahaba River, downstream of Pratts Ferry Bridge, 10 km (6.2 mi) northeast of Centreville, Alabama. A small portion (26 percent (5.88 ha (14.5 ac)) of the Cottingham Creek Bluff subunit is owned by The Nature Conservancy (TNC). A small number of plants are confined to an abandoned limestone quarry several hundred feet back from the southeastern side of the river's edge. Chinese privet and Japanese honeysuckle impact this site, particularly in the vicinity of the abandoned quarry. Nonnatives could become worse. Timber harvesting is of potential concern in an area adjacent to the population on the west side of the Cahaba River, which was selectively logged in the 1990s (Alison 1999, p. 3; Schotz 2010, pp. 34–35). Subunit 8A is 22 ha (55 ac), and subunit 8B is 11 ha (28 ac). In 2010, these two units together contained 299 Georgia rockcress plants. The physical or biological features essential to the conservation of the species in these subunits may require special management considerations or protection to address threats associated with road crossings, timber harvest, and nonnative species.

Unit 9A. Fern Glade, Bibb County Alabama

The 14-ha (34-ac) Fern Glade subunit is centered near the confluence of the Little Cahaba River and Sixmile Creek approximately 14.2 km (8.9 mi) northeast of Centreville, Alabama. Twelve percent of the Fern Glade subunit (4.2 ha (1.7 ac)) is owned by TNC, and 79 percent (10.9 ha (27 ac)) of this subunit is part of the Cahaba National Wildlife Refuge. A moderate incursion of invasive Chinese privet and Japanese honeysuckle occurs at this site. Nonnatives will likely become worse (Alison 1999, p. 3; Schotz 2010, p. 26). A small glade on the north side of the Little Cahaba River had 81 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with timber harvest and nonnative species.

Unit 9B. Sixmile Creek, Bibb County, Alabama

Privately owned, the Sixmile Creek subunit is located 13.7 km (8.5 mi) northeast of Centreville, 0.8 km (0.5 mi) upstream on Sixmile Creek from its confluence with the Little Cahaba River. The majority of this subunit (96.6 percent or 8.2 ha (20.3 ac)) is proposed for acquisition by TNC in 2013. This population of Georgia rockcress is on the west side of Sixmile Creek. In a relatively isolated site, Georgia rockcress occupies the upper slope and summit of a steep forested bluff overlooking Sixmile Creek. This 13-ha (21 ac) subunit had 59 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with timber harvest and nonnative species.

Unit 10A. Browns Dam Glade and Unit 10B. Browns Dam Glade 2, Bibb County, Alabama

Privately owned, the Browns Dam Glade subunits are located 15.8 km (9.8 mi) northeast of Centreville, Alabama, on both sides of the Little Cahaba River. Subunit 10A is on the north side of the river, and subunit 10B is in a sharp bend on the south side of the River. More than 96 percent of subunit 10A (13.7 ha (33.8 ac)) and all of subunit 10B are owned by TNC. A combination of open woodland and dolomitic glades characterize the site. An infestation of nonnatives, most notably Chinese privet, occurs at this unit. This site serves as a primitive recreation area for local residents, resulting in some trash disposal and the construction of fire pits (Alison 1999, p. 5; Schotz 2010, pp. 24–25). Subunits 10A and 10B are 14 ha (35 ac) and 15 ha (37 ac), respectively. A complex of dolomitic glades and associated woodlands along both sides of the Little Cahaba River contained 71 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in these subunits may require special management considerations or

protection to address threats associated with nonnative species.

Unit 11. McGuire Ford/Limestone Park, Bibb County, Alabama

Privately owned, the McGuire Ford/Limestone Park unit is located 18.7 km (11.6 mi) northeast of Centreville, Alabama, on the southeast side of the Little Cahaba River. A small number of plants occupy shallow soils of low, rocky limestone outcrops along the Little Cahaba River under a lightly shaded canopy of eastern red cedar, chinquapin oak, white ash, Southern sugar maple, and redbud, among others (Alison 1999, p. 5; Schotz 2010, p. 20). This 6-ha (15-ac) unit contained 50 Georgia rockcress plants during the 2010 survey. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with roads, development, and maintenance of a field.

Unit 12. Fort Toulouse State Park, Elmore County, Alabama

State-owned, the Fort Toulouse State Park unit is located 16 km (10 mi) north of Montgomery, Alabama, on the south side of the Coosa River. Georgia rockcress is widely scattered along the bluffs overlooking the Coosa River, primarily occupying mesic, sandy soils of upper slopes and crest. Japanese honeysuckle is beginning to severely impact many areas of the site (Alison 1999, p. 2; Schotz 2010, p. 42). This 7-ha (17-ac) unit contained 47 Georgia rockcress plants during the 2010 survey. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with maintenance of a field and nonnative species.

Unit 13. Fort Gaines Bluff, Clay County, Georgia

Privately owned, the Fort Gaines Bluff unit is located 1.5 km (0.9 mi) south of Fort Gaines, Georgia, on the Chattahoochee River. This high, steep, eroding river bank has sandy loam soils and an intact hardwood overstory. Japanese honeysuckle has become severe over much of area (Alison 1995, pp. 18–29; Moffett 2007, p. 9). This 17-ha (43-ac) unit contained 84 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with timber harvest and nonnative species.

Unit 14A. Fort Benning (GA), Chattahoochee County, Georgia

Federally owned, the Fort Benning (GA) subunit is 17.9 km (11.1 mi) south of Columbus, Georgia, on the Chattahoochee River, near its confluence with Oswichee Creek. The plants occupy the bluff and associated steep forested slopes along the Chattahoochee River, where they inhabit loamy, sandy soils under a partially open to filtered canopy of various hardwoods. Japanese honeysuckle is adversely affecting this site with an infestation of autumn olive (*Elaeagnus umbellata*) in the woodland habitat on top of the bluff (Alison 1995, pp. 19–20; Allison 1999, p. 1; Moffett 2007, pp. 5–9; Elmore 2010, pp. 1–3). Fort Benning has not completed an integrated natural resources management plan (INRMP) that addresses this species or its habitat (see Exemptions, below, for more details). This 14-ha (35-ac) subunit contained more than 850 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with nonnative species.

Unit 14B. Fort Benning (AL), Russell County, Alabama

Federally owned, the Fort Benning (AL) subunit is 21 km (13 mi) south of Columbus, Georgia, on the Chattahoochee River, across from the confluence of Red Mill Creek. An exceptionally vigorous occurrence, the site contains the greatest number of plants of any site in Alabama, and likely represents one of the highest quality examples known for the species rangewide. The plants occupy the bluff and associated steep forested slopes along the Chattahoochee River with loamy, sandy soils under a partially open to filtered canopy of various hardwoods. Japanese honeysuckle and Chinese privet are adversely affecting this site (Alison 1999, p. 1; Moffett 2007, pp. 5–9; Elmore 2010, pp. 1–3; Schotz 2010, pp. 48–49). This 11-ha (26-ac) subunit contained more than 800 Georgia rockcress plants in 2010. The physical or biological features essential to the conservation of the species in this subunit may require special management considerations or protection to address threats associated with roads and nonnative species.

Unit 15A. Goat Rock North and Unit 15B. Goat Rock South, Harris and Muscogee Counties, Georgia

Privately owned, the Goat Rock Dam is 18.5 km (11.5 mi) north of Columbus Georgia. The Goat Rock North subunit is immediately north of Goat Rock Dam on the banks of Goat Rock impoundment, while the Goat Rock South subunit is immediately downstream of Goat Rock Dam along the high bluffs overlooking the Chattahoochee River. All of Goat Rock North subunit and the majority of the Goat Rock South subunit are owned by a cooperation that supports conservation efforts for Georgia rockcress. The corporately owned property is provided modest protection in the shoreline management plan, which was developed during Federal Energy Regulatory Commission (FERC) licensing (FERC 2004, pp.29–30). However, the southernmost portion of the Goat Rock South subunit is privately owned. This high rocky bluff is mostly covered by a mature canopy of trees. A narrow portion of this habitat has a transmission line passing over the top where all woody species have been removed; however, Georgia rockcress plants are scattered in the transmission line right-of-way. This area contains PCEs 1 and 2. Nonnative species, including Chinese privet and Japanese honeysuckle, have severely impacted this site (Alison 1995, pp. 24–27; Moffett 2007, pp. 6–9). Conservation actions here have included invasive species/woody competition removal (both manually and chemically) to benefit existing Georgia rockcress plants, and prescribed burning to open up new adjacent sites for outplanting enhancement. The Chattahoochee Nature Center (CNC) outplanted approximately 300 Georgia rockcress plants of the Goat Rock genotype at this site in 2008. The local office of TNC has also expressed interest in possibly including this site in their long-range ecosystem planning (Elmore 2010, pp. 1–3). Subunits 15A and 15 B are 7 ha (19 ac) and 24 ha (59 ac), respectively. In 2007, approximately 1,000 Georgia rockcress plants were found scattered across these subunits. The physical or biological features essential to the conservation of the species in these subunits may require special management considerations or protection to address threats associated with hydropower, utility line maintenance, and nonnative species.

Unit 16. Blacks Bluff Preserve, Floyd County, Georgia

Privately owned, the 37 ha (92 ac) Blacks Bluff Preserve unit is located 6.5

km (4.0 mi) southwest of Rome, Georgia, on the Coosa River. Blacks Bluff is in private ownership with a conservation easement on the property. There were 27 Georgia rockcress plants reported on this site in 1995; however, the presence of nonnative species has since extirpated all Georgia rockcress from this site. The Georgia Plant Conservation Alliance (GPCA) and TNC agreed to bolster the existing population with plants grown from seed collected at the two nearby (Ridge and Valley physiographic province) populations, Whitmore Bluff, and Resaca Bluffs. The CNC collected seed and grew 35 plants from Whitmore Bluff and 65 plants from Resaca Bluffs. In 2008, 100 Georgia rockcress plants were planted in this unit, with 84 Georgia rockcress surveyed on this site in 2011 (Goldstrohm 2011, p. 1). This steep bluff with limestone ledges and boulders has a mature deciduous canopy. Multiple sources of disturbance, including an abandoned quarry, have impacted this site and resulted in the establishment of many nonnative species, including Japanese honeysuckle and Nepalese browntop (Alison 1995, pp. 19–20; Moffett 2007, pp. 5–9; Elmore 2010, pp. 1–3). The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with roads, mining, and nonnative species.

Unit 17. Whitmore Bluff, Floyd County, Georgia

Privately owned, the 17-ha (43-ac) Whitmore Bluff unit is located 6.5 km (4 mi) northeast of Rome, Georgia, on the east bank of the Oostanaula River. This steep bluff with limestone boulders has a mature canopy with *Ulmus alata* (winged elm), *Quercus montana* (chestnut oak), and *Fraxinus americana* (white ash), and an understory including *Hydrangea arborescens* (wild hydrangea), *Toxicodendron radicans* (poison ivy), and *Sedum ternatum* (woodland stonecrop). Japanese honeysuckle has severely impacted this site (Alison 1995, p. 21; Moffett 2007, pp. 6–9; Elmore 2010, pp. 1–3). Sixty-three rockcress plants were documented in this unit in 1995, but only 12 in 2010. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with timber harvest and nonnative species.

Unit 18. Resaca Bluffs, Gordon County, Georgia

Privately owned, the 5-ha (13-ac) Resaca Bluffs unit is located 0.8 km (0.5 mi) southwest of Resaca, Georgia, immediately east of I–75 along the northern bank of the Oostanaula River. A rocky limestone bluff with a mature canopy, including eastern red cedar, *Quercus nigra* (water oak), *Quercus velutina* (black oak), winged elm, white ash, southern sugar maple, and redbud. Nonnative species, including Chinese privet and Japanese honeysuckle, have severely impacted this site (Alison 1995, pp. 22–23; Moffett 2007, pp. 5–9; Elmore 2010, pp. 1–3). This unit contained 51 plants in 1995, and 42 in 2010. The physical or biological features essential to the conservation of the species in this unit may require special management considerations or protection to address threats associated with road crossings, development, and nonnative species.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service,* 245 F.3d 434 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect or are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for Georgia rockcress. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the Georgia rockcress. These activities include, but are not limited to:

(1) Actions that would significantly alter the canopy. Such activities could include, but are not limited to, silvicultural management, construction of utility lines, creation of pasture or maintained lawn, construction of buildings, and construction of roads or bridges. Invasive species should be precluded from the critical habitat units. A mature canopy on the bluffs and a surrounding buffer area will help to preclude nonnative and invasive species. Activities that alter the canopy could alter the natural canopy gap dynamic that provides Georgia rockcress a competitive advantage and result in direct or cumulative adverse effects to these individuals and their life cycles.

(2) Actions that would inundate habitat. Construction of a dam downstream of a critical habitat unit could result in the loss of habitat. These activities could alter the functioning bluff habitat and result in direct or cumulative adverse effects to these individuals and their life cycles.

(3) Actions that would significantly alter the soil. Such activities could include, but are not limited to, construction of roads or bridges, construction of buildings (e.g., dams, residential housing, or commercial buildings), and mining activities. These activities would permanently alter the soil that Georgia rockcress is dependent on to complete its life cycle.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) requires each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

We consult with the military on the development and implementation of INRMPs for installations with listed species. We analyzed INRMPs developed by military installations located within the range of the proposed critical habitat designation for Georgia rockcress to determine if the lands are exempt under section 4(a)(3) of the Act. In 2001, Fort Benning completed its Service-approved INRMP. The installation is currently revising its INRMP to include specific measures for the Georgia rockcress and its habitat. The revised INRMP is expected by July 2014. Therefore, we are notifying the public that this area is being considered for an exemption from the final designation based on the revised approved INRMP.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the

Secretary may exercise his discretion to exclude the area only if such exclusion would not result in the extinction of the species.

Economic Analysis

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors.

We will announce the availability of the draft economic analysis as soon as it is completed, at which time we will seek public review and comment. At that time, copies of the draft economic analysis will be available for downloading from the Internet at *http://www.regulations.gov,* or by contacting the Ecological Services Office in Athens, Georgia, directly (see **FOR FURTHER INFORMATION CONTACT**). During the development of a final designation, we will consider economic impacts, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands where a national security impact might exist. In preparing this proposal, we are considering exemption of lands owned and managed by the Department of Defense, and, therefore, we anticipate no impact on national security. Consequently, the Secretary does not intend to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether the landowners have developed any habitat conservation plans (HCPs) or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

We consider a current land management or conservation plan (HCPs as well as other types) to provide adequate management or protection if it meets the following criteria:

(1) The plan is complete and provides a conservation benefit for the species and its habitat;

(2) There is a reasonable expectation that the conservation management strategies and actions will be implemented for the foreseeable future, based on past practices, written guidance, or regulations; and

(3) The plan provides conservation strategies and measures consistent with currently accepted principles of conservation biology.

We are unaware of any plans meeting these criteria; however, we request public comment related to existing plans. At this time, we are not considering the exclusion of any areas from the proposed critical habitat for Georgia rockcress.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment during this public comment period on our specific assumptions and conclusions in this proposed designation of critical habitat.

We will consider all comments and information we receive during the comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include such businesses as

manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and forestry and logging operations with fewer than 500 employees and annual business less than $7 million. To determine whether small entities may be affected, we will consider the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Importantly, the incremental impacts of a rule must be both significant and substantial to prevent certification of the rule under the RFA and to require the preparation of an initial regulatory flexibility analysis. If a substantial number of small entities are affected by the proposed critical habitat designation, but the per-entity economic impact is not significant, the Service may certify. Likewise, if the per-entity economic impact is likely to be significant, but the number of affected entities is not substantial, the Service may also certify.

Under the RFA, as amended, and following recent court decisions, Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and not the potential impacts to indirectly affected entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried by the agency is not likely to adversely modify critical habitat. Therefore, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Under these circumstances, it is our position that only Federal action agencies would be directly regulated by this designation. Therefore, because Federal agencies are not small entities, the Service certifies that the proposed critical habitat rule, if adopted as proposed, would not have a significant economic impact on a substantial number of small entities.

In conclusion, based on our interpretation of directly regulated entities under the RFA and relevant case law, this designation of critical habitat, if adopted as proposed, would only directly regulate Federal agencies, which are not by definition small business entities. As such, we certify that, if promulgated, this designation of critical habitat will not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required. However, though not necessarily required by the RFA, in our draft economic analysis for this proposal we will consider and evaluate the potential effects to third parties that may be involved with consultations with Federal action agencies related to this action.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Two proposed subunits, 7A (Creekside Glades) and 15B (Goat Rock South), have major transmission lines passing through them. However, we do not expect the designation of this proposed critical habitat to significantly affect energy supplies, distribution, or use. The regular mowing and maintenance of these subunits will not destroy existing populations of Georgia rockcress at these sites. In fact, nonnative species will persist in these subunits, but regular mowing will prevent nonnatives from overtopping and out-competing Georgia rockcress. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments. The government-owned lands being proposed as critical habitat are owned by the State of Alabama, the Department of Defense, and the Department of the Interior. None of these government entities meets

the definition of ''small governmental jurisdiction.'' Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for Georgia rockcress in a takings implications assessment. The takings implications assessment concludes that this designation of critical habitat for Georgia rockcress does not pose significant takings implications. However, we will further evaluate this issue as we develop our final designation, and review and revise this assessment as warranted.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed critical habitat designation with appropriate State resource agencies in Alabama and Georgia. We are not currently proposing any unoccupied areas. The designation of critical habitat in areas currently occupied by the Georgia rockcress would impose no additional restrictions to those that would be put in place by listing the species and, therefore, would have little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the physical or biological features essential to the conservation of the species are more clearly defined, and the elements of the features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We propose designating critical habitat in accordance with the provisions of the Act. This proposed rule uses standard property descriptions and identifies the elements of physical or biological features essential to the conservation of the Georgia rockcress within the designated areas to assist the public in understanding the habitat needs of the species.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

We determined that there are no tribal lands that are occupied by Georgia rockcress at the time of listing that contain the features essential for conservation of the species, and no tribal lands that are unoccupied by the Georgia rockcress but are essential for the conservation of the species. Therefore, we are not proposing to designate critical habitat for the Georgia rockcress on tribal lands.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2013–0030 and upon request from the Field Supervisor, Ecological Services Office in

Athens, Georgia (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rulemaking are the staff members of the Ecological Services Office in Athens, Georgia.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

■ 2. In § 17.96, amend paragraph (a) by adding an entry for ''*Arabis georgiana* (Georgia rockcress)'' in alphabetical order under Family Brassicaceae, to read as follows:

§ 17.96 Critical habitat—plants.

(a) *Flowering plants.*

* * * * *

Family Brassicaceae: *Arabis Georgiana* (Georgia Rockcress)

(1) Critical habitat units are depicted in Georgia, including Chattahoochee, Clay, Gordon, Floyd, Harris, and Muscogee Counties, and in Alabama, including Bibb, Dallas, Elmore, Monroe, Russell, Sumter, and Wilcox Counties, on the maps below.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of *Arabis georgiana* (Georgia rockcress) consist of four components:

(i) Large river bluffs with steep and/or shallow soils that are subject to localized disturbances that limit the accumulation of leaf litter and competition within the Lower Gulf Coastal Plain, Upper Gulf Coastal Plain, Red Hills, Black Belt, Piedmont, and Ridge and Valley Physiographic Provinces of Georgia and Alabama.

(ii) Well-drained soils that are buffered or circumneutral generally within regions underlain or otherwise influenced by granite, sandstone, or limestone.

(iii) A mature, mixed-level canopy with spatial heterogeneity, providing mottled shade and often including species such as *Juniperus virginiana* (eastern red cedar), *Ostrya virginiana* (American hophornbeam), *Quercus muehlenbergii (*chinquapin oak), *Fraxinus americana* (white ash), *Acer barbatum* (southern sugar maple), and *Cercis canadensis* (eastern redbud) with a rich diversity of grasses and forbs characterizing the herb layer.

(iv) Intact habitat with mature canopy and discrete disturbances, buffered by surrounding habitat to impede the invasion of competitors.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining critical habitat map units were created using GIS shapefiles of Natural Heritage Element Occurrence (EO) data for *Arabis georgiana* (Georgia rockcress) locations that were provided by the Alabama Department of Conservation and Natural Resources and the Georgia Department of Natural Resources, and 1-meter resolution National Agricultural Imagery Program (NAIP) images from 2009. Each EO feature was buffered by 76 m (250 ft) up and down slope and 304.8 m (1,000 ft) laterally. The 76-m (250-ft) buffer was used as a guideline for delineating critical habitat upslope and downslope of the EO feature, with the downslope direction extending 76 m (250 ft) or to the edge of the water, whichever was shorter. The 304.8-m (1,000-ft) buffer was used a guideline for delineating critical habitat adjacent to the EO features along the length of the river. The critical habitat polygons were manually drawn using a mouse on a computer screen by visually checking for PCEs within the buffer areas against 2009 NAIP imagery. The critical habitat polygons were then viewed over the ArcGIS basemap Bing Aerial Imagery as an additional assessment tool for the placement of the critical habitat polygon boundaries. Critical habitat units were mapped using Universal Transverse Mercator (UTM), zone 16N. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's Internet site at *http://www.fws.gov/athens/,* at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2013–0030, and at the Ecological Services Office in Athens, Georgia. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index maps of critical habitat units for *Arabis georgiana* (Georgia rockcress) follow:

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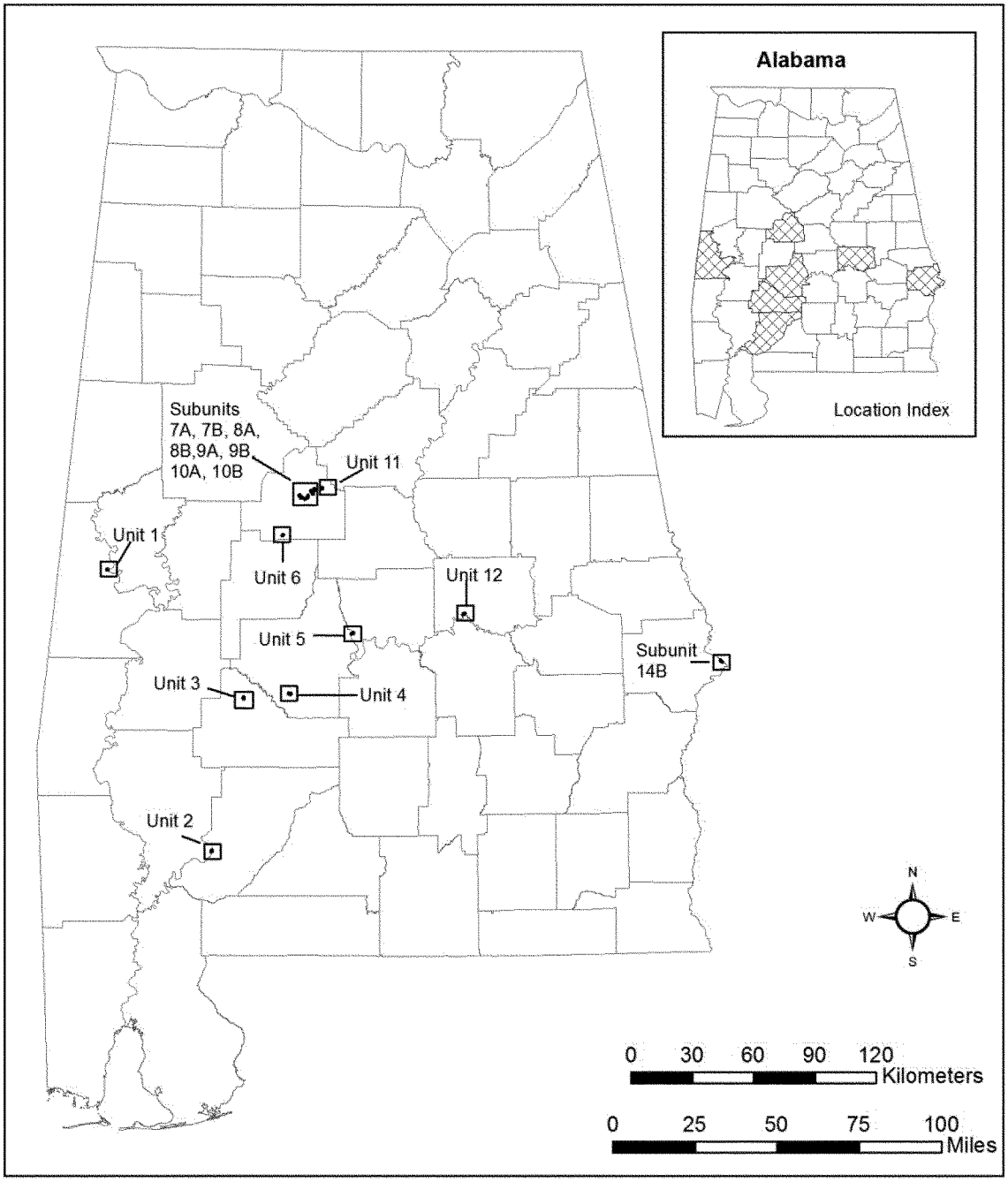
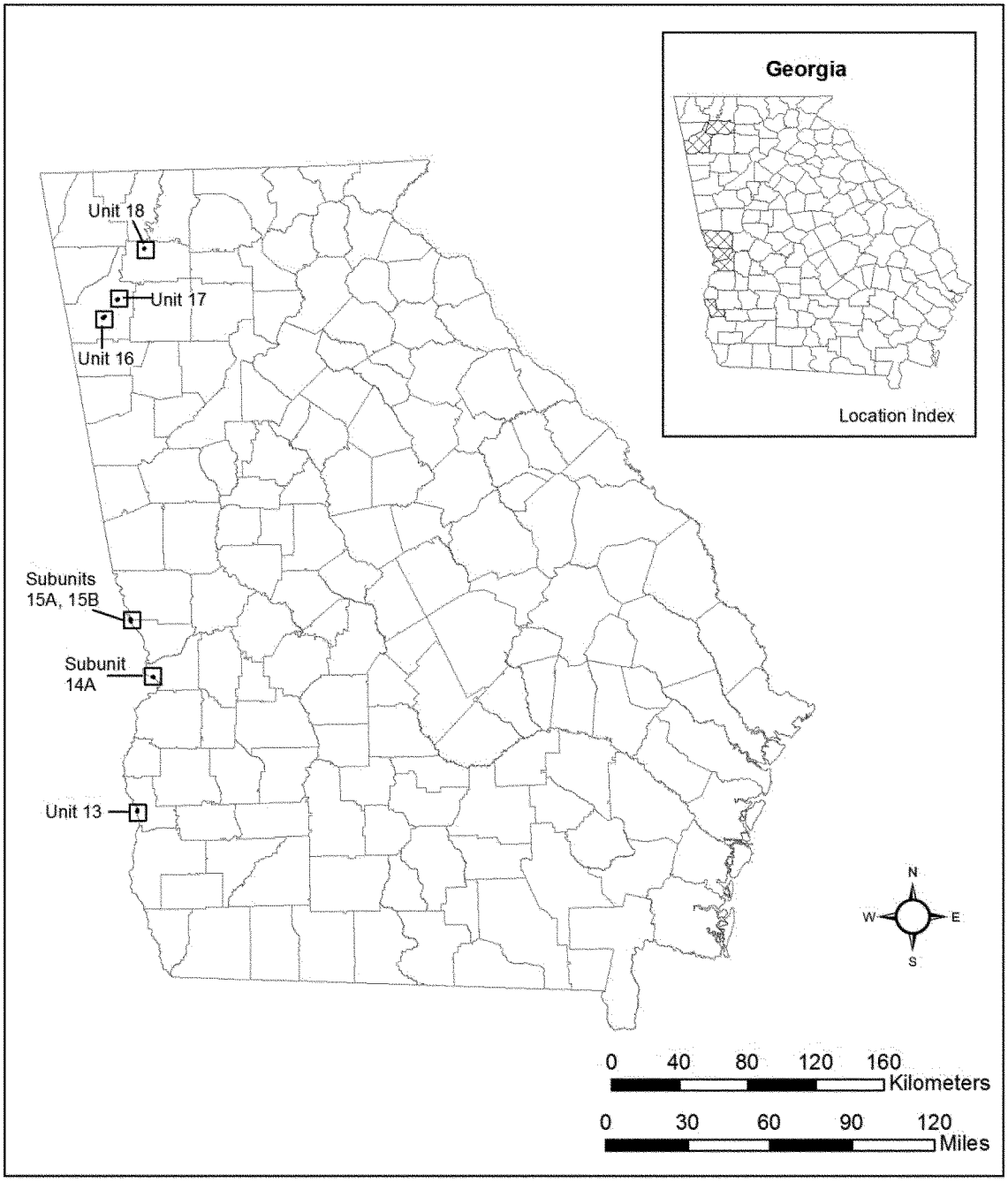
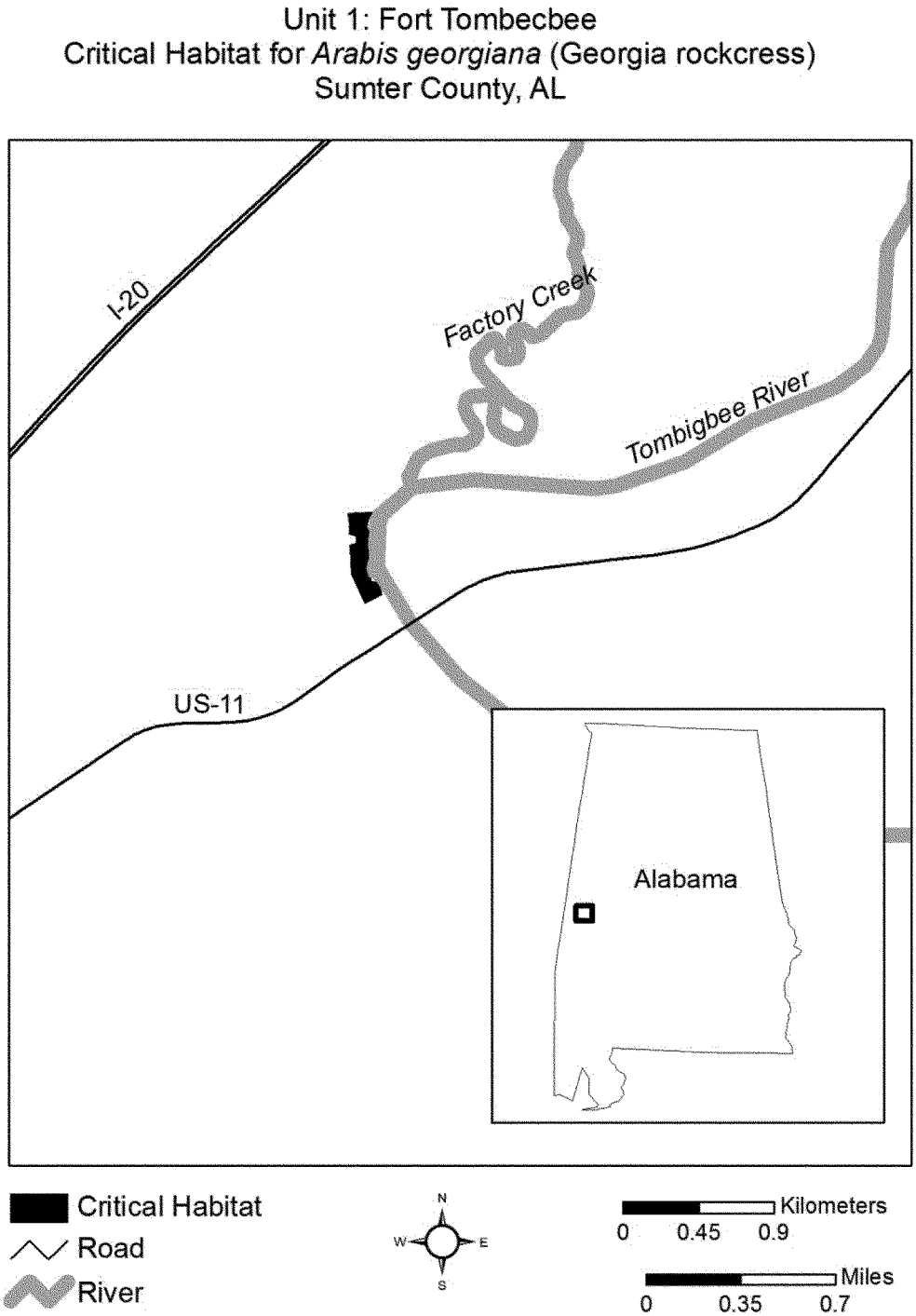
Georgia rockcress Critical Habitat Units, Alabama



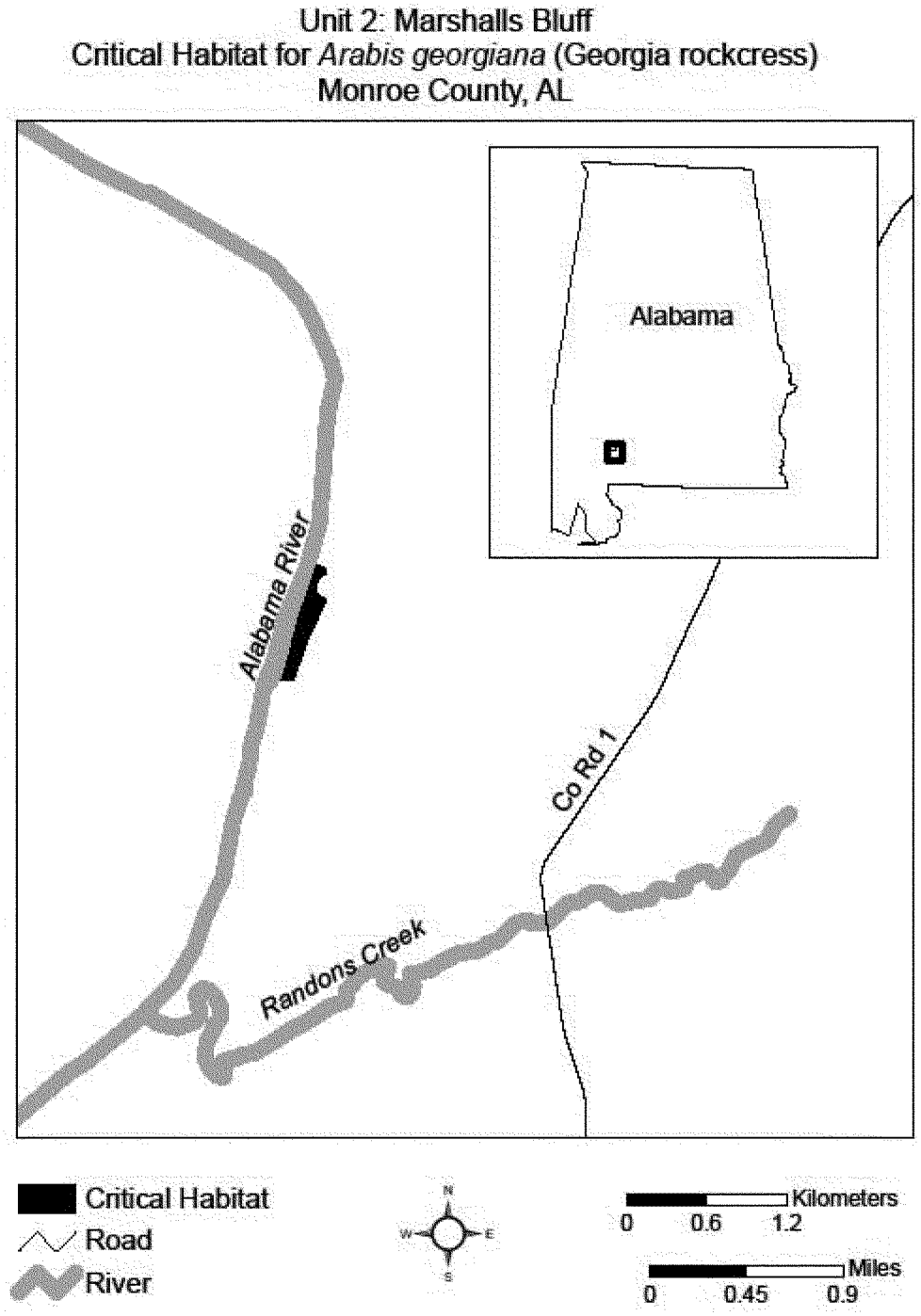
Georgia rockcress Critical Habitat Units, Georgia



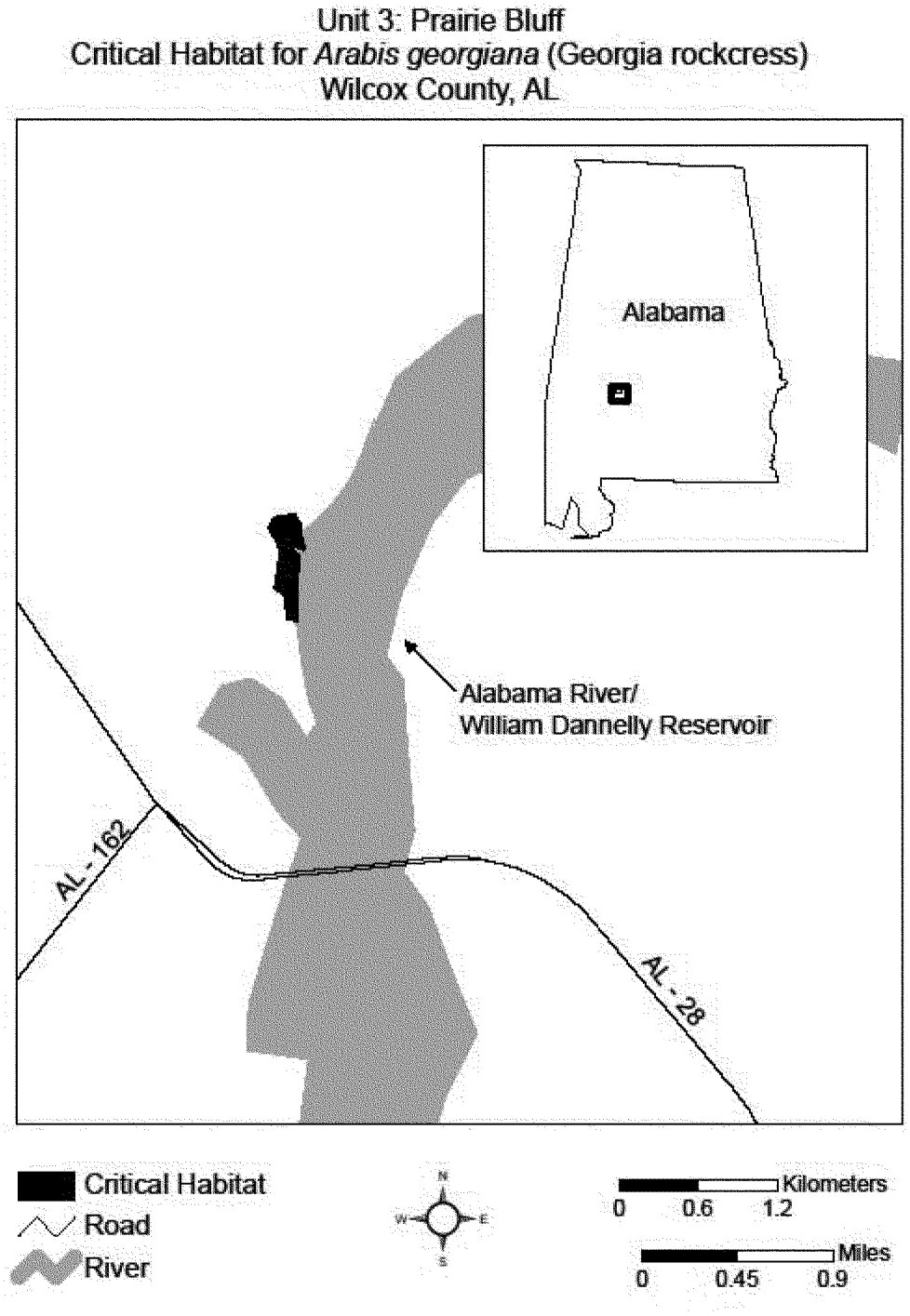
(6) Unit 1: Fort Tombecbee, Sumter County, Alabama. Map of Unit 1 follows:



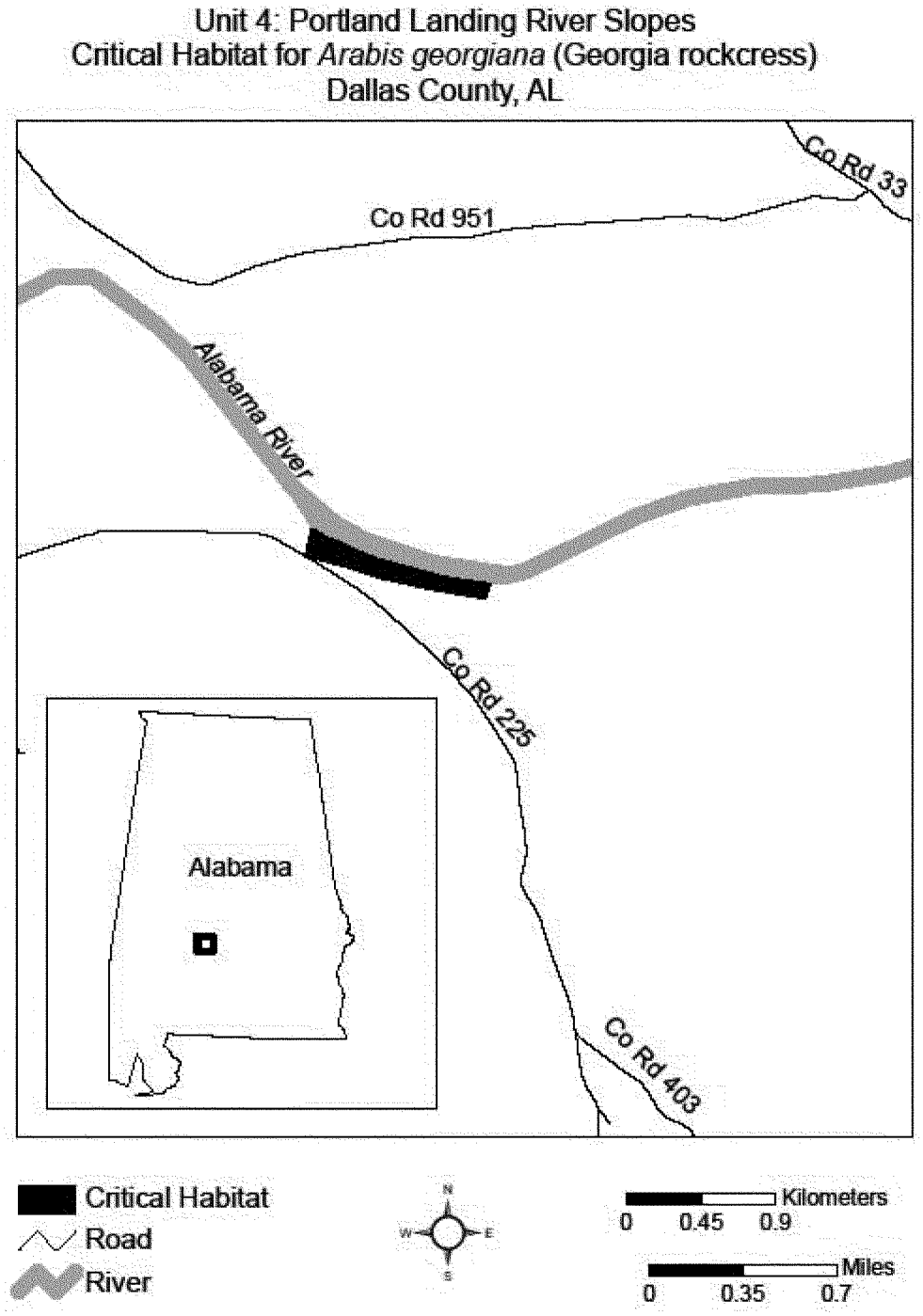
(7) Unit 2: Marshalls Bluff, Monroe County, Alabama. Map of Unit 2 follows:



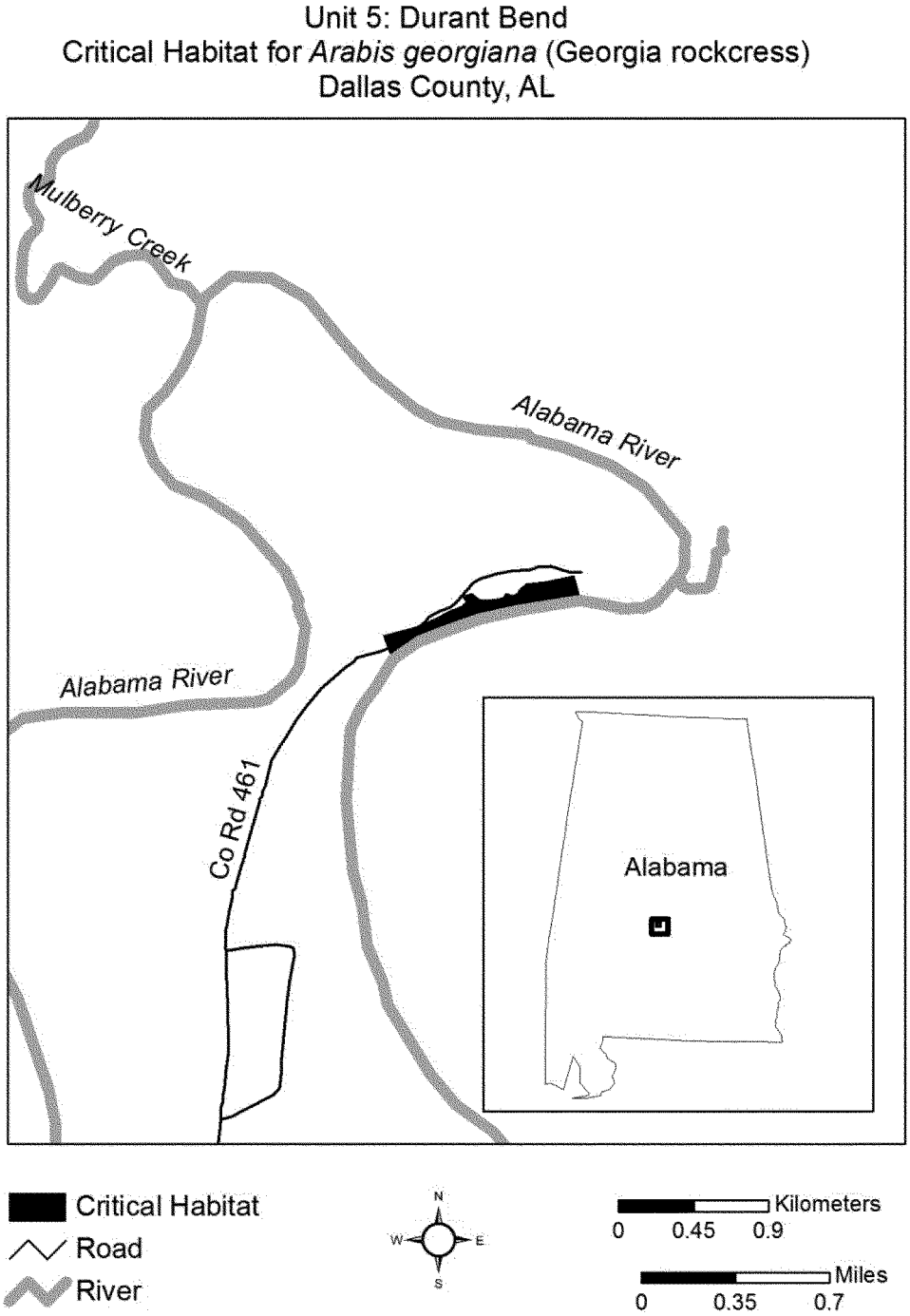
(8) Unit 3: Prairie Bluff, Wilcox County, Alabama. Map of Unit 3 follows:



(9) Unit 4: Portland Landing River Slopes, Dallas County, Alabama. Map of Unit 4 follows:

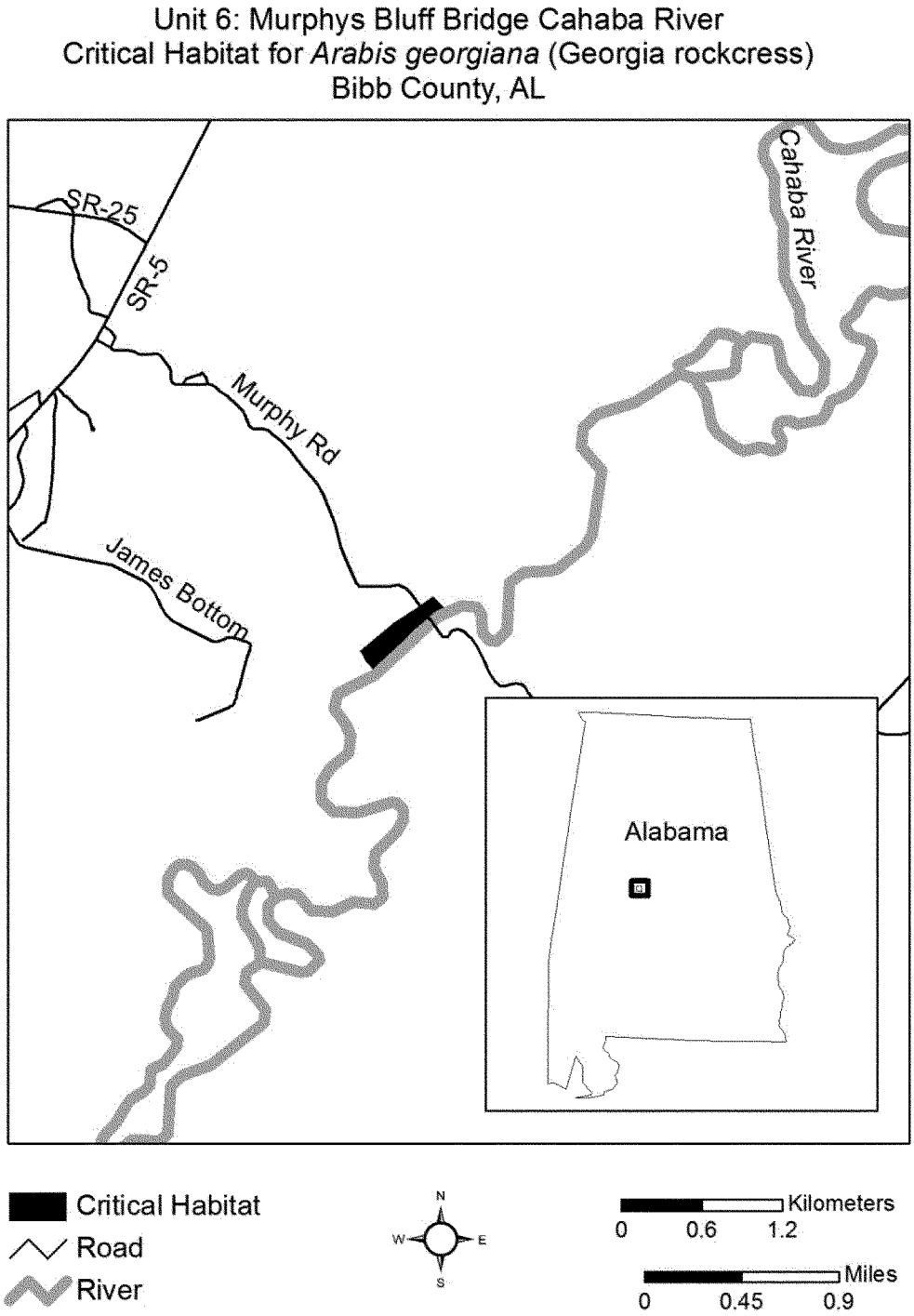


(10) Unit 5: Durant Bend, Dallas County, Alabama. Map of Unit 5 follows:

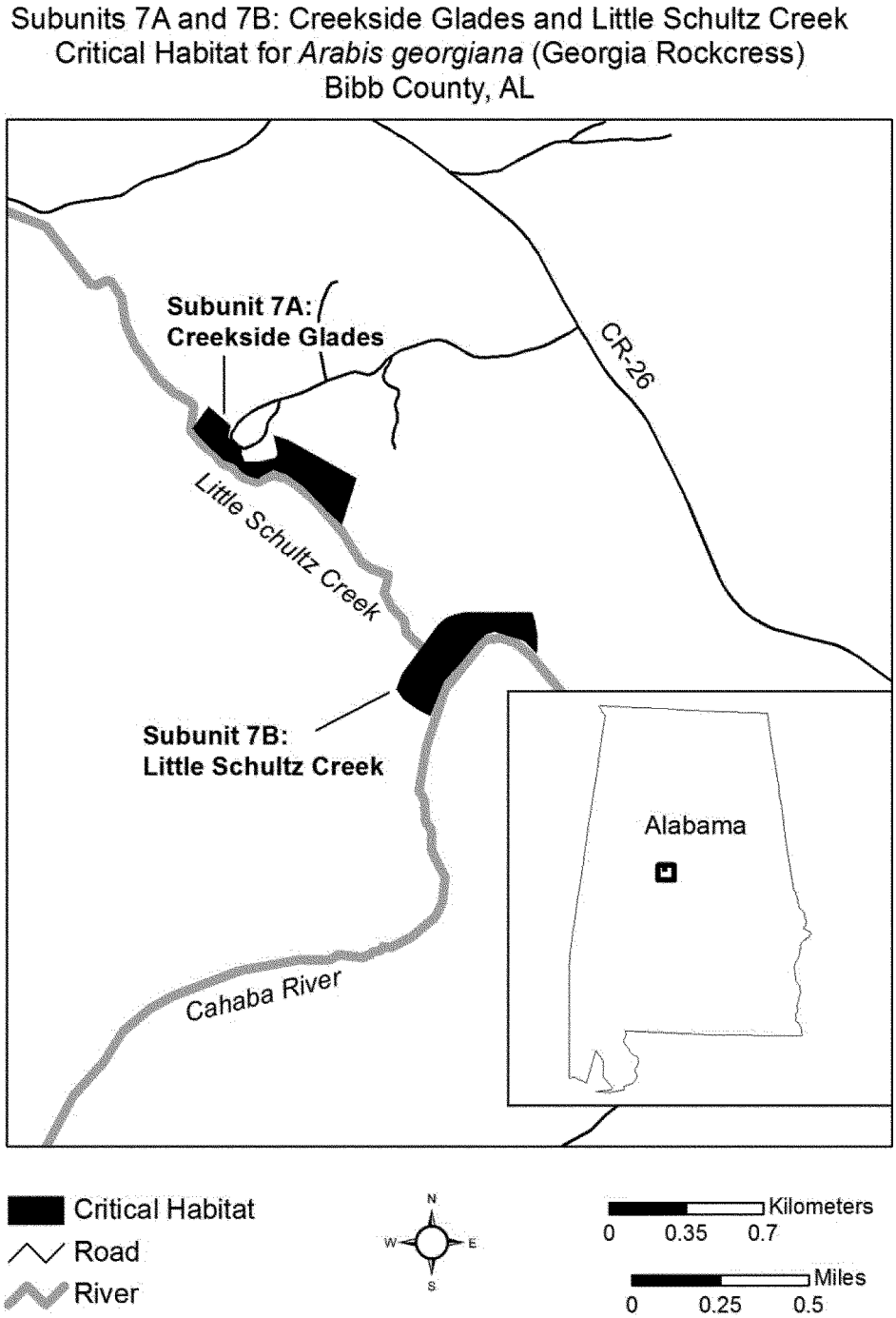


(11) Unit 6: Murphys Bluff Bridge Cahaba River, Bibb County, Alabama.

Map of Unit 6 follows:



(12) Unit 7, Bibb County, Alabama.
(i) Subunit 7A: Creekside Glades.
(ii) Subunit 7B: Little Schultz Creek.
(iii) Map of Subunits 7A and 7B follows:



(13) Unit 7B: Little Schultz Creek, Bibb County, Alabama. Map of Subunits 7A and 7B is provided in paragraph (12) of this entry.

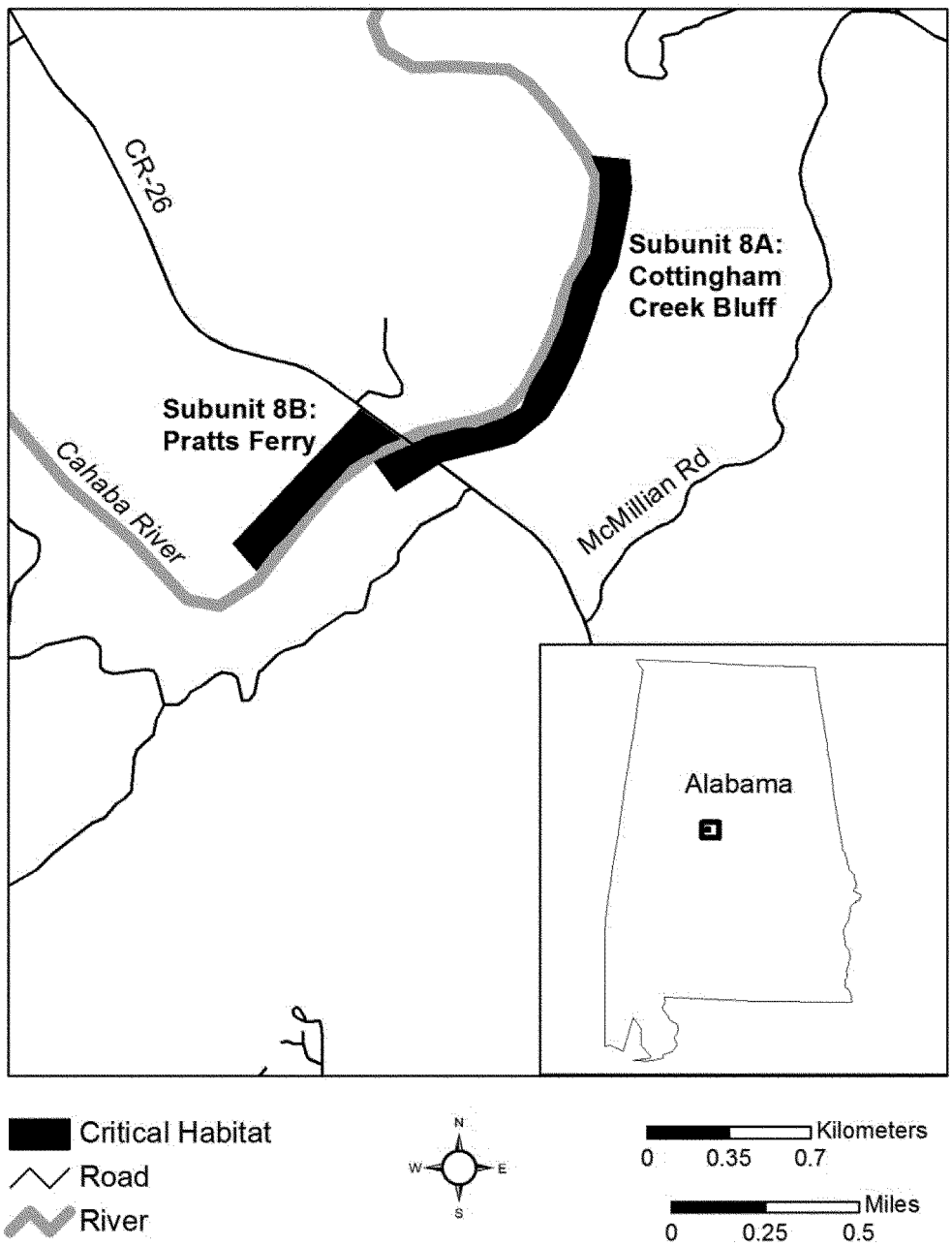
(14) Unit 8, Bibb County, Alabama.

(i) Subunit 8A: Cottingham Creek Bluff.

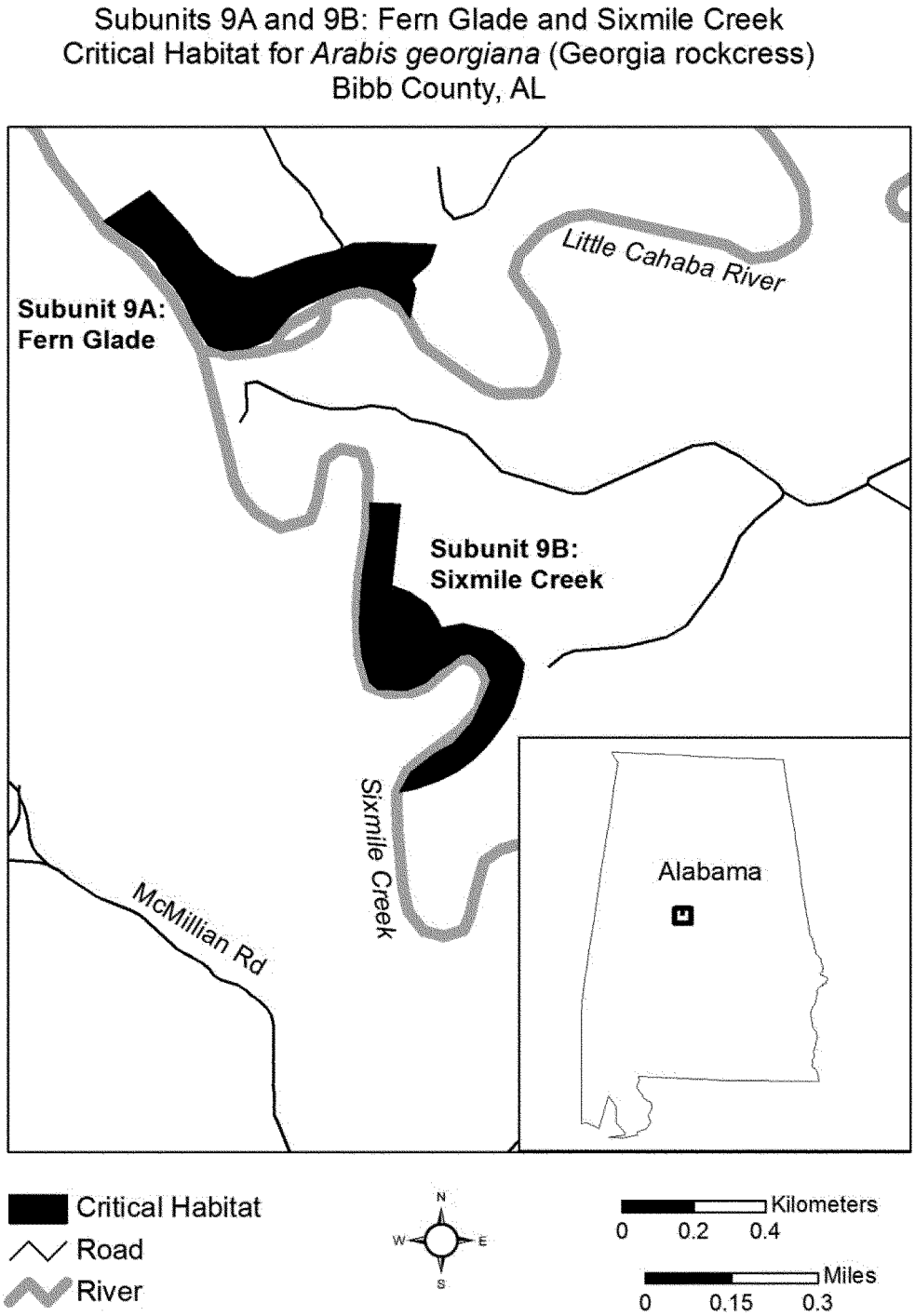
(ii) Subunit 8B: Pratts Ferry.

(iii) Map of Subunits 8A and 8B follows:

Subunits 8A and 8B: Cottingham Creek Bluff and Pratts Ferry
Critical Habitat for *Arabis georgiana* (Georgia rockcress)
Bibb County, AL



(15) Unit 9, Bibb County, Alabama.
(i) Subunit 9A: Fern Glade.
(ii) Subunit 9B: Sixmile Creek.
(iii) Map of Subunits 9A and 9B follows:



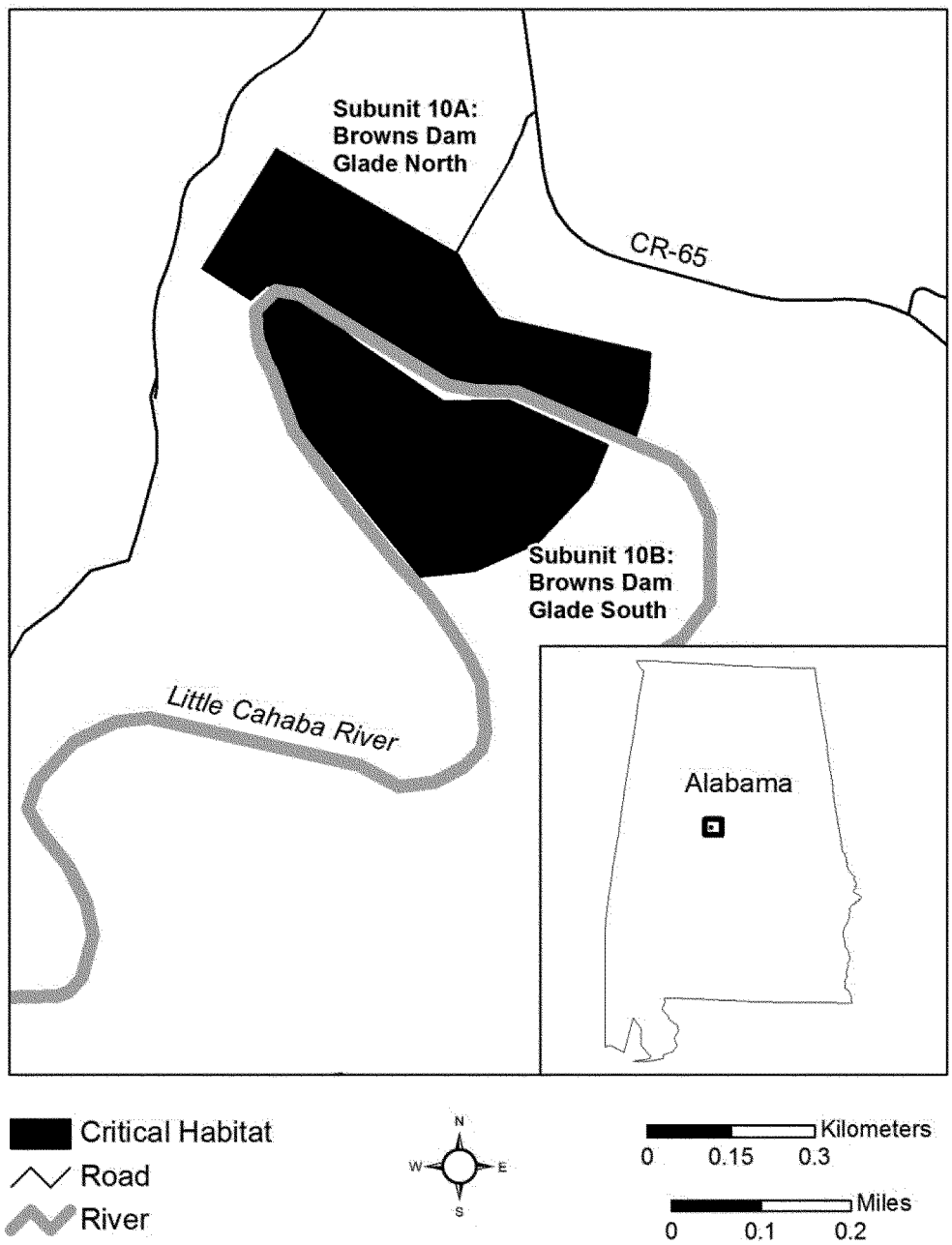
(16) Unit 10, Bibb County, Alabama.

(i) Subunit 10A: Browns Dam Glade North.

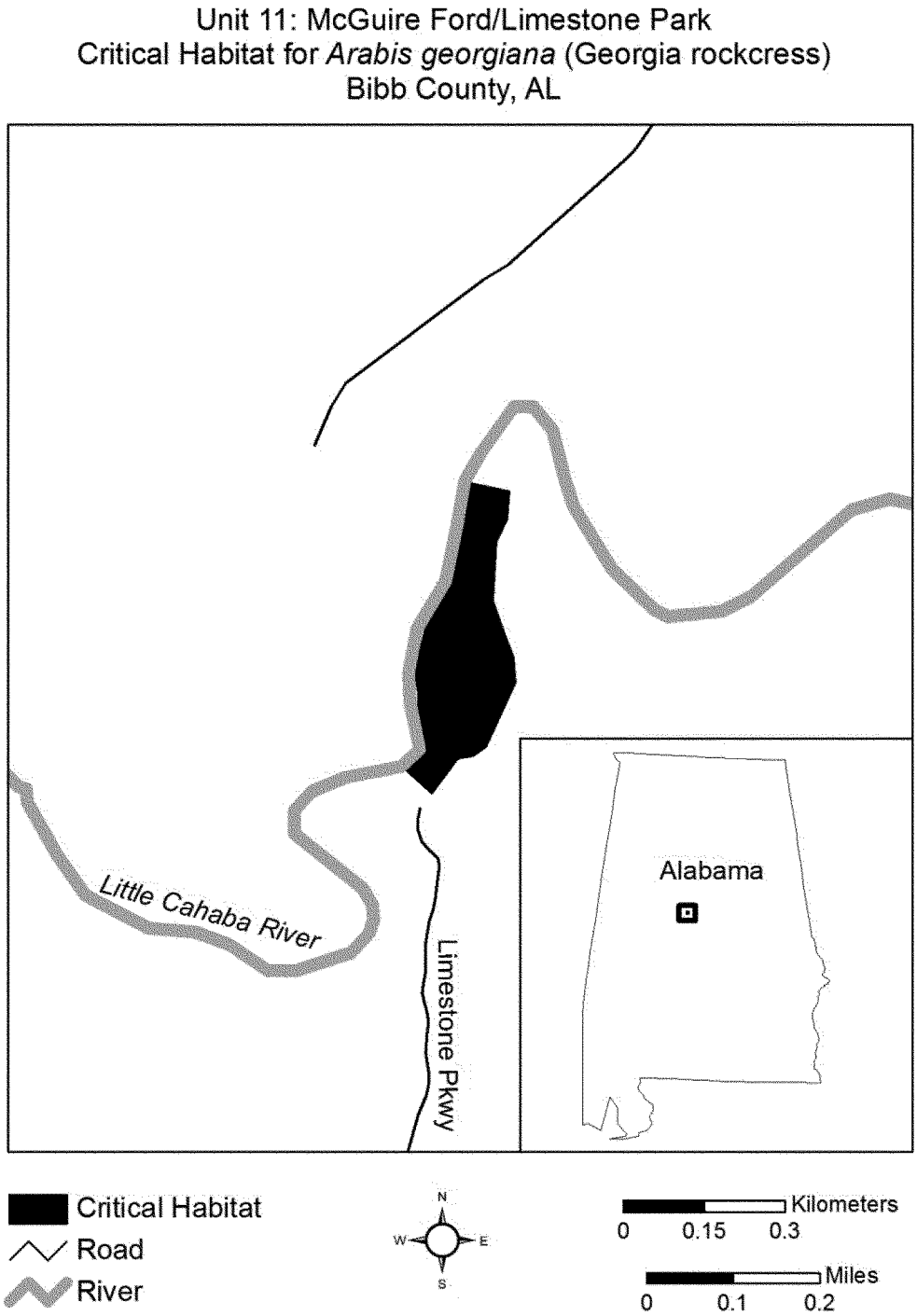
(ii) Subunit 10B: Browns Dam Glade South.

(iii) Map of Subunits 10A and 10B follows:

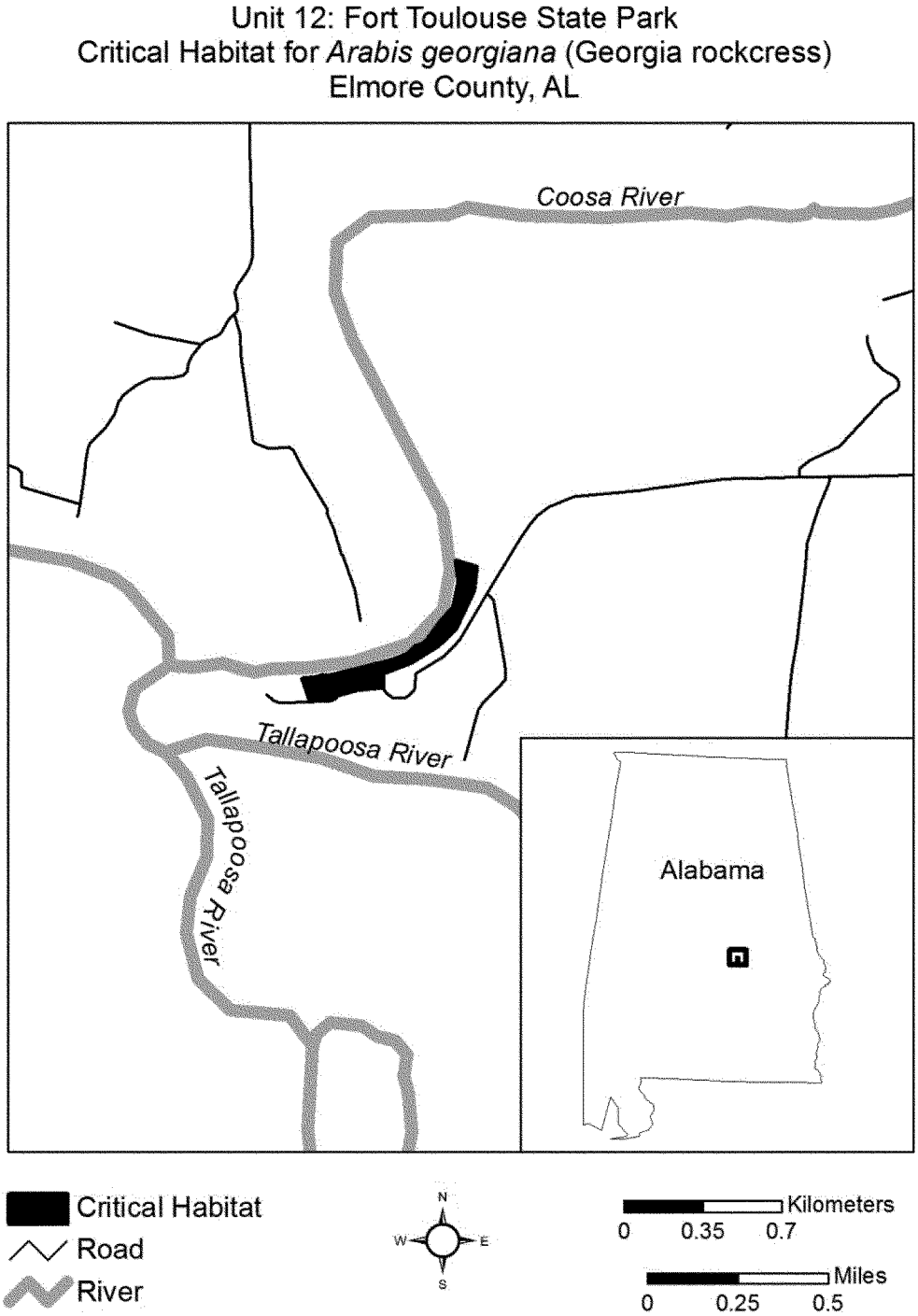
Subunits 10A and 10B: Browns Dam Glade North and Browns Dam Glade South
Critical Habitat for *Arabis georgiana* (Georgia rockcress)
Bibb County, AL



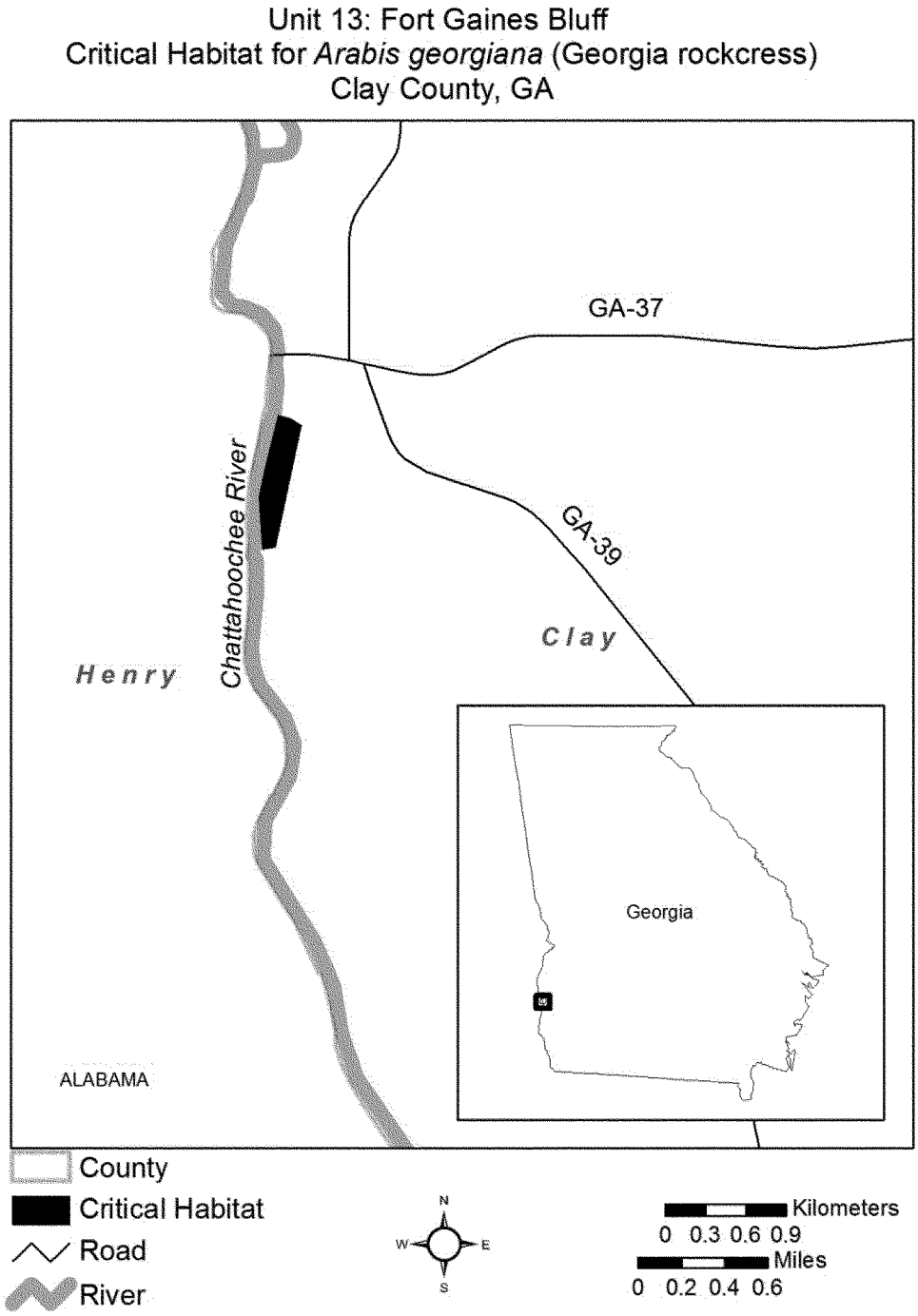
(17) Unit 11: McGuire Ford/Limestone Park, Bibb County, Alabama. Map of Unit 11 follows:



(18) Unit 12: Fort Toulouse State Park, Elmore County, Alabama. Map of Unit 12 follows:



(19) Unit 13: Fort Gaines Bluff, Clay County, Georgia. Map of Unit 13 follows:

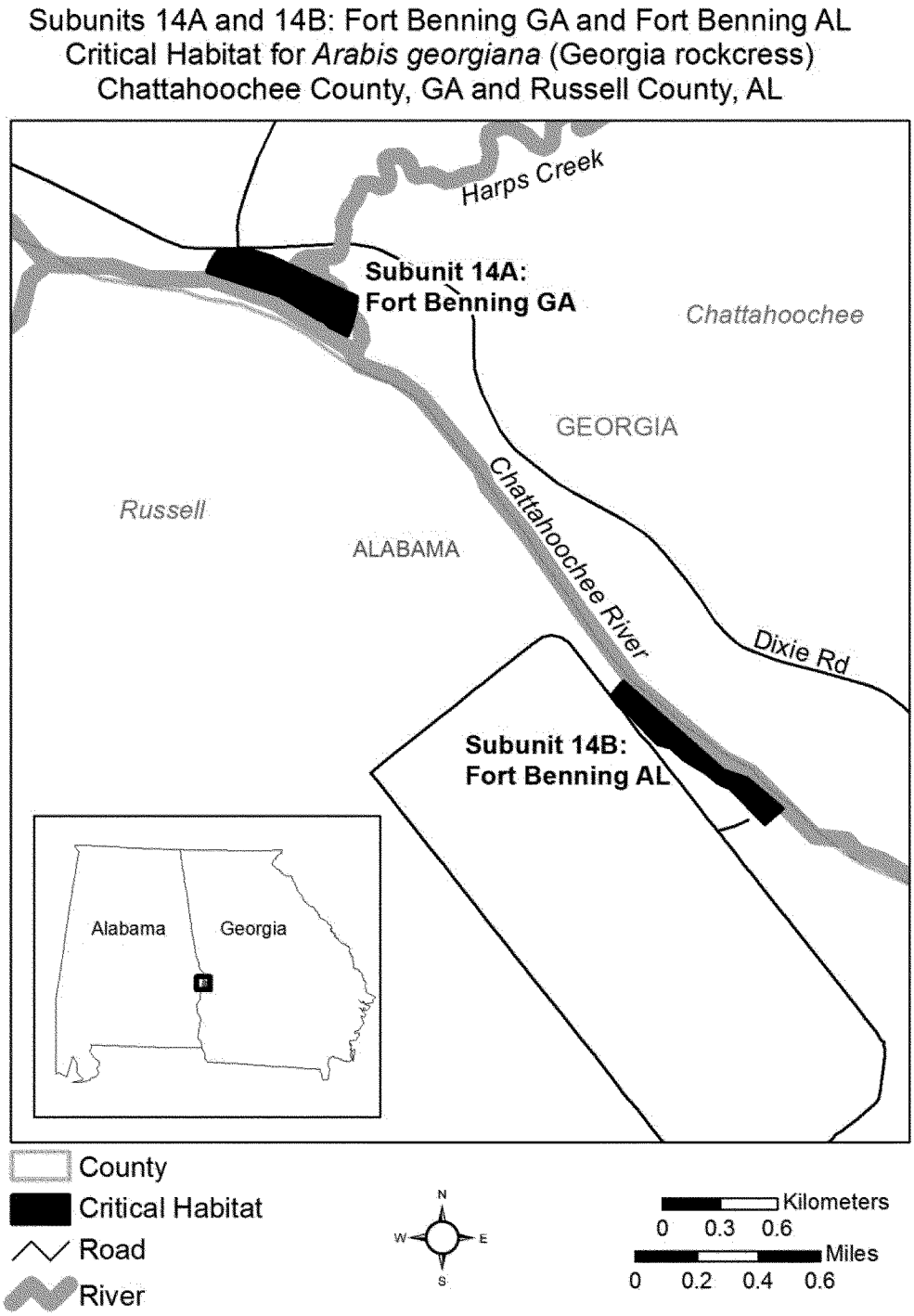


(20) Unit 14, Chattahoochee County, Georgia, and Russell County, Alabama.

(i) Subunit 14A: Fort Benning Georgia.

(ii) Subunit 14B: Fort Benning Alabama.

(iii) Map of Subunits 14A and 14B follows:

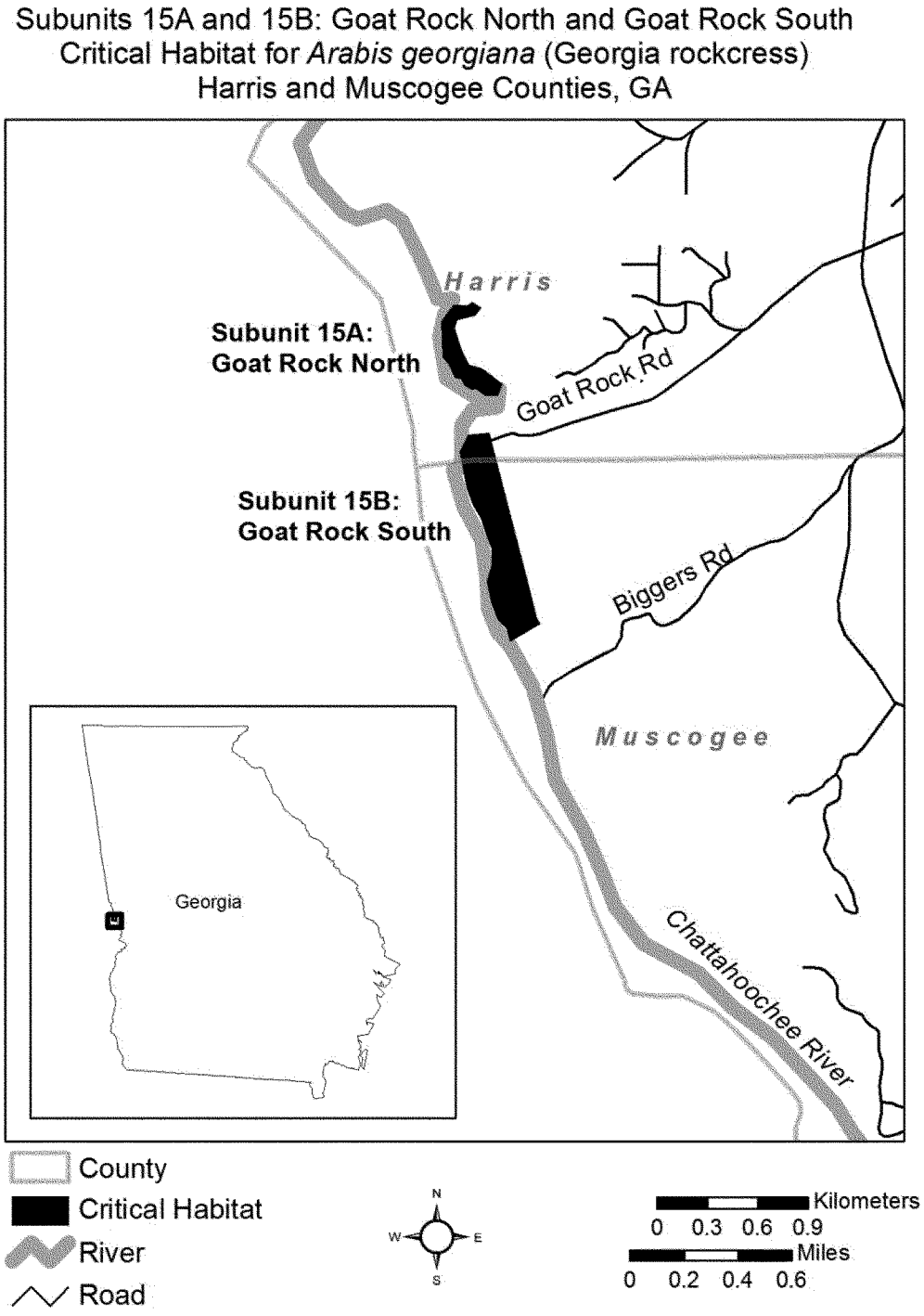


(21) Unit 15, Harris and Muscogee Counties, Georgia.

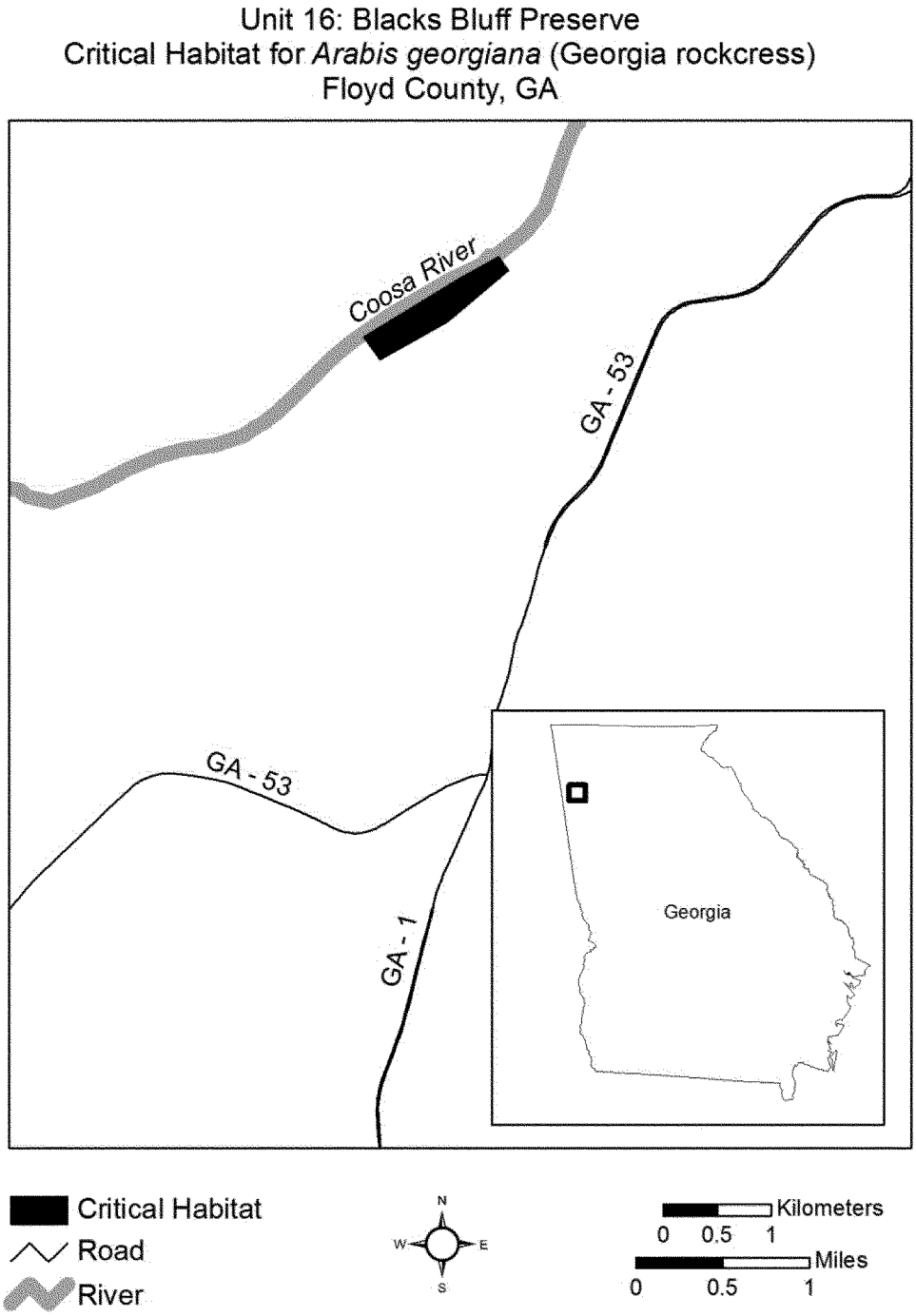
(i) Subunit 15A: Goat Rock North.

(ii) Subunit 15B: Goat Rock South.

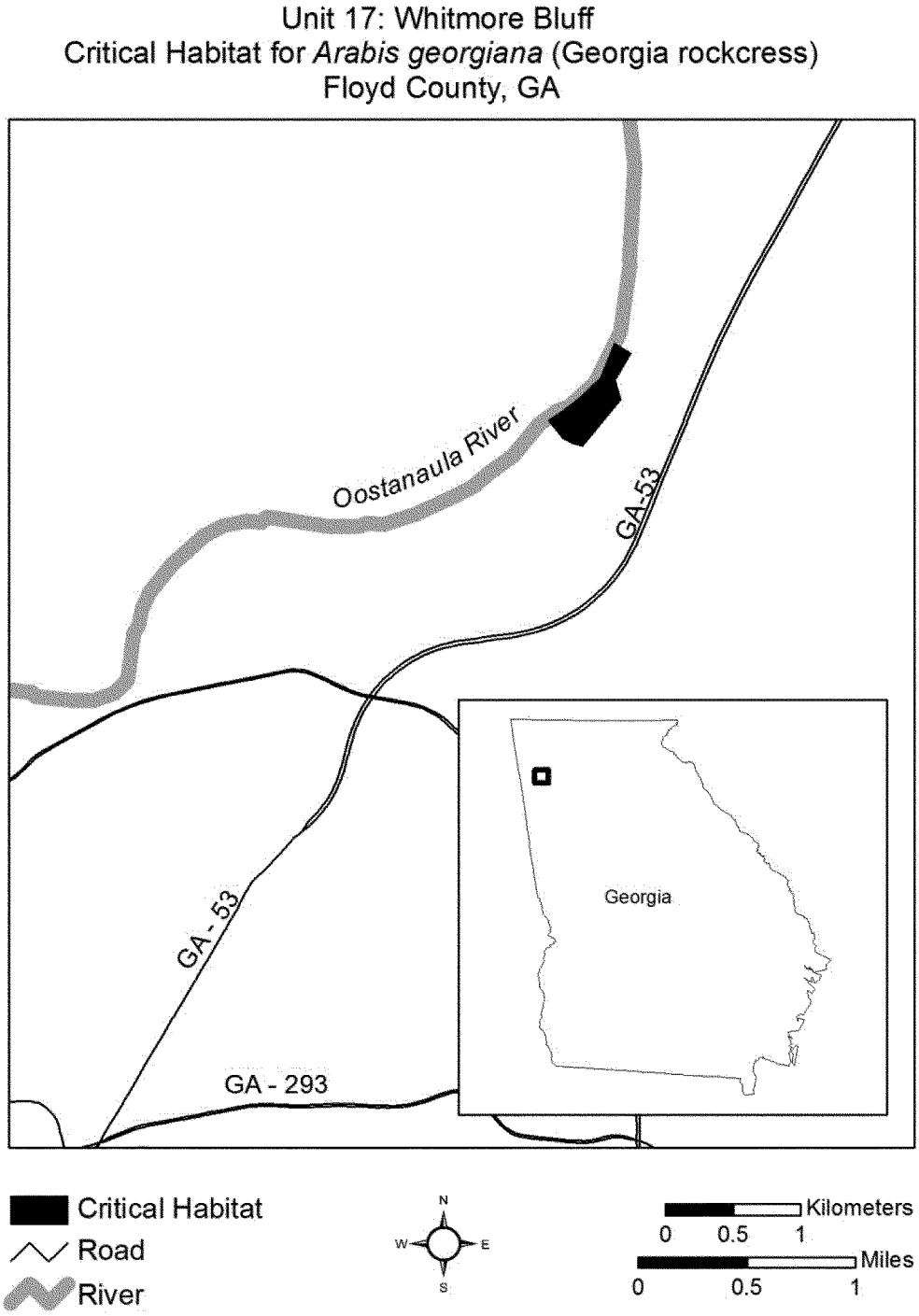
(iii) Map of Subunits 15A and 15B follows:



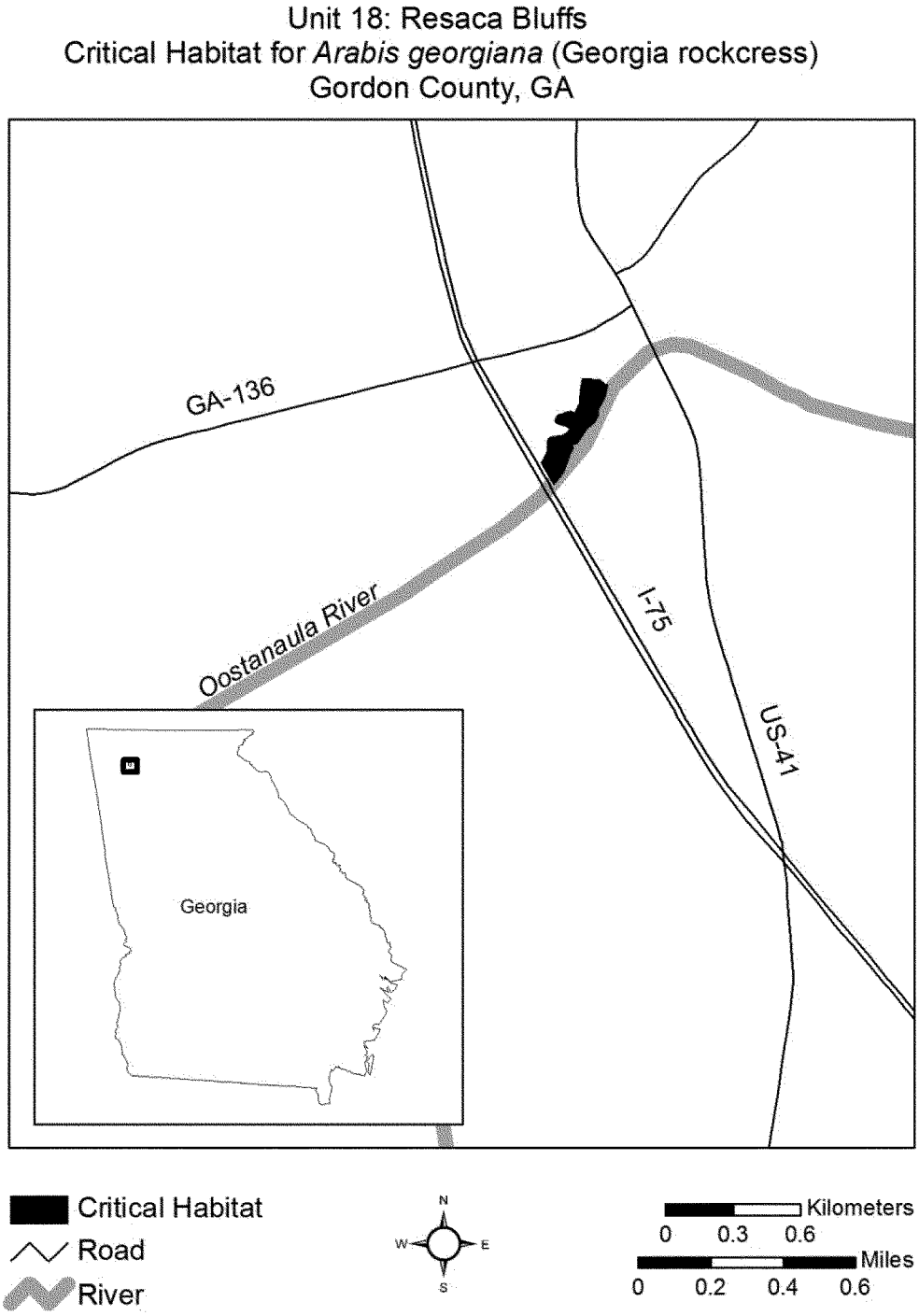
(22) Unit 16: Blacks Bluff Preserve, Floyd County, Georgia. Map of Unit 16 follows:



(23) Unit 17: Whitmore Bluff, Floyd County, Georgia. Map of Unit 17 follows:



(24) Unit 18: Resaca Bluffs, Gordon County, Georgia. Map of Unit 18 follows:



* * * * *

Dated: September 3, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–22128 Filed 9–11–13; 8:45 am]

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No. 177 September 12, 2013

Part IV

Commodity Futures Trading Commission

17 CFR Chapter I

Concept Release on Risk Controls and System Safeguards for Automated Trading Environments; Proposed Rule

COMMODITY FUTURES TRADING COMMISSION

17 CFR Chapter I

RIN 3038–AD52

Concept Release on Risk Controls and System Safeguards for Automated Trading Environments

AGENCY: Commodity Futures Trading Commission.

ACTION: Concept release; request for comments.

SUMMARY: U.S. derivatives markets have experienced a fundamental transition from human-centered trading venues to highly automated and interconnected trading environments. The operational centers of modern markets now reside in a combination of automated trading systems (''ATSs'') and electronic trading platforms that can execute repetitive tasks at speeds orders of magnitude greater than any human equivalent. Traditional risk controls and safeguards that relied on human judgment and speeds, and which were appropriate to manual and/or floor-based trading environments, must be reevaluated in light of new market structures. Further, the Commission and market participants must ensure that regulatory standards and internal controls are calibrated to match both current and foreseeable market technologies and risks. This Concept Release on Risk Controls and System Safeguards for Automated Trading Environments (''Concept Release'') reflects the Commission's continuing commitment to the safety and soundness of U.S. derivatives markets in a time of rapid technological change. The Concept Release serves as a platform for cataloguing existing industry practices, determining their efficacy and implementation to date, and evaluating the need for additional measures, if any. The Commission welcomes all public comments.

DATES: Comments must be received on or before December 11, 2013.

ADDRESSES: You may submit comments, identified by RIN 3038–AD52, by any of the following methods:

- *CFTC Web site, via Comments Online: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- *Mail:* Melissa D. Jurgens, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as ''mail,'' above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit comments by only one method. All comments should be submitted in English or accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in 17 CFR 145.9. The Commission reserves the right, but shall have no obligation, to review, prescreen, filter, redact, refuse, or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

FOR FURTHER INFORMATION CONTACT: Sebastian Pujol Schott, Associate Director, Division of Market Oversight, *sps@cftc.gov* or 202–418–5641; Marilee Dahlman, Attorney-Advisor, Division of Market Oversight, *mdahlman@cftc.gov* or 202–418–5264; Camden Nunery, Economist, Office of the Chief Economist, *cnunery@cftc.gov* or 202–418–5723; or Sayee Srinivasan, Research Analyst, Office of the Chief Economist, *ssrinivasan@cftc.gov* or 202–418–5309.

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2. Advances in High-Speed Communication Networks and Reductions in Latency
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I. Introduction

U.S. derivatives markets have experienced a fundamental evolution from human-centered trading venues to highly automated and interconnected trading environments. Traditionally, traders and market participants directly initiated, communicated and executed orders, while other personnel provided a range of order, trade processing and back office services. In contrast, automated trading environments are characterized precisely by their high degree of automation, and by the wide array of algorithmic and information technology systems that generate, risk manage, transmit and match orders and trades, as well as systems used to confirm transactions, communicate market data and link related systems through high-speed communication networks. Automated trading environments have conferred a number of benefits upon market participants, including an expanded range of potential trading strategies, and a surge in the speed, precision and tools

available to execute such strategies. In addition to these benefits, however, automated trading environments have also presented challenges unique to their speed, interconnectedness and reliance on algorithmic systems.

In recent years, a number of high-profile system events associated with automated trading have raised public, Commission and industry awareness. For example, on May 6, 2010, major equity indices in both the futures and securities markets lost more than 5% of their value in a matter of minutes when an automated order led to extreme downward price movement and a liquidity crisis in the Chicago Mercantile Exchange's (''CME'') E-mini futures contract.[1] In August 2012, a trading firm in the securities markets—Knight Capital Group—submitted a significant number of errant proprietary orders to the New York Stock Exchange (''NYSE''), causing price swings in nearly 150 securities and costing the firm approximately $440 million in the process.[2] Most recently, in August 2013, trading on the Nasdaq stock market was disrupted for three hours due to malfunctions in quote dissemination systems and potential connectivity issues between it and another trading platform's systems. These and other recent events in automated trading environments are discussed in greater detail in section II.C., below.

The Commission has taken steps to address the transition to automated trading and require appropriate risk controls for designated contract markets (''DCMs''), swap execution facilities (''SEFs''), futures commission merchants (''FCMs''), swap dealers (''SDs''), major swap participants (''MSPs'') and others. In April 2012, it adopted final rules requiring FCMs, SDs and MSPs that are clearing members to establish risk-based limits based on position size, order size, margin requirements, or similar factors, and requiring those entities to use automated means to screen orders for compliance with the risk limits when such orders are subject to automated execution. Further, in June 2012, the Commission adopted final rules with respect to DCMs, including requirements that DCMs establish and maintain risk control mechanisms to prevent and reduce the potential for price distortions and market disruptions. Relevant controls cited in the rule include trading pauses and halts under conditions prescribed by the DCM. The Commission adopted similar requirements in its final rules for SEFs in 2013. Finally, the DCM final rules also require risk control requirements for exchanges that provide direct market access (''DMA'') to clients.

The Commission has also adopted rules related to trading practices, including trading in automated environments. In July 2011, the Commission adopted final rules codified in 17 CFR Part 180 that, among other things, (i) broadly prohibit manipulative and deceptive devices, *i.e.,* fraud and fraud-based manipulative devices and contrivances employed intentionally or recklessly, regardless of whether the conduct in question was intended to create or did create an artificial price; and (ii) codify the Commission's long-standing authority to prohibit price manipulation by making it unlawful for any person, directly or indirectly, to manipulate or attempt to manipulate the price of any swap, or of any commodity in interstate commerce, or for future delivery on or subject to the rules of a registered entity. Further, section 747 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'')[3] amended the Commodity Exchange Act (''CEA'' or ''Act'') to make it unlawful for any person to engage in disruptive trading practices, and the Commission has provided guidance on the scope and application of the new statutory prohibitions. The Commission's measures to date are summarized in greater detail in section II.B., below. With respect to these measures and others discussed in this Concept Release, the Commission requests public comment regarding any additional steps, guidance or rulemaking that it should undertake.

Derivatives market participants, including DCMs, FCMs, clearing members and others, have themselves taken a number of steps to manage risks associated with automated trading. The Commission acknowledges these efforts, and, through this Concept Release, seeks public comment on the extent to which measures already in place may be sufficient to safeguard markets in automated trading environments. In particular, section III below summarizes relevant risk controls implemented by one or more market participants; requests comment regarding the extent of their implementation to date; and seeks input regarding whether existing controls would benefit from additional granularity or regulatory standardization.

A. Design of Concept Release and Request for Comments

This Concept Release provides an overview of the automated trading environment, including its principal actors, potential risks, and preventative measures designed to promote safe and orderly markets.[4] The Concept Release was informed by controls already in use today by one or more market participants or exchanges, and best practices, recommendations and concepts developed by the CFTC's Technology Advisory Committee (''TAC''); the Futures Industry Association's (''FIA'') Principal Traders Group and Market Access Working Group; the International Organization of Securities Commissions (''IOSCO''); the European Securities and Markets Authority (''ESMA''); and by existing CFTC regulatory requirements. It begins with an overview of automated trading, including the development of automated order generation and execution systems; advances in high-speed communication networks; the growth of interconnected automated markets; the changed role of humans in modern markets; and a discussion of

[1] *See* ''Findings Regarding the Market Events of May 6, 2010, Report of the Staffs of the CFTC and SEC to the Joint Advisory Committee on Emerging Regulatory Issues,'' September 30, 2010 [hereinafter, the ''CFTC and SEC Joint Report on the Market Events of May 6, 2010''], available at *http://www.cftc.gov/ucm/groups/public/@otherif/documents/ifdocs/staff-findings050610.pdf.*

[2] *See* Jenny Strasburg & Jacob Bunge, ''Loss Swamps Trading Firm,'' Wall St. J. (Aug. 2, 2012), available at *http://online.wsj.com/article/SB10000872396390443866404577564772083961412.html.*

On October 2, 2012, the Securities and Exchange Commission (''SEC'') conducted a roundtable entitled ''Technology and Trading: Promoting Stability in Today's Markets'' (''SEC Roundtable''). *See* SEC, Notice of Roundtable Discussion: Technology and Trading Roundtable, 77 FR 56697 (Sept. 13, 2012). A transcript of the SEC Roundtable [hereinafter, the ''SEC Roundtable Transcript''] is available at *http://www.sec.gov/news/otherwebcasts/2012/ttr100212.shtml.* At the SEC Roundtable, then-SEC Chairman Schapiro raised the Knight Capital incident and noted that ''[e]vents like these demonstrate the core infrastructure and technology issues that can be problematic in any market structure.'' *See* SEC Roundtable Transcript at 11.

[3] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203, 124 Stat. 1376 (2010).

[4] Many of these concepts are in harmony with evolving views of groups responsible for setting standards and developing regulations for other markets around the world. *See, e.g.,* IOSCO Technical Committee, ''Regulatory Issues Raised by the Impact of Technological Changes on Market Integrity and Efficiency: Consultation Report'' (July 2011) [hereinafter ''IOSCO Report on Regulatory Issues Raised by Technological Changes''], available at *http://www.iosco.org/library/pubdocs/pdf/IOSCOPD354.pdf.*

See also ESMA, ''Final Report: Guidelines on Systems and Controls in an Automated Trading Environment for Trading Platforms, Investment Firms and Competent Authorities'' (December 2011) [hereinafter, ''ESMA Guidelines on Systems and Controls''], available at *http://www.esma.europa.eu/system/files/2011–456_0.pdf.*

recent disruptive events in automated trading environments. The Concept Release then addresses these developments through a series of (1) pre-trade risk controls; (2) post-trade reports and other post-trade measures; (3) system safeguards; and (4) additional protections (collectively, ''risk controls'') that could be implemented by one or more categories of Commission registrants or other market participants.

The Commission seeks extensive public comment regarding each risk control contemplated herein. Commenters should address the effectiveness of each measure, and the degree to which it may already be in use by industry participants. Each commenter should identify the specific risk controls that it already employs. For all measures discussed in this Concept Release, commenters should also address whether there is a need for regulatory action to provide more uniform risk mitigation across CFTC-regulated derivatives markets.[5] Comments that address this question with respect to each proposed risk control and system safeguard individually would be particularly helpful. In all cases, commenters should discuss, and quantify wherever possible, the costs and benefits of the pre-trade risk controls, post-trade reports and other post-trade measures, system safeguards, and other protections discussed in this Concept Release.

The Concept Release recognizes that orders and trades in automated environments pass through multiple stages in their lifecycle from order generation, to execution, to clearing and allocation in proprietary or customer accounts, and steps in between. Accordingly, the Commission requests comment regarding the appropriate stage at which risk controls should be placed. Potential options include risk controls applicable to: (i) ATSs at the time of order generation; (ii) clearing firms during the order transmission process; (iii) trading platforms prior to exposing orders to the market; (iv) Derivatives Clearing Organizations (''DCOs''); and (v) other risk control focal points, including, for example, third-party ''hubs'' through which orders or order information could flow to uniformly mitigate risks across one or more trading platforms. Similarly, the Commission requests public comment regarding the appropriate focal point for system safeguards and testing and supervision standards for ATSs.

Finally, the Commission requests comment regarding a series of issues central to its improved understanding and surveillance of trading in automated environments. For example, the Commission requests comments regarding any surveillance tools that it should deploy specifically for the surveillance of automated trading and areas for academic research to improve its understanding of ATSs' impact on market microstructure. Section IV lists all questions raised in this Concept Release.

The Commission's Concept Release reflects fundamental statutory objectives under the CEA. Such objectives include fostering a system of effective self-regulation, deterring and preventing disruptions to market integrity, protecting market participants and ''promot[ing] responsible innovation and fair competition among boards of trade, other markets and market participants.''[6] Notably, the Commission must ensure that U.S. derivatives markets continue to serve as effective centers of price discovery and risk mitigation, regardless of the technologies employed by trading platforms, market participants, and others. The Commission must further ensure that its regulatory framework and industry practices are fully adapted to the automated technologies of modern derivatives markets.

II. Background

A. Characteristics of Automated Trading Environments

1. Automated Order Generation and Execution

Automated trading environments have developed in tandem with automated systems for both the generation and execution of orders. Systems related to the generation of orders (''automated trading systems'' or ''ATSs'')[7] operate at the beginning of the order and trade lifecycle; they reflect a set of rules or instructions (an algorithm) and related computer systems used to automate the execution of a trading strategy.[8] ATSs may operate as automated execution programs designed to minimize the price impact of large orders; achieve a benchmarked price (*e.g.,* volume-weighted average price and time-weighted average price algorithms); or otherwise execute instructions traditionally provided by a human agent.[9] They may be employed by a range of market participants, with varying degrees of sophistication, for both proprietary and customer trading. For example, buy-side firms (such as mutual funds and pension funds) may use automated systems and execution algorithms to ''shred'' one or more large orders (called ''parent order'') into a series of smaller trades (''child orders'') to be executed over time. Such systems can include additional algorithms to micro-manage the size, frequency and timing (often randomized) of child orders. In addition to automated execution, ATSs may also operate market-making programs; opportunistic, cross-asset and cross-market arbitrage programs; and a number of other strategies.

In Commission-regulated markets, orders generated by ATSs are ultimately transmitted to DCMs that have themselves become automated systems for the matching and execution of orders. Broadly, these trading platforms consist of a front-end to which market participants connect and communicate using standardized messaging formats, a matching engine that automatically matches orders to buy and sell, and a back-end that automatically provides all market participants with a market feed. Trade flows may make use of straight-through processing, where the entire trade execution process occurs without intermediation from humans, thereby

[5] In this regard, the Commission emphasized in the preamble to its final rules for part 38 that the efficacy of risk controls depends in part on the proper functioning of electronic systems, and that ''the Commission may address electronic system testing, controls, and supervision-related issues in a subsequent proceeding.'' *See* Commission, Final Rule: Core Principles and Other Requirements for Designated Contract Markets, 77 FR 36612, 36638 n.298, 36648, n.389 (Jun. 19, 2012) [hereinafter, the ''DCM Final Rules''].

Similarly, the system safeguards contemplated herein for ATSs are an outgrowth of the basic requirement in § 23.600(d)(9) that SDs and MSPs conduct testing and supervision of trading systems. There again, the Commission indicated that further measures would be forthcoming by stating that it ''anticipate[d] addressing the related issues of testing and supervision of electronic trading systems and mitigation of the risks posed by high frequency trading.'' *See* Commission, Final Rule: Swap Dealer and Major Swap Participant Recordkeeping, Reporting, and Duties Rules; Futures Commission Merchant and Introducing Broker Conflicts of Interest Rules; and Chief Compliance Officer Rules for Swap Dealers, Major Swap Participants, and Futures Commission Merchants, 77 FR 20128, 20141 (Apr. 3, 2012).

[6] *See* CEA section 3(b); 7 U.S.C. 5(b).

[7] While the Commission has no regulatory definition of ATS, the term is generally understood to mean a computer-driven system that automates the generation and routing of orders to one or more markets. Other elements of an ATS may also include systems for analyzing market data as a precursor to order generation, managing orders for conformance with establish risk tolerances, receiving confirmations of orders placed and trades executed, etc. Section III.E.4. of this Concept Release seeks public input regarding whether the Commission should formally define ATS and if so, how ATS should be defined.

[8] *See* IOSCO Report on Regulatory Issues Raised by Technological Changes, *supra* note 4, at 10.

[9] *See* John Bates, ''Algorithmic Trading and High Frequency Trading Experiences from the Market and Thoughts on Regulatory Requirements'' (July 2010), available at *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/tac_071410_binder.pdf.*

dramatically reducing the amount of time required to execute each transaction. The evolution from manual trading in open-outcry pits to electronic trading platforms is in many cases substantially complete.

An established body of data indicates the importance of electronic and algorithmic trading in U.S. futures markets. In 2012, approximately 91.50% of exchange trading volume in U.S. futures markets was executed electronically.[10] Estimates indicate that algorithmic trading first accounted for at least 50% of orders in 2009,[11] and accounted for over 40% of total trading volume in 2010.[12] By the end of the first quarter of 2010, ATSs accounted for over 50% of trading volume in a number of significant product categories at CME Group, Inc.'s (''CME Group'') DCMs.[13] For example, ATSs accounted for approximately 51% of trade volume in E-mini S&P 500 futures and 69% of trade volume in EuroFX futures.[14] Increased automation in both order generation and matching, combined with the exponentially faster communication networks discussed in section II.A.2., below, has in many cases reduced the trade lifecycle to as little as a few milliseconds. As a result, high-frequency trading (''HFT'') strategies have also become an increasingly important component of automated trading environments.

The Commission is working diligently to understand and keep pace with the growth of ATSs and HFT in its regulated markets. The TAC, for example, has worked to define HFT and received a definition of HFT from its working group panel of experts. The attributes of HFT, according to the TAC's working group, include:

(a) Algorithms for decision making, order initiation, generation, routing, or execution, for each individual transaction without human direction;

(b) low-latency technology that is designed to minimize response times, including proximity and co-location services;

(c) high speed connections to markets for order entry; and

(d) recurring high message rates (orders, quotes or cancellations) determined using one or more objective forms of measurement, including (i) cancel-to-fill ratios; (ii) participant-to-market message ratios; or (iii) participant-to-market trade volume ratios.[15]

In addition, the TAC's working group described automated trading as ''cover[ing] systems employed in the decision-making, routing and/or execution of an investment or trading decision, which utilizes a range of technologies including software, hardware, and network components to facilitate efficient access to the financial markets via electronic trading platforms.'' [16] Effectively, HFT is a form of automated trading, but not all automated trading is HFT.[17]

In this regard, the Commission is aware that instability in automated trading environments may be precipitated by ATSs regardless of whether they employ high-frequency or other trading strategies. Accordingly, the risk controls, system safeguards and other measures contemplated for ATSs in this Concept Release do not distinguish on the basis of ATSs' trading strategies. However, the Commission is interested in better understanding HFT and whether it should receive different regulatory attention than ATSs in general. The Commission requests comment on the following questions regarding HFT and related topics:

1. In any rulemaking arising from this Concept Release, should the Commission adopt a formal definition of HFT? If so, what should that definition be, and how should it be applied for regulatory purposes?

2. What are the strengths and weaknesses of the TAC working group definition of HFT provided above? How should that definition be amended, if at all?

3. The definition of HFT provided above uses ''recurring high message rates (orders, quotes or cancellations)'' as one of the identifying characteristics of HFT, and lists three objective measures (i) cancel-to-fill ratios; (ii) participant-to-market message ratios; or (iii) participant-to-market trade volume ratios) that could be used to measure message rates. Are these criteria sufficient to reliably distinguish between ATSs in general and ATSs using HFT strategies? What threshold values are appropriate for each of these measures in order to identify ''high message rates?'' Should these threshold values vary across exchanges and assets? If so, how?

4. Should the risk controls for systems and firms that engage in HFT be different from those that apply to ATSs in general? If so, how?

2. Advances in High-Speed Communication Networks and Reductions in Latency

Automated trading environments are also characterized by connectivity and infrastructure solutions that enable trading platforms to process orders and execute trades at ever increasing speeds, and enable market participants (including ATSs) to communicate with platforms at ever decreasing latencies.[18]

[10] This figure represents transactions executed competitively on DCM trading platforms and not off-exchange transactions such as block trades.

[11] *See* Paul Zubulake & Sang Lee, *The High Frequency Game Changer* at 84, fig. 6.3 (John Wiley & Sons, Inc. 2011) (source of data: Aite Group).

[12] *See* Barry Johnson, *Algorithmic Trading & DMA: An Introduction to Direct Access Trading Strategies* at 78, fig. 3–11 (4Myeloma Press 2010) (source of data: Aite Group).

[13] *See* CME Group, ''Algorithmic Trading and Market Dynamics'' (July 15, 2010) at 2, available at *http://www.cmegroup.com/education/files/Algo_and_HFT_Trading_0610.pdf.* At the time, the CME Group operated four DCMs: the Chicago Mercantile Exchange, the Chicago Board of Trade, the New York Mercantile Exchange (''NYMEX''), and the Commodity Exchange.

[14] *See id.*

[15] *See* TAC Subcommittee on Automated and High Frequency Trading, Working Group 1, Presentation to the TAC (Oct. 30, 2012), available at *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/tac103012_wg1.pdf.* In addition, the TAC Subcommittee on Automated and High Frequency Trading, Working Group 1, described high frequency trading as a mechanism used by a variety of trading strategies, including, but not limited to, liquidity provision and statistical arbitrage.

[16] *See id.*

[17] In March 2013, the German parliament approved legislation on high frequency trading (the ''HFT Act''). *See* Hans-Edzard Busemann, ''German upper house approves rules to clamp down on high-frequency trading,'' Reuters (March 22, 2013), available at *http://uk.reuters.com/article/2013/03/22/uk-germany-trading-idUKBRE92L0L820130322.* The legislation defines high frequency trading generally as follows: The sale or purchase of financial instruments for own account as direct or indirect participant in a domestic organized market or multilateral trading facility by means of a high-frequency algorithmic trading technique which is characterized by (i) the usage of infrastructures to minimize latency times, (ii) the decision of the system regarding the commencement, creation, transmission or execution of an order without human intervention for single transactions or orders, and (iii) a high intraday messaging volume in the form of orders, quotes or cancellations. *See* BaFin (Federal Financial Supervisory Authority), ''High-frequency trading: new rules for trading participants'' (March 26, 2013) (including Workshop on High Frequency Trading Act Presentations dated April 30, 2013 and Frequently Asked Questions Relating to the High Frequency Trading Act dated March 22, 2013) [hereinafter, the ''BaFin HFT Act Materials''], available at *http://www.bafin.de/SharedDocs/Veroeffentlichungen/EN/Meldung/2013/meldung_130322_hft-gesetz_en.html?nn=2821494.*

The German HFT Act also defines algorithmic trading. The HFT Act's definition is generally as follows: Trading with financial instruments such that a computer algorithm determines automatically the individual order parameters without being merely a system for the transmission of orders to one or several trading venues or to confirm orders. Order parameters within the meaning of the preceding sentence are decisions whether the order is given, the timing, price and quantity of an order or how the order will be executed with limited or no human interference. *See id.* As explained in footnote 103 below, the HFT Act also introduces a licensing requirement.

[18] Latency means ''the time it takes to learn about an event (*e.g.,* a change in the bid), generate a

Continued

Notably, however, such capabilities require equally sophisticated risk management systems whose speeds are commensurate with those of low-latency order generation and trade execution systems. Public data from one exchange group, for example, indicates that roundtrip trade times on its trading platform fell from 127 milliseconds in 2004 to 4.2 milliseconds in 2011.[19] Another exchange group reported in 2010 that its average blended transaction time in futures and OTC markets was 1.25 milliseconds.[20] Advances in trading speeds are partly due to the development of dedicated fiber-optic and microwave communications networks that have dramatically reduced latency across large distances. As of 2012, networks were being developed to reduce roundtrip messaging between New York and London from 65 milliseconds to 60 milliseconds.[21] In March 2013, CME Group Inc. and Nasdaq OMX Group Inc. announced plans to launch a wireless network that will provide roundtrip messaging between New York and Chicago in 8.5 milliseconds.[22]

Two common methods for reducing latency are co-location and proximity hosting, defined as the placement of a firm's trading technology in close proximity to the trading platform. They may be offered directly by an exchange or by a third-party service provider. Co-location denotes those connectivity solutions hosted by the exchange itself, while proximity hosting indicates services offered by third parties.[23] In 2010, the Commission published in the **Federal Register** a Notice of Proposed Rulemaking to require DCMs and others that offer co-location and/or proximity hosting to offer such services on an equal access basis, ensure that fees are uniform and non-discriminatory, and provide information about the latency for various connectivity options (''co-location rulemaking'').[24] The Commission intends to finalize the co-location rulemaking by the end of the year.

Another important latency-reducing advance in connectivity is DMA. For purposes of this Concept Release, DMA is defined as a connection method that enables a market participant to transmit orders to a trading platform without reentry or prior review by systems belonging to the market participant's clearing firm. DMA can be provided directly by an exchange or through the infrastructure of a third-party provider. In all cases, however, DMA connectivity implies that a market participant's order flow is not routed through its clearing firm prior to reaching the trading platform.[25]

Investment in high-speed communication networks and other technologies to reduce latency reflects the premium that some market participants place on speed relative to their competitors. Reductions in latency may be appropriately achieved through improvements in a range of technologies for the generation, transmission and execution of orders or management of other data. However, there are also incentives for market participants to reduce latency by minimizing pre-trade risk controls and other safeguards that might otherwise introduce unwanted delays. While latency-based incentive structures have promoted evident technological innovation in many derivatives markets, they can also lead to a competitive race to the bottom—a concern already expressed by some market participants.[26] A separate concern is that market participants may simply engage in trading at speeds greater than the speed of their risk management systems. In a trading environment where a single algorithm can submit hundreds of orders per second, risk management systems operating at slower speeds could allow an algorithm that is operating in unexpected ways to disrupt one or more markets.

5. Discussions on latency often focus on the how quickly an exchange processes orders, the time taken to submit orders, and how quickly a firm can observe prices of trades transacted on the exchange. The Commission is interested in understanding whether there are other types of messages transmitted between exchanges, firms and vendors wherein differences in latency could provide opportunities for informational advantage. Recent press reports have highlighted such advantages in the transmission of trade confirmations by a specific exchange.[27] Are there other exchanges and trading venues where similar differences in latency exist? The Commission is interested in understanding whether the extent of latency in any such message transmission process can have an adverse impact on market quality or fairness. Should any exchanges, vendors and firms be required to audit their systems and process on a periodic process to identify and then resolve such latency?

3. Rise of Interconnected Automated Markets

In addition to greater automation and decreased latency, derivatives markets are increasingly characterized by a high degree of interconnection. ATSs and algorithms deployed to trade particular products often interact directly and indirectly with ATSs and algorithms active in other markets and jurisdictions. Increased interconnectedness is facilitated by electronic access to real-time pricing information, automated order execution, and some standardization in communication protocols at various

response, and have the exchange act on the response.'' *See* Joel Hasbrouck & Gideon Saar, ''Low-Latency Trading'' (May 2013) at 1, available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1695460.*

[19] *See* CME Group, ''Oversight of Automated Trading at CME Group'' (March 29, 2012) at 4, available at *http://www.cftc.gov/ucm/groups/public/@aboutcftc/documents/file/tacpresentation032912_cme.pdf.*

[20] *See* IntercontinentalExchange, ''2010 Annual Report,'' at 26, available at *http://files.shareholder.com/downloads/ICE/1747226327x0x456112/BF6F428C-F8B3-4835-B22C-3F350FF13B89/ICE_2010AR.pdf.* IntercontinentalExchange indicated that it measures round trip performance end to end within its data center and through its matching engine.

[21] *See* Matthew Philips, ''Stock Trading is About to Get 5.2 Milliseconds Faster,'' BloombergBusinessweek (Mar. 29, 2012), available at *http://www.businessweek.com/articles/2012-03-29/trading-at-the-speed-of-light.*

[22] *See* Jacob Bunge, ''CME, Nasdaq Plan High-Speed Network Venture,'' Wall St. J. (Mar. 28, 2013), available at *http://online.wsj.com/article/SB10001424127887324685104578388343221575294.html.*

[23] *See* FIA Market Access Working Group, ''Market Access Risk Management Recommendations'' (April 2010) at 4 [hereinafter, ''FIA Market Access Recommendations''], available at *http://www.futuresindustry.org/downloads/Market_Access-6.pdf.*

[24] *See* Commission, Notice of Proposed Rulemaking: Co-Location/Proximity Hosting Services, 75 FR 33198 (Jun. 11, 2010).

[25] The Commission has taken steps to mitigate the risk associated with DMA. Rule 1.73, passed by the Commission in April 2012, requires FCMs that are clearing members to pre-screen orders of DMA clients against risk limits that are established by the FCM. *See* 17 CFR 1.73(a)(2)(i). *See* additional discussion in section II.B.

[26] As noted by FIA's Market Access Working Group, for example: ''[p]re-trade risk controls have become a point of negotiation between trading firms and clearing members because they can add latency to a trade.'' *See* FIA Market Access Recommendations, *supra* note 23, at 8.

Similarly, the TAC's Pre-Trade Functionality Subcommittee noted that latency is a key area where trading firms and brokers are competing to gain an advantage. *See* TAC Pre-Trade Functionality Subcommittee, ''Recommendations on Pre-Trade Practices for Trading Firms, Clearing Firms, and Exchanges Involved in Direct Market Access'' (March 1, 2011) at 2 [hereinafter, ''TAC Pre-Trade Functionality Subcommittee DMA Recommendations''], available at *http://www.cftc.gov/ucm/groups/public/@swaps/documents/dfsubmission/tacpresentation030111_ptfs2.pdf.*

[27] *See* Scott Patterson, Jenny Strasburg & Liam Pleven, ''High-Speed Traders Exploit Loophole,'' Wall St. J. (May 1, 2013), available at *http://online.wsj.com/article/SB10001424127887323798104578455032466082920.html.*

trading platforms.[28] ATSs can quickly execute strategies across multiple markets within very short periods of time. Often, cross-market activity is driven by latent arbitrage opportunities and faster access to multiple markets has led to a proliferation of strategies that seek to identify and trade on the basis of these relationships.[29]

Increased interconnectedness encourages price efficiencies when economically identical or related contracts are traded on multiple exchanges. However, it also increases the speed with which a disruption on one trading platform, or within one ATS or algorithm, can impact related markets. For example, a trading platform may experience changes in the prices, spreads or volatility of one or more of its products due to errors in an ATS or algorithm active in its markets. Even if this algorithm does not trade elsewhere, such changes are likely to quickly impact the prices, spreads, and volatility of related products on other platforms, as automated systems attempt to arbitrage price differences. The potential result is a cascading series of market disruptions, brought about by the malfunction of a single ATS or algorithm trading on a single platform.

Transmission effects such as this are illustrated by events like the May 6, 2010 ''Flash Crash.'' On that day, major equity indices in both the futures and securities markets fell over 5% in minutes before recovering almost as quickly. After investigation by both the Commission and the SEC, it was found that a fundamental seller utilized an automated execution algorithm to sell 75,000 E-mini contracts (valued at approximately $4.1 billion) over an abbreviated time interval. The algorithm placed orders based on recent trading volume but was not programmed to take price or time into account; because of this lapse, a feedback loop triggered continued orders from the algorithm even as prices moved far beyond traditional daily ranges. Like the hypothetical example provided above, these declines in the derivatives market quickly filtered over to different, but closely related, products on many other exchanges.[30] Soon after the initial moves in the E-mini contract, similar extreme volatility was experienced by the S&P 500 SPDR exchange traded fund and by many of the 500 underlying securities which make up the index itself.

In response to the May 2010 flash crash, regulatory authorities and market participants have taken steps to address volatility in U.S. markets, including trading pauses and halts that operate as ''circuit breakers.'' For example, in May 2012, the SEC approved a ''limit up-limit down'' mechanism in which a price band is set at a percentage level above and below the average price of the stock over the immediately preceding five-minute trading period.[31] If the stock's price does not naturally move back within the price bands within 15 seconds, there will be a five-minute trading pause. The limit up-limit down mechanism began implementation in April 2013, beginning with all stocks in the S&P 500 and Russell 1000 and select exchange traded products.

In addition, the SEC approved updates to market-wide circuit breaker rules that, when triggered, halt trading in all exchange-listed securities in U.S. markets. Among other things, the new rules lower the percentage-decline thresholds for triggering a market-wide trading halt. The thresholds (Level 1 (7%), Level 2 (13%), and Level 3 (20%)) are set at levels calculated daily based on the prior day's closing price of the S&P 500 index.[32] To be consistent with these circuit breakers, the CME Group, effective April 8, 2013, reduced the price limit levels for CME and CBOT U.S. equity index futures to 7%, 13% and 20%.[33] When a trading halt is declared in the primary securities market in accordance with these levels, trading in the S&P 500 index futures contracts will be halted at the CME. When trading in the primary securities market resumes after any such halt, trading in the S&P index futures contracts will resume. Similar rules apply to other equity index futures contracts listed on CME. In March 2012, ICE Futures U.S. introduced a circuit breaker functionality called Interval Price Limits, in which prices may not move more than a pre-determined amount away from the current market price within a pre-determined period.[34]

Throughout section III below, the Commission seeks public comment on the benefits of standardizing various risk controls and system safeguards, including through the uniform application of regulatory standards to help ensure an integrated risk management infrastructure in regulated derivatives markets. The Commission draws commenters' particular attention to the joint regulatory and industry response to the Flash Crash summarized above and seeks public input regarding the need for similar joint efforts with respect to the pre-trade risk controls, post-trade reports, and system safeguards contemplated in this Concept Release.

4. Manual Risk Controls and System Safeguards in Automated Trading Environments

Orders in automated trading environments may be initiated by ATSs and algorithms. Multiple other automated systems perform other processing, communicating, and other functions. The speed of such automated processes has necessarily shifted risk management functions to parallel automated risk management systems acting with equal speed.

Within this context, manual risk controls, and particularly systems safeguards, remain crucial to orderly markets. In many cases, manual risk controls have shifted ''upstream'' to system design and ''downstream'' to system management. In automated trading, humans design and test ATSs, establish decision criteria, manage implementation, and intervene when technology systems fail. ATS designers must identify the range of market conditions that an ATS could reasonably face, and determine the range of permissible responses by the ATS to each condition. Designers must also consider the array of information that ATS operators will need to effectively monitor their ATSs and the markets in which their ATSs operate. ATS operators, in turn, must be

[28] For example, FIX language makes it possible for ATS to be ''platform independent''—to incorporate interfaces to multiple brokers, ECNs, or exchanges. *See* Irene Aldridge, *High-Frequency Trading: A Practical Guide to Algorithmic Strategies and Trading Systems* at 31 (John Wiley & Sons, Inc. 2010). *See also* Cliff, Brown, & Treleaven, ''Technology Trends in the Financial Markets: A 2020 Vision,'' United Kingdom Government Office for Science—Foresight, at 10, available at *http://www.bis.gov.uk/assets/foresight/docs/computer-trading/11-1222-dr3-technology-trends-in-financial-markets.pdf.*

[29] For example, ''basis trading,'' and ''futures/equity arbitrage'' are statistical arbitrage strategies that seek to capitalize on deviations between prices on futures contracts and related securities contracts after macroeconomic news announcements. *See* Aldridge, *supra* note 28, at 197–98.

[30] *See* CFTC and SEC Joint Report on the Market Events of May 6, 2010, *supra* note 1, at 1–6; ''Recommendations Regarding Regulatory Responses to the Market Events of May 6, 2010, Summary Report of the Joint CFTC-SEC Advisory Committee on Emerging Regulatory Issues'' (February 18, 2011), available at *http://www.cftc.gov/ucm/groups/public/@aboutcftc/documents/file/jacreport_021811.pdf.*

[31] *See* SEC, ''Investor Bulletin: New Measures to Address Market Volatility'' (Apr. 9, 2013), available at *http://www.sec.gov/investor/alerts/circuitbreakersbulletin.htm.*

[32] *See id.*

[33] *See* CME Group, ''Changes to CME and CBOT Equity Index Price Limits: Frequently Asked Questions,'' available at *http://www.cmegroup.com/education/files/faq-eq-hours-and-limits.pdf.*

[34] *See* IntercontinentalExchange, Inc., ''ICE Circuit Breakers (IPL) Price Limits'' (March 2012), available at *https://www.theice.com/publicdocs/technology/IPL_Circuit_Breaker.pdf.*

prepared to intervene when market conditions are outside of an ATS's design parameters, when an ATS's trading strategy must be modified, or when an ATS appears to be malfunctioning and must be shut down. Rapid decisions must be made while simultaneously digesting large quantities of information regarding multiple, fast-moving markets. Accordingly, this Concept Release contemplates a number of risk controls and system safeguards that emphasize the role and interaction of manual processes with automated trading environments, particularly ATSs.

B. The Commission's Regulatory Response to Date

The Commission has responded to the development of automated trading environments through a number of regulatory measures that address risk controls within both new and existing categories of registrants, including DCMs, SEFs, FCMs, SDs, MSPs and others. In April 2012, the Commission adopted rules requiring FCMs, SDs and MSPs that are clearing members to establish risk-based limits based on ''position size, order size, margin requirements, or similar factors'' for all proprietary accounts and customer accounts.[35] The rules, codified in §§ 1.73 and 23.609, also require these entities to ''use *automated* means to screen orders for compliance with the [risk] limits'' when such orders are subject to automated execution (emphasis added).[36] Such screening must, by definition, occur pre-trade. The Commission also adopted rules in April 2012 requiring SDs and MSPs that are clearing members to ensure that their ''use of trading programs is subject to policies and procedures governing the use, supervision, maintenance, testing, and inspection of the program.'' [37] The specific content of those policies and procedures are left up to the SDs and MSPs.

The Commission has also adopted relevant rules with respect to exchange platforms, including rules with respect to DCMs (adopted in June 2012).[38] Regulation 38.255, for example, requires DCMs to ''establish and maintain risk control mechanisms to prevent and reduce the potential risk of price distortions and market disruptions, including, but not limited to, market restrictions that pause or halt trading in market conditions prescribed by the designated contract market.'' [39] In addition, the acceptable practices for DCM Core Principle 4 identify pre-trade limits on order size, price collars or bands, and message throttles as responsive measures that a DCM may implement to demonstrate compliance with elements of the core principle.[40] The Commission has adopted trading pause and halt requirements for SEFs similar to those for DCMs.[41]

In the DCM final rules, the Commission also adopted new risk control requirements for exchanges that provide DMA to clients. Regulation 38.607 requires DCMs that permit DMA to have effective systems and controls reasonably designed to facilitate an FCM's management of financial risk. These systems and controls include automated pre-trade controls through which member FCMs can implement financial risk limits.[42] As the Commission noted in the preamble to the DCM final rules, in DMA arrangements ''it is impossible for an FCM to protect itself without the aid of the DCM.'' [43] The Commission also noted in the DCM final rules, however, that ''the responsibility to utilize these [DCM-provided] controls and procedures remains with the FCM. Each FCM permitting direct access must use DCM-provided controls . . . .'' [44] Accordingly, regulation 38.607 requires DCMs to implement and enforce rules requiring member FCMs to use these systems and controls.[45]

In addition to the foregoing, section 753 of the Dodd-Frank Act amended section 6(c) of the CEA to prohibit manipulation and fraud in connection with any swap, or a contract of sale of any commodity in interstate commerce, or for future delivery on or subject to the rules of any registered entity. In July 2011, the Commission adopted final rules implementing this new authority under the CEA. CFTC Regulation 180.1, among other things, broadly prohibits manipulative and deceptive devices, *i.e.,* fraud and fraud-based manipulative devices and contrivances employed intentionally or recklessly, regardless of whether the conduct in question was intended to create or did create an artificial price.[46] CFTC Regulation 180.2 codifies the Commission's long-standing authority to prohibit price manipulation by making it unlawful for any person, directly or indirectly, to manipulate or attempt to manipulate the price of any swap, or of any commodity in interstate commerce, or for future delivery on or subject to the rules of a registered entity.[47]

Finally, section 747 of the Dodd-Frank Act amended the CEA to make it unlawful for any person to engage in disruptive trading practices. Under section 4c(a)(5) of the CEA, it is unlawful for any person to engage in any trading, practice, or conduct on or subject to the rules of a registered entity that: Violates bids or offers, demonstrates intentional or reckless disregard for the orderly execution of transactions during the closing period, or is, is of the character of, or is commonly known to the trade as, ''spoofing.'' In May 2013, the Commission provided guidance on the scope and application of these statutory prohibitions.[48] In July 2013, the Commission issued an order filing and settling charges against a high-speed trading firm for engaging in the disruptive practice of ''spoofing'' by utilizing a computer algorithm that was designed to illegally place and cancel bids and offers in futures contracts.[49]

C. Recent Disruptive Events in Automated Trading Environments

Recent malfunctions in ATS and trading platform systems, in both derivatives and securities markets, illustrate the technological and operational vulnerabilities inherent to automated trading environments. ATSs,

[35] 17 CFR 1.73(a)(1) and 23.609(a)(1).

[36] 17 CFR 1.73(a)(2)(i) and 17 CFR 23.609(a)(2)(i).

[37] 17 CFR 23.600(d)(9).

[38] *See* DCM Final Rules, 77 FR 36612.

[39] 17 CFR 38.255.

[40] Part 38, Appendix B, Core Principle 4, section (b)(5), provides: *Risk controls for trading.* An acceptable program for preventing market disruptions must demonstrate appropriate trade risk controls, in addition to pauses and halts. Such controls must be adapted to the unique characteristics of the markets to which they apply and must be designed to avoid market disruptions without unduly interfering with that market's price discovery function. The designated contract market may choose from among controls that include: Pre-trade limits on order size, price collars or bands around the current price, message throttles, and daily price limits, or design other types of controls. Within the specific array of controls that are selected, the designated contract market also must set the parameters for those controls, so long as the types of controls and their specific parameters are reasonably likely to serve the purpose of preventing market disruptions and price distortions. If a contract is linked to, or is a substitute for, other contracts, either listed on its market or on other trading venues, the designated contract market must, to the extent practicable, coordinate its risk controls with any similar controls placed on those other contracts. If a contract is based on the price of an equity security or the level of an equity index, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on national security exchanges. *See* DCM Final Rules, 77 FR at 36718.

[41] 17 CFR 37.405.

[42] *See* 17 CFR 38.607.

[43] *See* DCM Final Rules, 77 FR at 36648.

[44] *Id.*

[45] *See* 17 CFR 38.607.

[46] *See* 17 CFR 180.1.

[47] *See* 17 CFR 180.2.

[48] *See* Commission, Interpretive Guidance and Policy Statement, 78 FR 31890 (May 28, 2013).

[49] *See* Commission, Press Release No. 6649–13 (July 22, 2013), available at *http://www.cftc.gov/PressRoom/PressReleases/pr6649-13.*

for example, are vulnerable to algorithm design flaws, market conditions outside of normal operating parameters, the failure of built-in risk controls, operational failures in the communication networks on which ATSs depend for market data and connectivity with trading platforms, and inadequate human supervision. Incidents involving an automated trading firm active in Commission-regulated markets are illustrative of these concerns. For example, in 2011 NYMEX fined a firm $350,000 for failing to adequately supervise, test, and have controls in place related to its ATS.[50] NYMEX cited a 2010 event where the firm launched an ATS after limited testing. The firm was also fined a total of $500,000 by CME for failure to effectively supervise its ATSs on multiple occasions.[51] A panel of the CME Business Conduct Committee found that the firm had experienced malfunctions with the same ATS multiple times, causing it to submit error trades.

In another example, in 2012 a securities trading firm, Knight Capital Group, launched new software on the NYSE that conflicted with already existing code.[52] At the time, the firm was one of the largest participants and a market maker on the NYSE. The firm's ATS inadvertently established larger positions than intended, resulting in a $440 million loss for the firm. The malfunction impacted the broader market, creating swings in the share prices of almost 150 companies, and the high volatility linked to the algorithm designed by the firm also triggered pauses in the trading of five stocks. In addition to the software malfunction itself, some have reported that there was a delay of approximately 40 minutes before humans intervened.[53]

A leading example of ATS malfunction that impacted both the derivatives and securities markets in the Flash Crash of May 2010. As described in detail in section II.A.3. above, the Flash Crash illustrates the potential consequences of ATS design flaws as an automated execution algorithm failed to take price or time variables into account, and feedback loops triggered continued orders from the algorithm even as prices moved far beyond traditional daily ranges.[54] Finally, the Commission notes the recent systems malfunction at Goldman Sachs Group Inc. that inadvertently flooded U.S. options markets with a large number of unintended orders.[55]

In addition to ATSs, trading platforms have also suffered malfunctions and illustrate another area in which market disruptive events can occur. In November 2010, for example, untested code changes implemented by a U.S. stock exchange operator resulted in errors within its trading platforms. As a result, the platforms overfilled orders in over 1,000 stocks, resulting in $773 million of unwanted trading activity.[56] In March 2012, a software problem on BATS Global Markets, whose software had undergone testing, led to a disruption of the exchange's own IPO. The glitch caused opening orders for ticker symbols beginning within a certain letter range to become inaccessible on the platform.[57] Once the system failed, circuit breakers were triggered and erroneous trades were cancelled.[58] In May 2012, Facebook's IPO experienced significant problems as a result of technical errors on Nasdaq OMX Group Inc.'s U.S. exchange.[59] Many customer orders from both institutional and retail buyers were unfilled for hours or were never filled at all, while other customers ended up buying more shares than they had intended. Finally, the Commission notes the recent three-hour halt in trading on the Nasdaq, which according to reports was caused when the exchange experienced a disruption in its stock quote dissemination systems and a disruption in its connectivity with another trading platform's systems.[60]

Taken together, these events illustrate the importance of effective testing, circuit breakers, and error trade policies as vehicles for reducing the likelihood of disruptive events and mitigating their impact when they occur.[61] A number of the risk controls contemplated in this Concept Release could help limit the extent of market disruption caused by ATS or trading platform malfunctions similar to those described above. For example, an order ''kill switch'' enables a market participant to immediately cancel all working orders generated by one or more of its ATSs, and prevents the submission of additional orders until the appropriate natural persons allow order placement to resume. Such a kill switch could be operated by the market participant generating orders, the clearing firm guaranteeing its trades, or the trading platform on which its orders would be executed. As another example, ATS monitoring and supervision standards, as well as pre-established crisis management protocols, could help ensure that human supervisors intervene quickly when ATSs experience degraded performance, and that supervision staff have the both the authority and knowledge to intervene as required. Further, requiring exchanges to calculate and disseminate market quality metrics could enable both exchanges and market participants to better anticipate and mitigate destabilizing events. In addition, the Commission believes that change management standards that are beneficial to ATSs could also be applied to trading platforms to help prevent operational or programming errors in that element of the automated trading environment. In section III below, the

[50] *See* NFA, Case Summary: Infinium Capital Management, NYME 10–7565–BC (Nov. 25, 2011), available at *http://www.nfa.futures.org/basicnet/Case.aspx?entityid=0338588&case=10-7565-BC+INFINIUM+CAPITAL+MGMT&contrib=NYME.*

[51] *See* NFA, Case Summary: Infinium Capital Management, CME 09–06562–BC (Nov. 25, 2011), available at *http://www.nfa.futures.org/basicnet/Case.aspx?entityid=0338588&case=09-06562-BC&contrib=CME.*

[52] *See* Strasburg & Bunge, *supra* note 2.

[53] *See* SEC Roundtable Transcript, *supra* note 2, at 55–56.

[54] *See* CFTC and SEC Joint Report on the Market Events of May 6, 2010, *supra* note 1.

[55] *See* Jacob Bunge, Kaitlyn Kiernan & Justin Baer, ''Bad Trades' Ripple Effect,'' W. St. J. (Aug. 21, 2013), available at *http://online.wsj.com/article/SB10001424127887324165204579026611410016876.html.*

[56] *See* Securities and Exchange Act Release No. 65556, In the Matter of EDGX Exchange, Inc., EDGA Exchange, Inc. and Direct Edge ECN LLC (Oct. 13, 2011), available at *http://www.sec.gov/litigation/admin/2011/34-65556.pdf; see also* SEC News Release, 2011–208, ''SEC Sanctions Direct Edge Electronic Exchanges and Orders Remedial Measures to Strengthen Systems and Controls'' (Oct. 13, 2011), available at *http://www.sec.gov/news/press/2011/2011-208.htm.*

[57] *See* Olivia Oran, Jonathan Spicer, Chuck Mikolajczak & Carrick Mollenkamp, ''BATS exchange withdraws IPO after stumbles,'' Reuters (Mar. 24, 2012), available at *http://uk.reuters.com/article/2012/03/24/us-bats-trading-idUKBRE82M0W020120324;* Michael J. De La Merced & Ben Protess, The N.Y. Times Dealbook (Mar. 25, 2012), available at *http://dealbook.nytimes.com/2012/03/25/little-fallout-expected-from-bats-trading-error/.*

[58] *See id.*

[59] *See* Jenny Strasburg and Jacob Bunge, ''Social network's debut on Nasdaq disrupted by technical glitches, trader confusion,'' Wall St. J. (May 18, 2012), available at *http://online.wsj.com/article/SB10001424052702303448404577412251723815184.html?mod=googlenews_wsj;* Jenny Strasburg, Andrew Ackerman & Aaron Lucchetti, ''Nasdaq CEO Lost Touch Amid Facebook Chaos,'' Wall St. J. (June 11, 2012), available at *http://online.wsj.com/article/SB10001424052702303753904577454611252477238.html.*

[60] *See* Chris Dieterich & Jacob Bunge, ''Nasdaq Offers Details on Trading Outage,'' Wall St. J. (Aug. 23, 2013), available at *http://online.wsj.com/article/SB10001424127887324165204579030681671164404.html.*

[61] In addition, although in some ways distinct from the events summarized above, the Commission notes the significant impact of Hurricane Sandy in October 2012. U.S. stock markets closed for two days partially in response to concerns over preparedness to trade exclusively on electronic venues while trading floors were potentially closed, as well as the availability of technology and other relevant personnel. *See* Jenny Strasburg, Jonathan Cheng & Jacob Bunge, ''Behind Decision To Close Markets,'' Wall St. J. (Oct. 29, 2012), available at *http://online.wsj.com/article/SB10001424052970204789304578087131092892180.html.*

Commission seeks public comment on these and other potential risk controls.

III. Potential Pre-Trade Risk Controls, Post-Trade Reports, System Safeguards, and Other Protections

A. Overview of Existing Industry Practices

The transition to automated trading in derivatives markets, as described above, has been followed by an evolution in what market participants, regulators and others understand to be necessary risk controls for various points in the order and trade lifecycle. Many of the measures identified herein are consistent with recommendations made by industry groups, other regulatory authorities, international standard setting bodies, and others. Certain measures, or variants of them, have been discussed within the futures industry for some time, or may already be in operation at one or more exchanges, clearing members, or market participants. For example, the system safeguards pertaining to the cancellation of orders or disconnecting a market participant in emergency situations are similar to proposals made separately by FIA's Principal Traders Working Group and Market Access Working Group in 2010 and the TAC's Pre-Trade Functionality Subcommittee in 2011.[62]

The Principal Traders Group also addressed the need to properly monitor ATSs in its 2010 recommendations by noting that ''firms must ensure their [ATSs] are supervised at all times while operating in the markets. Staff must have training, experience and tools that enable them to monitor and control the trading systems and troubleshoot and respond to operational issues in a timely and appropriate manner. Firms should have processes and procedures to ensure trading operations staff is trained on the expected operating parameters of any [ATS] for which they are responsible.'' [63] ATS design and operation was addressed by FIA's Market Access Working Group and by ESMA, the latter requiring that market participants ''make use of clearly delineated development and testing methodologies'' for ATSs prior to their deployment or the deployment of system updates.[64] Among other considerations, ESMA emphasized that ATS testing should address embedded compliance and risk management controls and operation during stressed market conditions.

As with the pre-trade and post-trade risk controls, certain system safeguards would be applicable to more than one entity or would require coordination between entities. For example, ATS design and operation tests will require that trading platform operators provide suitable test environments that accurately recreate the ''live'' trading platform. Similarly, safeguards that provide for the immediate disconnection of a market participant in the event of emergency or breach of tolerances should be available to the market participant, its clearing firm, and the relevant trading platform so that all parties have the capacity to initiate a disconnect when necessary. As with other overlapping measures contemplated in this Concept Release, the Commission requests public comment regarding the necessity of such overlaps and the most efficient way to administer them.

1. Existing DCM Risk Controls

Risk controls implemented by one or more exchanges broadly address market stability. One large DCM (''DCM A'') employs price reasonability validation controls (aimed at preventing ''fat finger'' type errors) and position validation controls (both absolute limits and net long/short limits). In addition, DCM A has implemented a circuit breaker protection against price spikes. This control provides floor and ceiling price limits within a specific timeframe and market, and recalculates new floor and ceiling price limits based on current market prices for each new timeframe. If the floor or ceiling price is exceeded, the market is put in a ''hold'' state, although trading will not be halted in the opposite direction of the hold. The length of the hold varies depending on the market and orders submitted during the hold state will remain in the order book but will not be matched. DCM A has also implemented kill switches that provide it and risk managers at trading firms with the ability to halt trading.

Similarly, another large DCM (''DCM B'') also employs a limit price to each market order and stop order to prevent orders from being filled at significantly aberrant price levels, and maximum order size protection to prevent entry of erroneous orders for quantities above a designated threshold. DCM B employs a functionality that introduces a 5–20 second market pause when triggered stops would cause the market to trade outside of predefined values. This is designed to prevent excessive price movements caused by cascading stop orders. DCM B also employs a functionality that introduces a 5–20 second market pause when a sub-second, extreme market move occurs as a result of order entry. This functionality is designed to detect significant price moves of futures contracts occurring within a predetermined period of time, and triggers a pause in matching activity to provide time for additional resting orders to populate the order book.

DCM A seeks to optimize message flow through both hard limits and market incentives. It employs a message throttle limit which sets a maximum message rate per second for each user session and prevents the submission of messages in excess of the maximum rate. The second form of message control used by DCM A is a system of fees based on Weighted Volume Ratio (''WVR'') calculations designed to discourage inefficient messaging among firms with high message volumes. The WVR is a ratio between the number of messages submitted by a market participant and the total volume of orders that it executes. The ratio of unfilled orders is also weighted based on how far away from the best bid or offer each unfilled order was when it was entered. Orders that are farther away from the best bid or offer when entered are weighted more heavily. The DCM assesses fees against market participants when they exceed WVR limits.

DCMs A and B both employ an ''orders removed upon logout'' function in which all orders are removed upon the user's logout or disconnection, and that they maintain error trade policies that incorporate a no cancellation range.

With respect to ATSs, DCMs A and B both employ a certification and testing process for connecting entities. For example, one DCM described this process as testing a firm's messaging ability (*i.e.,* that firm's ability to send and receive data). As part of the testing process, the DCM will transmit market data to the firm and this provides the firm with the opportunity to run its own algorithms and for that firm to determine if its algorithms are functioning as it intended. Firms must pass additional conformance tests when the exchange's own system functionality changes. DCM B indicated that its testing process allows customers to test

[62] *See* FIA Principal Traders Group, ''Recommendations for Risk Controls for Trading Firms,'' (November 2010) at 5 [hereinafter, ''FIA Recommendations for Risk Controls''], available at *http://www.futuresindustry.org/downloads/Trading_Best_Pratices.pdf*; FIA Market Access Recommendations, *supra* note 23, at 9; TAC Pre-Trade Functionality Subcommittee DMA Recommendations, *supra* note 26, at 5.

[63] *See* FIA Recommendations for Risk Controls, *supra* note 62, at 3.

[64] *See* FIA Market Access Recommendations, *supra* note 23; ESMA Guidelines on Systems and Controls, *supra* note 4, at 33.

new products prior to their production launch.

In addition to their internal risk mitigation programs, DCMs also provide risk mitigation tools to intermediaries such as FCMs, allowing the intermediaries to set risk control parameters on controls that reside at the trading platform level. Clearing firms, for example, are able to set risk tolerance levels for their customers based on position size, order activity, executions, among other variables.

2. Existing Trading and Clearing Firm Risk Controls

Risk controls at the level of individual market participant firms, whether trading firms or clearing firms, are necessarily entity specific. Accordingly, industry groups have collaborated to determine best practices for risk controls. As noted previously, other entities, including the TAC, have also developed best practices or recommendations. One goal of this Concept Release is to determine how consistently these, and other, recommendations are today being implemented by market participants. As noted by FIA, ''all principal traders have a vested interest in well-functioning markets with effective risk controls, clear error trade policies that focus on trade certainty, and a strong regulatory framework.'' [65] Comments to this Concept Release will allow the Commission to best ensure this strong framework. Questions about the general use of automated risk controls at the level of a firm are also informed by two reports prepared by authors affiliated with the Federal Reserve Bank of Chicago. One report details the current practices of nine proprietary trading firms, with special attention to risk mitigating practices currently applied to their automated systems.[66] Through interviews, the authors found that (1) all firms have maximum order sizes in place and intraday position limits; (2) all but one firm has credit limits by account, which monitor open positions, dollar value of positions and quantity of working orders; [67] (3) half of the firms have price protection points for orders; (4) most firms had message throttles, set at order volume per unit of time; and (5) all firms had kill buttons. The risk controls included in this list, and others discussed within the report, are expanded upon in the below discussion. In its questions for comment, the Commission seeks to understand what types of risk controls are most commonly used throughout the industry, and the degree to which those risk controls are standardized across the industry.

A second report [68] summarized interviews with five Broker/Dealers (''B–Ds'') and FCMs, again detailing their current practices in automated risk controls. As at the trading level, some firms have implemented pre-trade and post-trade checks, along with other credit related controls to mitigate trading losses and resulting burdens on the clearing firm. The report details categories of risks considered by the B–D or FCM when signing on a new client, or updating controls as a client enters new businesses or expands on old ones. These include: Credit risks, market risks, counterparty risks, portfolio risks and regulatory risks. Through these assessments, clearing firms are able to determine appropriate risk thresholds for a given client, and apply them as necessary at multiple points in the trading chain. Specific controls come in forms quite similar to those outlined above in the case of the trading firm. Pre-trade risk controls span order size limits, intraday position limits, credit limits, and message throttles. These can vary by asset class, exchange, and other market factors, along with coincident market dynamics such as volatility levels and current positions of the trading firm. The monitoring done by the clearing firm is aided by post-trade measures such as the drop-copy of executions, which allows for the monitoring of positions and associated credit risks.

B. Overview of Risk Controls Addressed in This Concept Release

The risk controls presented below describe specific measures which could be taken by exchanges and participants in automated trading environments. To better understand current industry practices, the Commission is interested in determining, for each risk control: (1) Whether the entity commenting has implemented the control; (2) whether the entity believes implementation of the control within the marketplace is consistently applied; and (3) the benefits and costs of a regulatory mandate of the control. If the Commission determines that the types of risk controls employed across the industry vary widely, the Commission would be aided by understanding the extent of this variance, the reasons for it, and whether regulatory standardization can be of benefit. By gathering this information, the Commission will be better informed regarding beneficial future regulation surrounding automated systems.

The Commission emphasizes that this Concept Release is intended to serve as a high-level enunciation of potential measures intended to reduce the likelihood of market disrupting events and mitigate their impact when they occur. Many of the risk controls listed below are in effect, in part or in full, across multiple entities. Others have been included in recommendations by industry groups and standard-setting bodies, or addressed by foreign regulatory authorities. The Commission also notes that a number of the measures described below offer similar risk controls at various stages in the life of an order (*e.g.,* a safeguard applicable to the ATS generating an order and a similar safeguard applicable to the trading platform receiving such order). Added security through redundancy of risk controls is a feature of safeguard documents reviewed by the Commission in preparing this Concept Release. The Commission seeks public comment on merits of single versus redundant risk control models. Market participants and members of the public are encouraged to comment on the potential risk controls, and the Commission anticipates further refinement of the measures described herein based on the comments received.

The discussion of risk controls below is followed by a number of general questions on which the Commission requests comment (see section III.G. below). These questions are applicable to all the risk controls discussed below.

C. Pre-Trade Risk Controls

The Commission includes below a set of pre-trade risk controls aimed at reducing market disruptions related to automated trading due to errors, system malfunctions or other events with similar effects. In general, pre-trade risk controls seek to protect against the accumulation of a large volume of orders, executions, or positions over an abbreviated period of time. Some market participants are currently using controls which address this accumulation, including maximum order size limits, message rate limits, and similar measures. Pre-trade risk controls can also promote fair and orderly markets, through the use of circuit breakers, execution throttles and self-trade

[65] *See* FIA Recommendations for Risk Controls, *supra* note 62, at 2.

[66] *See* Carol Clark & Rajeev Ranjan, ''How Do Proprietary Trading Firms Control the Risks of High Speed Trading?'' (March 2012), available at *http://www.chicagofed.org/digital_assets/publications/policy_discussion_papers/2012/PDP2012-1.pdf.*

[67] The final firm also sets credit limits, but only for new traders. *See id.* at 7.

[68] *See* Carol Clark & Rajeev Ranjan, ''How Do Broker-Dealers/Futures Commission Merchants Control the Risks of High Speed Trading?'' (June 2012), available at *http://www.chicagofed.org/Webpages/publications/policy_discussion_papers/2012/pdp_3.cfm.*

monitoring. Finally, the pre-trade risk controls also include pre-trade credit limits designed to protect clearing firms, and their clients, with respect to customer and proprietary orders.[69] Each of these groups is discussed below in greater detail.

In order to fully address possible disruptions, the pre-trade risk controls apply at one or more of three points in the execution chain: (1) Individual firms; (2) intermediaries of many forms (including SDs, MSPs, FCMs, Floor Traders, Commodity Pool Operators (''CPOs'') and DCOs); and (3) exchanges (including DCMs and SEFs). In many cases, the same or similar risk controls are implemented at more than one point in the execution chain, such as first at the firm, then perhaps at the clearing firm, and then finally at the DCM. The Commission believes that this approach offers a number of advantages.[70] First, it allows individual entities to calibrate the relevant risk control in accordance with their own objectives and risk tolerances. For example, an exchange may set a per-product maximum order size to ensure orderly trading in its markets, with the same limit applying equally to all market participants. A clearing firm, however, may wish to address its customers' distinct risk profiles by setting different maximum order sizes for different customers.

Second, by indicating that some risk controls should reside at the exchange level in addition to the market participant and clearing firm levels, the Commission is responding to competitive and ''race to the bottom'' concerns raised by several observers. FIA's Market Access Working Group, for example, noted that ''[p]re-trade risk controls have become a point of negotiation between trading firms and clearing members because they can add latency to a trade. To avoid such negotiations, the Market Access Working Group believes that certain risk controls should reside at the exchange level and be required for all trading to ensure a level playing field.'' [71]

Third, the risk controls listed below acknowledge a variety of industry practices with respect to order generation, such as whether the order passes through intermediaries prior to execution. The Commission seeks to understand how increased standardization in risk controls at the level of exchanges or exchange members could provide strengthened protection for the markets and the public.[72] Notably, if the Commission were to require the placement of credit controls, maximum order size limits, and maximum message rate limits at both exchanges and clearing members, it could address both traditional means of order flow (*i.e.,* through a clearing firm) and newer DMA practices, which require controls at the exchange set by the relevant clearing firm. In combination, these reasons demonstrate the strength, in certain cases, of putting into practice standardized risk controls, with similar goals, at multiple entity types.[73]

Finally, the Commission notes the importance of risk controls designed to protect the financial integrity of DCOs, and to address risks posed by market participants utilizing DMA. Throughout the range of pre-trade risk controls discussed below, and other measures discussed later in this Concept Release, the Commission specifically solicits public comment regarding the following questions:

6. Are there distinct pre-trade risk controls, including measures not listed below, or measures in addition to those already adopted by the Commission, that would be particularly helpful in protecting the financial integrity of a DCO?

7. Are there distinct pre-trade risk controls, including measures not listed below, or measures in addition to those already adopted by the Commission, that should apply specifically in the case of DMA?

The following sections describe the pre-trade risk controls inquired about in this Concept Release, and present a series of questions to assist the Commission in determining the effectiveness, adoption rate, and need for any additional action with respect to these pre-trade risk controls or others that commenters may think advisable.

1. Message and Execution Throttles

The Commission seeks public comment regarding the potential benefits and existing use of maximum message rate and execution rate throttles (''execution throttles''). The Commission also seeks public comments regarding the types of execution throttles that would be most effective at alerting market participants to potential algorithm malfunctions and limiting the extent of market disruption when there is a malfunction.[74]

[69] The pre-trade risk controls contemplated herein are consistent with general principles or specific recommendations (in DMA context) expressed in the TAC Pre-Trade Functionality Subcommittee DMA Recommendations, *supra* note 26, at 2–5; IOSCO Technical Committee, Final Report on Principles for Direct Electronic Access to Markets (August 2010) at 20, available at *http://www.iosco.org/library/pubdocs/pdf/IOSCOPD332.pdf*; and the FIA Recommendations for Risk Controls, *supra* note 62, at 4. The pre-trade risk controls described herein are also consistent with the principles included in the ESMA Guidelines on Systems and Controls, *supra* note 4.

[70] In this regard, the Commission notes that the TAC's Pre-Trade Functionality Subcommittee described ''three levels in the electronic trading 'supply chain' where pre-trade risk safeguards could happen: Trading firms (as principal or agent), clearing firms (as principal or agent), and exchanges.'' The Subcommittee's recommendations to the TAC noted that it ''believe[s] strongly that all three levels of the supply chain should institute pre-trade risk management measures.'' *See* TAC Pre-Trade Functionality Subcommittee DMA Recommendations, *supra* note 26, at 1.

[71] *See* FIA Market Access Recommendations, *supra* note 23, at 8. *See also* TAC Pre-Trade Functionality Subcommittee DMA Recommendations, *supra* note 26, at 2. The TAC Pre-Trade Functionality Subcommittee called for a ''realistic view'' of the incentives under which market participants, clearing firms, and exchanges operate. The Subcommittee identified these incentives as follows:

- ''Trading firms are competing with one another to have the smallest time delays (lowest latency) in getting their orders into the exchange's matching engine, and are thus negotiating with brokers to reduce latency. At the same time they are trying to protect their capital from rogue trading, technological deficiencies or other adverse, unintended events.
- Brokers (clearing FCMs) are competing with one another to attract the business of these high-volume, speed-seeking trading firms, and are thus trying to reduce latency. At the same time, they are trying to protect themselves from loss due to unauthorized trading by their trading firm clients or other adverse, unintended events.
- Exchanges (Designated Contract Markets, or DCMs, and Foreign Boards of Trade, or FBOTs) are competing with one another to provide low latency execution, and will soon be competing with Swaps Execution Facilities (SEFs), to attract the business of these trading firms.''

The Subcommittee expressed its concern that risk controls should ensure fairness so that one trading firm is not disadvantaged relative to another ''because its clearing firm chose to act more responsibly.''

[72] For example, trading platforms provide a range of risk controls, but there is limited standardization in the types of risk controls available to customers from one exchange to the next. The Commission seeks to understand whether diverse risk management tools and policies at various exchanges complicate risk management for intermediaries and traders.

[73] The Commission notes that some existing regulations address pre-trade risk controls. *See supra* section II.B.

[74] The Commission understands that some trading firms and several exchanges already have limits on the number of orders that can be sent to a trading venue during a specified period of time. *See* Clark & Ranjan, ''How Do Proprietary Trading Firms Control the Risks of High Speed Trading,'' *supra* note 66, at 7; Oliver Linton & Maureen O'Hara, ''Economic impact assessments on MiFID II policy measures related to computer trading in financial markets,'' United Kingdom Government Office for Science—Foresight (August 2012) at 24–25, available at: *http://www.futuresindustry.org/epta/downloads/Economic-Impact-assessments-on-MiFID-2-policy-measures_083012.pdf*. However, the Commission would like to understand whether requiring some measure of standardization and the use of such tools among exchanges, FCMs, and trading firms would provide additional protection for the market.

Execution throttles prevent an algorithm from exceeding its expected message rate or rate of execution, and when tripped, can alert monitors at both the exchange and the trading firm. Such alerts can facilitate rapid detection of malfunctioning algorithms. Depending on the nature of the malfunction, execution throttles may also reduce the damage and monetary losses caused by the disruptive algorithm during the time when it is being investigated. The Commission understands that trading firms [75] and exchanges [76] employ individual variants of throttles to limit the number of orders that can be transmitted to or processed by an exchange. The Commission requests public comment regarding the extent to which market participants that already utilize execution throttles apply them in a static manner (*i.e.,* a fixed threshold, beyond which notifications are generated), or dynamically (*i.e.,* dependent on the time of day or the previous activity of the algorithm).[77] The Commission also requests public comments regarding the extent to which throttles are applied by trading firms on a per-algorithm basis, calibrated to take into account the expected message and execution rates of each algorithm for a given time period.

In addition, the Commission asks whether maximum message rates and execution throttles could be used as a mechanism to prevent individual entities from submitting messages or executing orders at speeds that are misaligned with their risk management capabilities. Execution throttles of this type would be unique to individual firms or accounts, and could be set by the exchange or clearing firm after reviewing the risk management capabilities of the entity to which the throttle will apply. For some firms, there may be a delay before effective risk management begins; in these cases, execution throttles may mitigate harm to the firm or other market participants prior to the firm's response to a malfunction. Last, message rate limits could be used to mitigate the risk of manipulative or disruptive messaging strategies such as ''order stuffing,'' where firms use ATSs to submit large numbers of orders that are cancelled before execution in order to slow down the matching engine and create arbitrage opportunities in or across products.

8. If, as contemplated above, maximum message rates and execution throttles were used as a mechanism to prevent individual entities or accounts from trading at speeds that are misaligned with their risk management capabilities, how should this message rate be determined?

9. Message and execution throttles may be applied by trading firms (FCMs and proprietary trading firms), clearing firms, and by exchanges. The Commission requests public comment regarding the appropriate location for message and execution throttles.

a. If throttles should be implemented at the trading firm level, should they be applied to all ATSs, only ATSs employing HFT strategies, or both?

b. What role should clearing firms play in the operation or calibration of throttles on orders submitted by the trading firms whose trades they guarantee?

10. Should the message and execution throttles be based on market conditions, risk parameters, type of entity, or other factors?

11. What thresholds should be used for each type of market participant in order to determine when a message or execution throttle should be used? Should these thresholds be set by the exchange or the market participant?

12. Are message and execution thresholds typically set by contract, or by algorithm? What are the advantages and disadvantages to each method?

13. Who should be charged with setting message rates for products and when they are activated?

14. Would message and execution throttles provide additional protection in mitigating credit risk to DCOs?

2. Volatility Awareness Alerts

Automated volatility awareness alerts implemented by trading firms are another form of risk control contemplated in this Concept Release. Volatility awareness alerts could be triggered when price movements in a given product move beyond a certain threshold within a previously specified time period. Such alerts could assist in identifying market conditions that may exceed an algorithm's parameters, or may highlight unintended effects of an algorithm's orders. Given an alert, human monitors at the trading firm could then intervene either by halting the relevant algorithms under their control, or by conveying the information to other relevant parties. Unlike exchange trading pauses and halts, volatility awareness alerts inform firm personnel as to changes in market conditions that may disrupt the parameters within which their ATSs and algorithms were programmed to operate, rather than immediately triggering a pause in trading.

15. The Commission is aware that alarms can be disruptive or counterproductive if ''false alarms'' outnumber accurate ones. How can volatility alarms be calibrated in order to minimize the risk that false alarms could interrupt trading or cause human monitors to ignore them over time?

3. Self-Trade Controls

A trade that results from the matching of opposing orders between a firm or a single or commonly owned account, such as a wash trade, does not shift risk between different market participants. In addition, such trades may inaccurately signal the level of liquidity in the market and may result in a non-bona fide price. Risk controls that identify and limit self-trading may result in more accurate indications of the level of market interest on both sides of the market and help ensure arms-length transactions that promote effective price discovery. Some regulated exchanges have tools specifically designed to identify and limit self-trading. The Commission is interested in better understanding those risk controls and how widespread their use may be.

For example, the Commission understands that in June 2013, CME Group introduced a voluntary self-match prevention functionality that allows market participants to prevent buy and sell orders for the same account (or for an account with common beneficial ownership) from matching with each other.[78] Market participants

[75] *See* Clark & Ranjan, ''How Do Proprietary Trading Firms Control the Risks of High Speed Trading,'' *supra* note 66, at 7.

[76] *See* Carol Clark & Rajeev Ranjan, ''How Do Exchanges Control the Risks of High Speed Trading?'' (November 2011) at 3, available at *http://www.chicagofed.org/digital_assets/publications/policy_discussion_papers/2011/PDP2011–2.pdf.*

[77] The Commission notes that the Futures and Options Association (''FOA'') expressed the opinion that throttles may hinder price formation and market integrity if applied dynamically during a period of market stress. However, the FOA generally supported the use of throttles that are ''pre-defined, transparent and certain (*i.e.,* the member obtains connections with a specified bandwidth in terms of maximum messages per second).'' *See* FOA, ''ESMA's Consultation Paper: Guidelines on Systems and Controls in a highly automated trading environment for trading platforms, investment firms and competent authorities: A response paper by the Futures and Options Association'' (October 2011) at 2, available at *http://www.esma.europa.eu/system/files/11-FOA.pdf.*

[78] *See* CME Group, ''CME Globex Self-Match Prevention Functionality FAQ'' (2013), available at *http://www.cmegroup.com/globex/resources/smpfaq.html.* On July 9, 2013, CME Group requested Commission approval to issue a market regulation advisory notice intended to provide guidance with respect to the types of activity that may constitute a violation of the exchange's wash trades rule and to provide additional information concerning its self-match prevention technology. This notice, which is under review by the Commission, is available at *http://www.cftc.gov/*

Continued

that wish to opt-in to this functionality populate a new FIX tag on all orders with a ''Self Match Prevention Identifier,'' in addition to an executing firm number. When the exchange's matching engine detects buy and sell orders at the same executable price level in a particular contract and both orders have the same Self Match Prevention Identifier and the same executing firm number, the engine will automatically cancel the resting order(s) on one side of the market and process the incoming order on the other side of the market.

In addition, the Commission understands that ICE Futures U.S. (''ICE'') offers voluntary self-trade prevention functionality for preventing inter- and intra-company orders from matching in the exchange's matching engine. This functionality was initially designed to prevent the matching of inter- and intra-company trades by automatically rejecting the taking order. The Commission understands that in May 2013, this functionality was expanded to allow for the rejection of the resting order.

16. What specific practices or tools have been effective in blocking self-trades, and what are the costs associated with wide-spread adoption of such practices or tools?

17. Please indicate how widely you believe exchange-sponsored self-trading controls are being used in the market.

18. Should self-trade controls cancel the resting order(s)? Or, instead, should they reject the taking order that would have resulted in a self-trade? If applicable, please explain why one mechanism is more effective than the other.

19. Should exchanges be required to implement self-trading controls in their matching engines? What benefits or challenges would result from such a requirement?

20. Please explain whether regulatory standards regarding the use of self-trading control technology would provide additional protection to markets and market participants.

21. If you believe that self-trading controls are beneficial, please describe the level of granularity at which such controls should operate (*e.g.,* should the controls limit self-trading at the executing firm level? At the individual trader level?) What levels of granularity are practical or achievable?

22. If you believe that self-trading controls are beneficial, please explain whether exchanges should require such controls for market participants and identify the categories of participants that should be subject to such controls. For example, should exchanges require self-trading controls for all participants, some types of participants, participants trading in certain contracts, or participants in market maker and/or incentive programs? What benefits or challenges would result from imposing such controls on each category of participant?

4. Price Collars

The Commission is also inquiring about price collars for both orders and executions. Price collars on orders prevent orders outside of acceptable price ranges from either entering the order book or executing at extreme levels; in effect, collars prevent market or stop orders (which execute as market orders) from trading at levels far beyond that expected at order entry. Similarly, price collars for execution prevent an order that is already in the book from being executed by the matching engine if it is outside of the acceptable range. Price collars can be contract specific and dynamic, responding to changes in market prices and market volatility for each contract. Price collars may reduce realized volatility by preventing a large, aggressive order from sweeping the book and matching at prices outside the range allowed by the collar, or allowing isolated market orders to execute during periods when one-sided liquidity is extremely low.[79]

23. The Commission is aware that some exchanges already have price collars in place for at least a portion of the contracts traded in their markets. Please comment on whether exchanges should utilize price collars on all contracts they list.

24. Would price collars provide additional protection in mitigating credit risk to DCOs?

5. Maximum Order Sizes

Maximum order sizes are intended to protect against execution of orders for a quantity larger than a predetermined ''fat finger'' limit. Like other controls, these limits can function at multiple levels; for example, at the firm level, in which firms prevent the submission of orders beyond certain limits, or at the clearing level, in which clearing members prohibit transmission of customer orders in excess of predetermined limits.

The Commission believes that most, if not all, exchanges currently have the capability to set maximum order sizes, but understands that such controls may vary among exchanges in their ability to set limits by product, product class, customer, or clearing member.[80] The Commission is interested to understand the following:

25. Are such controls typically applied to all contracts and customers, or on a more limited basis?

26. Do exchanges allow clearing members to use the exchange's technology to set maximum order sizes for specific customers or accounts?

27. Would additional standardization in the capabilities of this technology or more uniform application of this technology to all customers and contracts improve the effectiveness of such controls?

The Commission understands that some, but perhaps not all clearing firms may utilize the exchange's systems, and possibly their own systems, in order to conduct pre-trade maximum order size screens.[81] The Commission is interested to understand the following:

28. To what extent are clearing firms and trading firms conducting pre-trade maximum order size screens? Please explain whether firms are conducting such screens by utilizing: (1) Their own technology; (2) the exchange's technology, or (3) a combination of both.

29. Would regulatory standards regarding the use of such technology provide additional protection to the markets?

6. Trading Pauses

The Commission wants to better understand the existing implementation of trading pauses for trading platforms, and whether any additional types of pause mechanisms would be beneficial. A wide range of pause methodologies are currently in effect at exchanges, such as stop-logic functionality and interval price limits. These methodologies include market pauses when the execution of resting stop orders would cause excessive price movements, when prices move in excess of a dynamic threshold over a given time period, or simply when prices have

stellent/groups/public/@rulesandproducts/documents/ifdocs/rul070913cmecbotnymexcomandkc1.pdf.

[79] The Commission currently estimates that about half of the trading firms operating ATS have limits that check orders against a specific price range before sending them to the exchange. *See* Clark & Ranjan, ''How Do Proprietary Trading Firms Control the Risks of High Speed Trading,'' *supra* note 66, at 7. However, the Commission would like to better understand whether standardizing such controls at the level of exchanges or requiring such controls at the level of trading firms would further promote stable and reliable markets.

[80] *See* Carol Clark & Rajeev Ranjan, ''How Do Exchanges Control the Risks of High Speed Trading?'' *supra* note 76, at 3.

[81] *See, e.g.,* Carol Clark, Rajeev Ranjan, John McPartland, & Richard Heckinger, ''What Tools Do Vendors Provide to Control the Risks of High Speed Trading?'' (October 2011) at 2–3, available at *http://www.chicagofed.org/digital_assets/publications/policy_discussion_papers/2011/PDP2011-1.pdf.*

moved more than a given amount during the trading day.[82] Often, the market will monitor the order book during the pause, and determine when it is ''safe'' to re-open the market to further executions or re-open after a specified interval. Trading pauses have mitigated price movements during particularly volatile times in the past.[83]

The Commission is interested in better understanding the relative costs and benefits of each type of pause functionality and whether certain types of pause mechanisms are more effective than others with respect to ATS trading. The Commission is also interested to understand whether additional types of pause triggers would be advisable. These might cover a wider array of adverse states of an automated central limit order book, including, for example, significant depth imbalance, a significant number of aggressive orders, or a significant number of cancelled orders.

30. Trading pauses, as currently implemented, can be triggered for multiple reasons. Are certain triggers more or less effective in mitigating the effects of market disruptions?

31. Are there additional triggers for which pauses should be implemented? If so, what are they?

32. What factors should the Commission or exchanges take into account when considering how to specify pauses or what thresholds should be used?

33. How should the re-opening of a market after a trading pause be effected?

7. Credit Risk Limits

Credit risk limits are a valuable protection for limiting the activity of malfunctioning ATSs. Risk limits are most valuable when implemented as a pre-execution filter. Alternatively, low-latency post-trade risk limits may also provide some risk mitigation. Credit risk controls may be implemented by different entities, including the trading firms that originate orders, the clearing firms that guarantee the orders, the trading platforms matching the orders, and the DCOs that clear the orders. The Commission acknowledges that some trading firms and FCMs conduct post-trade credit checks with varying degrees of latency and that pre-trade credit risk screens are already required pursuant to §§ 1.73 and 23.609.[84] As noted above, however, the Commission seeks public comments regarding any additional measures that could help protect the financial integrity of DCOs, including measures discussed in this Concept Release or other measures that may be recommended by interested parties.

The TAC has received proposed models for implementing certain pre-trade risk controls for swaps, particularly those pertaining to credit risk.[85] Relevant solutions for implementing credit-based pre-trade risk controls include those in which credit limits reside at the FCM, at the trading platform (based on instruction from the clearing firm), or, for example, at a ''hub'' which applies credit controls on a per-order basis.[86] The Commission is interested to understand whether the ''hub'' model, one of several proposed solutions received by the TAC, could be usefully applied to futures markets.

The Commission is also interested in credit risk limits as a mechanism for limiting the disruptive activity of a malfunctioning ATS. Therefore, the Commission requests comment on the following:

34. What positions should be included in credit risk limit calculations in order to ensure that they are useful as a tool for limiting the activity of a malfunctioning ATS? Is it adequate for such a screen to include only those positions entered into by a particular ATS or should it include all the firm's positions?

35. Should pre-trade credit screens require a full recalculation of margin based on the effect of the order?

36. In light of your answers to the previous two questions, where in the lifecycle of an order should the credit limits be applied and what entity should be responsible for conducting such checks?

37. If credit checks are conducted post-trade, what should be done when a trade causes a firm to exceed a limit?

38. Please describe any technological limitations that the Commission should be aware of with respect to applying credit limits.

39. The Commission is particularly interested to receive public comment on the ''hub'' model and its applicability to different types of pre-trade risk controls. What are the strengths and weaknesses of this approach relative to other pre-trade or post-trade approaches to checking trades against credit limits? How would the latency between the ''hub'' and the exchanges be managed to provide accurate limits for high frequency ATS?

40. If you believe that post-trade credit checks would be an effective safeguard against malfunctioning ATSs, what is the maximum amount of latency that should be allowed for conducting such checks? What technological or information flow challenges would have to be addressed in order to implement post-trade checks with that degree of latency?

41. With respect to any entity that you believe should be responsible for applying credit risk limits, please describe the technology necessary to implement that risk control and the cost of such technology.

The pre-trade risk controls described above are summarized in Appendix A.

D. Post-Trade Reports and Other Post-Trade Measures

The Commission understands that, even with the presence of the most robust set of pre-trade risk controls, unanticipated events occur within a complicated marketplace. For example, the emergence of unexpected feedback loops between multiple algorithms, or malfunctioning pre-trade risk controls can lead to unintended order submissions that adversely impact market quality and investor confidence. Post-trade reports have the potential to mitigate the impact of such events, particularly if the post-trade reports are made available and utilized on a low-latency basis, such that market participants are quickly aware of any malfunction. Other post-trade measures, including enhanced error trade policies, may help counterparties to errant trades to better anticipate and address risk associated with trade uncertainty when such events occur. The post-trade reports and other measures are summarized below.

1. Order, Trade, and Position Drop Copy

The Commission is inquiring about the potential advantages of increased

[82] The Commission understands that some triggers leading to a market pause are not necessarily best classified as ''pre-trade'' risk controls. Some pauses, as described, may be in anticipation of a certain set of executions, and are pre-trade, while others may be in response to a given execution. The discussion here implicitly includes all of the above, and the Commission requests comment on the full range of pause types.

[83] *See* CFTC and SEC Joint Report on the Market Events of May 6, 2010, *supra* note 1, at 6 (noting that CME's stop logic functionality that triggered a halt in E-Mini trading shows that pausing a market can be an effective way of providing time for market participants to reassess their strategies, for algorithms to reset their parameters, and for an orderly market to be re-established).

[84] *See* Commission, Final Rule: Customer Clearing Documentation, Timing of Acceptance for Clearing, and Clearing Member Risk Management, 77 FR 21278 (Apr. 9, 2012).

[85] *See, e.g.,* ''Managing Credit Lines in a SEF/Cleared World,'' a presentation by MarkitServ at the March 29, 2012 TAC meeting [hereinafter, the ''MarkitServ Presentation'']. Available at: http://www.cftc.gov/ucm/groups/public/@aboutcftc/documents/file/tacpresentation032912_markitse.pdf.

[86] *See id.* The presentation also noted that post-trade checks at the DCO is another form of risk control based on end-customer position or credit limits. *See* section III(D) for additional discussion of post-trade reports and other post-trade measures.

standardization of real-time order, trade, and position reports for use by clearing firms and market participants. Real-time information is critical to market participants managing the risk of their own, and their customers' trades. The Commission is inquiring as to the advisability of requiring all exchanges and DCOs to provide real-time order and trade reports to each market participant, and the clearing firm serving that client for that particular trade. This information would give clearing firms real-time updates of their customers' order and trading activities.

These reports could improve the effectiveness of automated credit risk limits, which require current order and trade information in order to calculate current positions and monitor credit risk effectively. In some cases order information may be available to a trading platform before it is available to the relevant clearing member (*e.g.,* in the case of DMA-enabled participants), and trade information is always available first to the trading platform. Therefore, there is a strong interdependency between exchanges, DCOs and clearing firms as the latter seek to manage their credit risk.

Any time lag in the clearing firm's ability to construct a retrospective view of their customers' positions could diminish a clearing firm's ability to assess its customer's risk profile before such customer enters additional orders or establishes additional positions and accumulates greater risk.

More generally, widespread use of order and trade reports may be beneficial in both DMA and non-DMA situations to help market participants to track all order and trade activity quickly and efficiently. The Commission notes that some or all DCOs already provide post-trade information to clearing members, and that some DCOs charge for that information and others do not.[87] However, the Commission believes that the content of the data vary among DCOs and that not all market participants choose to purchase data when it is available. As described above, the Commission preliminarily believes that more standardized access to real-time data from exchanges and DCOs could be valuable to clearing firms, and possibly to trading firms, as they manage their risks. The Commission encourages interested parties to comment, again, on the current use of real-time reports, the consistency of this use, and the potential benefits and nature of additional order and trade reports.

42. What order and trade reports are currently offered by DCMs and DCOs? What aspects of those reports are most valuable or necessary for implementing risk safeguards? Please also indicate whether the report is included as part of the exchange or clearing service, or whether an extra fee must be paid.

43. If each order and trade report described above were to be standardized, please provide a detailed list of the appropriate content of the report, and how long after order receipt, order execution, or clearing the report should be delivered from the trading platform to the clearing member or other market participant.

2. Trade Cancellation or Adjustment Policies

The Commission is interested to know whether it would be beneficial for exchanges to develop more uniform and objective trade cancellation or adjustment policies. These policies should apply to cancellation or adjustment of individual trades, as well as to cancellation or adjustment of a large quantity of trades in response to a disruptive market event at the direction of a regulatory body or in accordance with the exchange's own determination that such cancellation or adjustment of a large quantity of trades is necessary. The policies could include (1) Clear principles on when trades will be cancelled or adjusted; (2) a requirement that traders notify the exchange of error trades within a specified number of minutes; and (3) a requirement that the exchange notify market participants of possible adjusted or busted trades immediately. Requiring traders to notify the exchange quickly and requiring the exchange to communicate the situation to market participants immediately helps to ensure that any market participants potentially affected by impending adjustment or cancellation actions are made aware of the additional risk they bear and can take steps to mitigate that risk.

It may be advisable to base cancellation and adjustment policies on pre-defined, objective criteria in order to minimize the time for identification and notification. Such criteria may include the minimum trade size for which cancellation will be considered, the minimum and maximum range in which a trade will be adjusted, the time a market participant has to request the cancellation or adjustment, the specific circumstances under which trades will be adjusted or canceled (*e.g.,* an exchange system error, specific types of human errors) and factors to be taken into account (*e.g.,* market conditions, whether other market participants have relied on the price). Last, the Commission is inquiring as to the advisability of policies to favor trade adjustment over trade cancellation in order to help ensure that market participants are able to keep the positions they have entered into, even if the prices are adjusted. The Commission is interested in receiving comments on whether additional standardization in error trade policies would be beneficial, and whether this prioritization scheme is appropriate.[88]

44. Is a measure that would obligate exchanges to make error trade decisions (*i.e.,* decisions to cancel a trade or to adjust its price) within a specified amount of time after an error trade is reported feasible? If so, what amount of time would be sufficient for exchanges, but would be sufficiently limited to help reduce risk for counterparties to error trades?

45. Should exchanges develop detailed, pre-determined criteria regarding when they can adjust or cancel a trade, or should exchanges be able to exercise discretion regarding when they can adjust or cancel a trade? What circumstances make pre-determined criteria more effective or necessary than the ability to exercise discretion, and vice versa?

46. Do error trade policies that favor price adjustment over trade cancellation effectively mitigate risk for market participants that are counterparties to error trades? Are there certain situations where canceling trades would mitigate counterparty risk more effectively? If so, what are they and how could such situations be identified reliably by the exchange in a short period of time?

47. Should error trade policies be consistent across exchanges, either in whole or in part? If so, how would harmonization of error trade policies mitigate risks for market participants, or contribute to more orderly trading?

E. System Safeguards

In this Concept Release, the Commission inquires about a range of system safeguards for trading platforms,[89] clearing firms, and market participants (including ATSs). Those system safeguards are intended to address a number of operational, market

[87] *See* Carol Clark & John McPartland, ''How Do Clearing Organizations Control the Risks of High Speed Trading?'' (May 2012) at 6–7, available at *http://www.chicagofed.org/Web pages/publications/policy_discussion_papers/2012/pdp_2.cfm.*

[88] The Commission notes that error trade policies may vary for different exchanges and for different products at each exchange. *See id.* at 7.

[89] The Commission notes that the system safeguards contemplated herein for DCMs address trading-related risks, and are therefore distinct from the requirements of DCM Core Principle 20 and SEF Core Principle 14, which address business continuity and disaster recovery capabilities.

abuse and transmission risks, and may protect against potential disruptions and abuses that are unique to electronic trading. The potential system safeguards are broadly grouped into those that address (1) Controls related to order placement; (2) policies and procedures for the design, testing and supervision of ATSs; (3) self-certifications and notifications; (4) ATS or algorithm identification; and (5) data reasonability checks. Each system safeguard is summarized below.

1. Controls Related to Order Placement

a. Order Cancellation Capabilities

The Commission is inquiring about various standards related to order cancellation capabilities. Auto-cancel on disconnect requirements would ensure that working orders do not remain in the limit order book when a firm loses connectivity with the exchange, ensuring that unwanted trades avoid execution even if the firm is unable to cancel them. The speed of disconnect notification and the cancellation of orders on disconnect can be helped by the exchange of ''heartbeat'' messages between exchange and user which continuously monitor the response ability of a given algorithm. In addition, by requiring exchanges to develop and maintain the capacity to selectively cancel working orders at the level of individual algorithms, individual accounts, or individual firms, as deemed necessary in an emergency, the trading platform would be able to mitigate the risk or quantity of error trades due to a malfunction.[90]

The Commission is also inquiring as to the advisability of requiring market participants operating ATSs, clearing members, and exchanges to develop and maintain ''kill switch'' capabilities. A market participant's kill switch could immediately cancel all working orders from that firm to the exchange and could prevent them from submitting further orders until natural persons with the proper authority at both the firm and the exchange allow the firm to resume trading. A kill switch at clearing members could cancel all working orders attributable to the clearing member, including both proprietary orders and orders placed on behalf of their clients, and prevent the clearing member from transmitting additional orders until natural persons at both the clearing firm and the exchange allow the clearing member to resume trading. An exchange's kill switch could cancel all working orders from an individual market participant or clearing firm and could prevent additional orders from the same market participant or clearing firm from being accepted at the exchange until authorized natural persons at both the exchange and affected market participant or clearing firm allow trading to resume.

48. The Commission's discussion of kill switches assumes that certain benefits accrue to their use across exchanges, trading and clearing firms, and DCOs. Please comment on whether such redundant use of kill switches is necessary for effective risk control.

49. What processes, policies, and procedures should exchanges use to govern their use of kill switches? Are there any different or additional processes, policies and procedures that should govern the use of kill switches that would specifically apply in the case of DMA?

50. What processes, policies, and procedures should clearing firms use to govern their use of kill switches when using such a safeguard to cancel and prevent orders on behalf of one or more clients?

51. What objective criteria regarding kill switch triggers, if any, should entities incorporate into their policies and procedures?

52. What benefits or problems could result from standardizing processes, policies, and procedures related to kill switches across exchanges and/or clearing firms?

53. Please explain how kill switches should be designed to prevent them from canceling or preventing the submission of orders that are actually risk reducing or that offset positions that have been entered by a malfunctioning ATS.

54. The Commission requests comment regarding whether kill switches used by clearing firms already have or should have the following capabilities: (a) Distinguish client orders from proprietary orders; (b) distinguish among orders from individual clients; and (c) cancel working orders and prevent additional orders from one or more of the clearing firm's clients, or for all the clearing firm's proprietary accounts, without cancelling and preventing all orders from the clearing firm.

55. The Commission is aware of proposals that would enable FCMs to establish credit limits for customers that are stored at a central ''credit hub'' for the purpose of pre-trade credit checks.[91] If such a model were implemented, is it possible that it could also be enabled with kill switches that cancel existing working orders and prevent additional orders from being submitted by one or more market participants? Should such an approach be designed to complement kill switches that are controlled by exchanges, clearing members, and trading firms, or to replace these kill switches? What benefits and drawbacks would result from each approach?

b. Repeated Automated Execution Throttle

A further potential risk control of interest to the Commission is a ''Repeated Automated Execution Throttle.'' This risk control was highlighted in FIA's Principal Traders Group recommendations regarding risk controls.[92] For this control, ATSs would be required to monitor the number of times a strategy is filled and then re-enters the market without human intervention. After a configurable number of repeated executions the system should be disabled until a human re-enables it. The Commission would like to better understand the value of this safeguard. The Commission understands that it would disable automated systems which have experienced activity levels far beyond that anticipated by its designers, and then notify monitors regarding this activity. Through this, human review would independently verify the operation of an ATS at regular intervals, and in doing so, could help to ensure that an algorithm's strategy is currently acting as anticipated and that it is appropriately responding to current market conditions. The Commission requests comments as to whether there could be adverse effects of automatically disabling an ATS after a given number of order executions, and also requests comment regarding the potential value, proper use, and limitations of this safeguard.

2. Policies and Procedures for the Design, Testing and Supervision of ATSs; Exchange Considerations

Taken as a whole, the ATS monitoring and supervision standards, ATS design and testing standards, ATS crisis management procedures standards, and ATS monitoring staff training standards inquired about in this Concept Release constitute a set of standards related to

[90] In addition to order cancellation capabilities, the Commission is inquiring about various related measures that concern connectivity testing, including that trading platforms and all entities connected to a trading platform for purposes of transmitting orders together must test that the systems of all such entities are properly connected to and communicating with the trading platform, and that trading platforms must provide, and market participants operating ATSs must utilize, heartbeats that indicate proper connectivity between the trading platform and an ATS.

[91] *See* MarkitServ Presentation, *supra* note 85.

[92] *See* FIA Recommendations for Risk Controls, *supra* note 62, at 4.

policies and procedures for firms operating ATSs. Existing rules require SDs and MSPs to ensure that their ''use of trading programs is subject to policies and procedures governing the use, supervision, maintenance, testing, and inspection of the program,'' [93] but there is no corresponding rule for FCMs or other market participants operating ATSs. Moreover, even when applied to SDs and MSPs, section 23.600(d)(9) does not have any prescriptive requirements related to supervision and testing and does not require formal review or approval of each firm's policies and procedures by an informed, independent party other than at the time of registration.[94] As a consequence, there is no minimum amount of testing that SDs and MSPs or other market participants operating ATSs are required by the Commission to perform before deploying an algorithm or before re-deploying an algorithm that has been altered. Nor are there any minimum standards for training or sophistication in the areas of supervision, maintenance, and inspection of the ATS.[95] Because of this, the Commission is interested in better understanding whether more standardized requirements, or clearer minimum standards, related to policies and procedures for firms operating ATSs would benefit the markets and the public. The policies and procedures relating to the design, testing and supervision of ATSs are summarized below, and addressed in greater detail in Section V, Appendix C.

a. ATS Development, Change Management, and Testing; Development, Change Management, and Testing of Exchange Systems

The Commission requests public comment regarding the necessity for ATS development, change management and testing standards in CFTC-regulated markets. Potential benefits to such standards include ensuring that ATSs are designed and modified in an environment where there is no risk that the ATS could interfere with activity in or related to the live market and ensuring that appropriate personnel have approved changes and verified proper testing before a system is moved to the production environment. Standards concerning the retention and control of access to current and historical versions of source code may help to ensure that changes are only made by appropriate personnel and reviewable when necessary. Finally, audit trail material may assist regulators when investigating problems.

With respect to testing, a firm's ATS testing standards could require it to test an ATS on the trading platform(s) where it will trade, prior to deploying such ATS into the live environment. Such testing standards may reduce the incidence of technical errors at the level of individual algorithms and firms. In addition, a firm's ATS testing standards may require it to test an ATS on the trading platform(s) after modifying the underlying algorithms or other system components to a degree subject to further definition. ATS testing could include tests against historical data, especially periods for which the relevant algorithm would likely have been stressed, or would have been active during periods with unanticipated market activity. In addition, exchanges could also be required to provide a test environment to simulate production trading so that market participants can conduct exchange-based conformance testing, which would include tests of compatibility with the matching engine (including initiation and cessation of the ATS connection) and verification of risk controls required by the trading platform.

The Commission is particularly interested to understand when it is most beneficial for firms to test an ATS after it has been modified. Some have asserted that the amount of testing should be calibrated to the significance of the change and the risk it poses to the proper function of the ATS.[96] The Commission would like to better understand how market participants estimate the significance of a change and the risk that a given change might pose to the proper function of an ATS. Also, the Commission would like to understand what current best practices are for testing ATSs and how those practices are tailored to the extent of the modification.

56. Please describe the necessary elements of an effective ATS testing regime, in connection with both the initial deployment and the modification of an ATS.

57. With respect to testing of modifications, how should the Commission and market participants distinguish between major modifications and minor modifications? What are the objective criteria that can be used to make such distinctions? Should any testing regime applicable to ATS modifications distinguish between major and minor modifications, and if so, how?

58. What challenges or benefits may result from exchanges implementing standardized procedures regarding the development, change management, and testing of exchange systems? Please describe, if any, the types of standardized procedures that would be most effective.

b. ATS Monitoring and Supervision

The Commission is aware that many exchanges and software design firms offer extensive testing platforms to validate algorithm functionality before deployment in a live trading environment. The Commission wants to better understand the extent to which testing is utilized and would like to better understand the methodology supporting these test environments. Further, the Commission believes that many, if not all, firms operating ATSs have human monitors supervising ATSs when they are operating. However, the Commission is uncertain to what degree such monitors have been sufficiently trained in how to respond to unexpected problems, and been given the requisite authority to intervene at these times.[97] A firm's ATS training standards could require that relevant staff members be able to understand how to identify malfunctions, evaluate the risk resulting from those malfunctions, and respond constructively to those malfunctions, including elevating the problem to the attention of more senior personnel. The Commission would like to better understand whether regulatory measures or new standards in this area would promote more effective ATS monitoring and supervision.

c. Crisis Management Procedures

Well-designed crisis management procedures may help to ensure that

[93] *See* 17 CFR 23.600(d)(9).

[94] 17 CFR 23.600(b)(4) requires SDs and MSPs to ''furnish a copy of its written risk management policies and procedures to the Commission, or to a futures association registered under section 17 of the Act, if directed by the Commission, upon application for registration and thereafter upon request.''

[95] It is also possible that SDs and MSPs could fail to incorporate emerging industry best practices for managing operational risk of ATSs into their policies and procedures as effective risk management technology and practices are introduced to the market.

[96] *See* SEC Roundtable Transcript, *supra* note 2, at 49–51.

[97] The Commission would like to better understand what sorts of training and policies market participants use in order to ensure that human monitors have the capability to respond to operational issues in a timely way. In particular, the Commission is interested in better understanding what training monitors receive in the rationale for the trading patterns executed by the ATS, the scope of intervention authority given to human monitors, and the procedures firms use to escalate questions or decisions from such human monitors to more senior personnel during a crisis.

firms are prepared to conduct rapid triage in the event of a problem, including the ability to escalate decisions quickly to the proper individuals or provide notification to their clearing firms, exchanges, or the Commission.[98] Such procedures may promote common expectations among monitoring staff, firm leadership, and exchange leadership about basic procedures in the event of market destabilizing events, facilitating more rapid intervention and mitigating the effects of an individual disruption.

59. Should basic crisis management procedures be standardized across market participants? If so, what elements should be addressed in an industry-wide standard?

60. Are there specific, core requirements that should be included in any crisis management procedures? Similarly, are there specific types of crisis events that should be addressed in any crisis management procedures? If so, please identify such requirements and/or crisis events and the level of granularity or specificity that the procedures should have with respect to each.

3. Self-Certifications and Notifications

a. Self-Certification and Clearing Firm Certification

To ensure that market participants employ the pre-trade risk controls, post-trade reports and other measures, and system safeguards described herein, the Commission is inquiring whether it would be appropriate to require a periodic self-certification program for all market participants operating ATSs and for clearing firms providing services to those market participants. These certifications could refer to the extent of implementation of those risk control mechanisms discussed in the other sections of this Concept Release. With respect to ATSs, an acceptable certification might attest that: (1) The ATS contains structural safeguards to provide reasonable assurance that the trading system will not be disruptive to fair and equitable trading; (2) the market participant's ATSs have been designed to avoid violations of the CEA, Commission regulations, or exchange rules related to fraud, disruptive trading practices, manipulation and trade practice violations; and (3) such systems have been sufficiently tested and documented in a manner that is appropriate to the intended design and use of that system. Additionally, the Commission asks whether the chief executive officer, chief compliance officer, or similar ranking official of each market participant should attest to the certification. The Commission is interested in receiving comment on the costs and benefits of a certification program, what elements should be included in the program, and whether that program should be self-executed, or, if not, overseen by what authority.

61. How often should a market participant certify that their pre-trade risk controls, post-trade reports and other measures, and system safeguards meet the necessary standards?

62. Which representative of the market participant should be required to attest that the certification standards have been met? Should it be the market participant's chief executive officer, chief compliance officer, or similar high-ranking corporate official, or some other individual?

63. Which entity(ies) should receive certifications from market participants? For example, should it be the market participant's clearing firm, its designated self-regulatory organization (if applicable), one or more trading platforms, a registered futures association, the Commission, or other entity?

64. Should DCMs, SEFs or clearing member firms be required to audit market participant certifications? What would be covered in an audit and how often should these audits occur? Should the same entity that receives the certification be required to perform the audit?

b. Risk Event Notification Requirements

The Commission also seeks information as to whether it would be beneficial for market participants operating ATSs to notify one or more of trading platforms, their clearing firms, the Commission, or others of risk events.[99] Entities receiving notifications could, when they deem it appropriate based on the magnitude of a single event or a pattern of smaller related events, review further with the market participant to remedy the underlying cause(s) of the risk event. Such reviews would allow market participants, clearing firms, trading platforms, and the Commission to respond and proactively reduce risk in automated trading environments.

The Commission seeks comment on the types of risk events that should be reported. For example, reportable risk events generally could include any instances where design parameters of an ATS are violated and where risk control processes or technologies do not function as anticipated, regardless of whether these events lead to error trades or market destabilization. Violated design parameters and unanticipated lapse of risk management processes and technology create conditions that may presage future malfunctions, even absent a current disruption.

65. Do commenters believe that risk event notifications would help to better understand and ultimately reduce sources of risk in automated trading environments? What information should be contained in a risk event notification to maximize its value?

66. What types of risk events should trigger reporting requirements, and what entities should receive risk event notifications from market participants operating ATSs?

67. Which entities should receive risk event notifications?

4. ATS or Algorithm Identification

The Commission is considering measures to improve the identification of ATS or their underlying algorithms in messages generated by ATSs. The Commission believes that identification of ATSs or underlying algorithms could help both firms and trading platforms to more quickly identify malfunctioning systems that could disrupt markets. Fuller identification of automated systems may also improve oversight by the Commission, including the ex post analysis of disruptive events aimed at preventing or mitigating similar recurrences.

The Commission is aware of the inherent complexity in any ATS or algorithm identification system and seeks public comment on this potential measure. Specific questions of interest to the Commission include:

68. Should the Commission define ATS or algorithm for purposes of any ATS identification system that may arise from this Concept Release? If so, how should ATS or algorithm be defined? Should a separate designation be reserved for high frequency trading algorithms and if so, what is the threshold difference?

[98] *See* SEC Roundtable Transcript, *supra* note 2, at 133–34.

[99] The SEC is presently considering a set of rules that would require self-regulatory organizations, significant alternative trading systems, certain disseminators of market data, and exempt clearing agencies to notify SEC staff of events including systems disruptions, compliance issues, or intrusions. *See* SEC, Notice of Proposed Rulemaking: Regulation Systems Compliance and Integrity, 78 FR 18084 (Mar. 25, 2013). Under the proposed rules, these entities would be required to notify and provide the SEC with detailed information when such systems issues occur as well as when there are material changes in its systems. *Id.* The Commission notes that it may consider distinctive aspects of the SEC's proposed rules, and public comments with respect to it, when developing any future proposals arising from this Concept Release. Commenters with respect to this Concept Release are encouraged to indicate in their comments any elements of the SEC's proposed rules that they believe are relevant.

69. What are the existing practices within trading firms for internally identifying ATSs or algorithms and for tracking their performance, including profit and loss? What elements of existing practices could be leveraged in any ATS or algorithm identification system proposed by the Commission in the future?

70. The Commission understands that an ATS may consist of numerous algorithms, each of which contributes to a trading decision. If an algorithm-based identification system is proposed, which of the potentially multiple algorithms that constitute an ATS should carry the ID? In addition, what degree of change to an algorithm should necessitate the use of a new ID, and how often does this change typically occur? What is the appropriate definition of ''algorithm'' for purposes of an algorithm identification system?

71. If the identification system resides at the ATS level, how should such IDs be structured to ensure that they are nonetheless sufficiently granular to identify components that may be leading or have led to unstable market conditions?

72. What message traffic between an ATS and a trading platform should include the ATS or algorithm ID (all messages, orders only, etc.)?

73. What relationship should this ATS ID have to the legal entity identifier (LEI)?

5. Data Reasonability Checks

The Commission is interested in the range of information sources used by ATSs to inform their trading decisions, and in how market participants form reasonable beliefs as to the accuracy of such data. For example, following recent media reports regarding the adverse market impact of false information distributed through unauthorized use of a social media outlet used by the Associated Press, the Commission is asking questions to broaden its understanding of the extent to which ATSs in derivatives markets use social media to inform their trading decisions, and the extent to which information derived from social media is verified by the ATS prior to its use. One potential risk control of interest to the Commission is the ''market data reasonability check,'' which was included in FIA's Principal Traders Group recommendations regarding risk controls.[100] In those recommendations, the FIA recommended that trading firms' systems have ''reasonability checks'' on incoming market data.

74. Please describe existing practices in the industry concerning how and the extent to which ATSs use (1) market data; and (2) news and information providers, including social media, to inform trading decisions.

75. The Commission requests comment regarding any risk controls, including reasonability checks, currently being used by market participants operating ATSs to review market data and news and information providers, including social media. Please describe the risk control, including the purpose of the control, the extent of its use among derivatives market participants, and any other aspects of the risk control that you believe would be helpful for the Commission to understand.

In addition, the data analyzed by trading algorithms can include government economic reports (*e.g.,* GDP, unemployment, and inflation data), as well as economic reports from non-governmental organizations such as universities, trade groups, and other sources. While government reports are released pursuant to a lock-up process that is intended to ensure that no entity receives them ahead of others, it has been reported that early access to some non-government economic reports is available for a fee. For example, according to recent reports, the University of Michigan's consumer report was available to certain investors two seconds ahead of the rest of the market.[101]

76. The Commission requests public comment concerning the lock-up process for government economic reports, and any additional measures that might be taken to protect against inappropriate disclosure.

77. Please describe the extent to which potentially market-moving data from non-governmental economic reports can be obtained prior to its public release for a fee. Are there specific reports or types of reports for which early disclosure should not be permitted? What process should be used for identifying non-governmental economic reports whose early release should not be permitted? Should the data release process for such reports be similar to the data lock-up process implemented for the release of government economic data?

The system safeguards described above are also listed in Appendix C.

F. Other Protections

1. Registration of Firms Operating ATSs

Although the Commission can currently take several actions to seek information from firms, such as the issuance of subpoenas to investigate a firm's trading activities on a registered exchange or to compel a firm to provide books and records, some have suggested that a registration requirement for firms operating ATSs and not otherwise registered with the Commission would enhance the Commission's oversight capabilities. Additionally, a registration requirement may allow for wider implementation of some or all of the pre-trade controls and risk management tools discussed in this Concept Release and currently deployed in various degrees in the market today.

In considering the registration of specific entities using ATSs and not otherwise registered with the Commission, the ''floor broker'' definition in CEA 1a(23), in pertinent part, states that, in general, the term ''floor trader'' means any person who, in or surrounding any pit, ring, post *or other place* provided by a contract market for the meeting of person similarly engaged, purchases, or sells solely for such person's own account.[102]

In addition to seeking input on whether it would be beneficial to require registration, the Commission also requests specific public comments in response to the following questions:[103]

78. Should firms operating ATSs in CFTC-regulated markets, but not otherwise registered with the Commission, be required to register with the CFTC? If so, please explain.

79. Please identify the firm characteristics, trading practices, or technologies that could be used to trigger a registration requirement.

80. Should all firms deploying ATS be required to register, and should there be different standards for firms deploying

[100] *See* FIA Recommendations for Risk Controls, *supra* note 62, at 4.

[101] *See* Brody Mullins, Michael Rothfeld, Tom McGinty & Jenny Strasburg, ''Traders Pay for Early Peek at Key Data,'' Wall St. J. (June 12, 2013), available at *http://online.wsj.com/article/SB10001424127887324682204578515963191421602.html.*

[102] *See* CEA section 1a(23), as amended by section 721 of the Dodd-Frank Act; 7 U.S.C. 1a(23) (emphasis added).

[103] In March 2013, the German parliament approved the HFT Act, which requires any firm using HFT strategies to become licensed as a financial services institution subject to the supervision of BaFin (Germany's banking regulator) or to passport an existing license granted by another member state of the European Economic Area. The licensing requirement includes ''indirect'' trading, meaning that it applies to foreign firms that are trading through a direct exchange member on a German-regulated market or a German multilateral trading facility. As a result of becoming licensed, HFT firms become subject to a general regulatory framework applicable to investment firms under German statutes, and specific organizational requirements applicable to HFT firms imposed by the HFT Act. *See* BaFin HFT Act Materials, *supra* note 17.

HFT strategies? What are the appropriate thresholds levels below which registration would not be required?

81. Since the floor trader distinction only addresses proprietary traders, please explain whether there is any other category of market participant, such as those deploying ATS or HFT strategies and trading on behalf of clients (aside from market participants already subject to Commission jurisdiction, such as Introducing Brokers and FCMs) that the Commission should consider with respect to potential registration requirements.

82. Should software firms providing algorithms be required to register, and under what authority? What standards should apply to such firms?

83. Please identify the functionalities discussed in this Concept Release that could be applied to floor brokers that operate ATSs. Are there any other controls not mentioned in this Concept Release that should be under consideration?

84. Please supply any information or data that would help the Commission in deciding whether firms may or may not meet the definition of ''floor trader'' in § 1a(23) of the Act.

85. Do you believe that the registration of such firms as ''floor traders'' would effectuate the purposes of the CEA to deter and detect price manipulation or any other disruptions to market integrity?

86. Considering the broad deployment of automated trading systems across both equities and derivatives markets, the Commission seeks to understand the appropriate level of coordination between itself and the SEC in defining and applying possible standards to the ATS and HFT trading space. How closely should the CFTC and SEC coordinate on possible rules and requirements for trading firms? The Commission also seeks public comment on the appropriate level of coordinated oversight between itself and relevant Self-Regulatory Organizations such as National Futures Association and FINRA.

87. Using the Flash Crash as an example, is it important to have identical definitions and remedies in the case of ATS and HFT registration requirements or do the existing market controls, such as circuit breakers, provide the necessary market protections in both the equities and derivatives markets? If the rules are not coordinated, what impact would this have on market interaction and oversight?

88. If trading venues apply mandatory functionalities to access derivatives markets, what benefit would a registration requirement provide to the Commission?

2. Market Quality Data

The Commission is inquiring as to the advisability of requiring each trading platform to provide market quality indicators for each product traded on its platform at a regular frequency. Some metrics of the type below are currently calculated by exchanges, often at an account level, and provided to market participants. Some metrics are currently used in aid of various exchange programs (such as order efficiency programs). Other metrics are not currently used but may, nonetheless, provide the Commission and the public potentially useful information.

The Commission envisions that increased transparency through the regular disclosure of market quality indicators will allow the Commission and market participants to better understand, among other things (1) The stability and efficiency of each market, (2) the degree of informed versus uninformed order flow, and (3) the nature and degree of liquidity in each market. In addition, the transparency provided by these metrics may better enable market participants to manage their ATSs in ways that further promote market stability and integrity.

The Commission is interested in receiving comment on the usefulness of various market indicators that could be prepared for each contract. The list of indicators would, for a given product and tenor, include measures of: (1) Effective spreads; (2) order-to-fill ratios; (3) execution speeds by order type and order size; (4) average aggressiveness imbalances; (5) price impact for given trade sizes;[104] (6) average order duration;[105] (7) order efficiency;[106] (8) rejection order ratios; (9) net position changes versus volume;[107] (10) branching ratios;[108] (11) volume imbalance and trade intensity;[109] (12) Herfindahl-Hirschman Indexes based on market share of open positions under common control; and (13) metrics on the number of price changing trades involving ATSs.[110] Calculation methodologies for each of the measures would be consistent across exchanges in order to ensure compatibility and comparability across market venues.[111]

Several of the measures described in this Concept Release would provide additional information about market quality that market participants cannot derive exclusively from real-time order book information provided by each exchange. The Commission expects that market participants could use this additional information, together with information currently available in the order book, in order to better inform their trading efficiency and strategies and to mitigate adverse effects of their actions and other market participants' on the market. Further, the Commission expects that these measures could be used to help understand changes in market quality. In addition, the Commission believes that providing consistent measures of market quality across exchanges would promote market efficiency through transparency and market competition.

To clarify what costs and benefits these market metrics may provide to participants, the Commission requests comment to the questions below, including that, if these metrics are beneficial, the appropriate frequency of publication.

89. What market quality indicators are in place today? Please describe the metrics, how and where they are deployed, and how market participants access these indicators and at what cost.

90. What value would each of the market quality metrics described above provide to market participants receiving them? If possible, please be specific about how each market quality measure could be used to enhance reliability and risk management of ATSs.

[104] The size of the price change that would occur if specific sizes of market orders were executed at that instant.

[105] Average length of time that orders for a specific instrument remain in the book before being modified, filled, or cancelled.

[106] Notional value executed vs. notional value entered or modified.

[107] *See* CFTC Net Position Changes Data, available at *http://www.cftc.gov/MarketReports/NetPositionChangesData/index.htm.*

[108] *See* Vladimir Filimonov, David Bicchetti, Nicolas Maystre, & Didier Sornette, ''Quantification of the High Level of Endogeneity and of Structural Regime Shifts in Commodity Markets'' (Mar. 20, 2013), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2237392.*

[109] *See* David Easley, Marcos M. Lopez de Prado & Maureen O'Hara, ''Flow Toxicity and Liquidity in a High Frequency World'' (Feb. 20, 2012), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1695596.*

[110] For a given market, such metrics would be calculated by identifying the relevant category of trader on trades that result in a price move from a previous trade and determining the percentage of those trades where an ATS was on one or both sides of the trade.

[111] SEC Rules 605 (Disclosure of Order Execution Information) and 606 (Disclosure of Order Routing Information) of Regulation NMS respectively require market centers (as defined in the rules) to make publicly available standardized, monthly reports of statistical information concerning their order executions and broker-dealers to make publicly available quarterly reports that, among other things, identify the venues to which customer orders are routed for execution. *See* 17 CFR 242.605 *(formerly Securities Exchange Act Rule 11Ac1–5) and* 17 CFR 242.606 (formerly Securities Exchange Act Rule 11Ac1–6).

91. Conversely, could any of the market quality metrics described above be used by market participants to manipulate the order book,[112] to identify competitors' trading strategies, or to engage in other trading activities that do not contribute to effective risk management and efficient discovery the traded asset's economic value? If so, please provide specific information regarding how such information could be misused. If possible, please provide recommendations regarding steps the Commission could take to prevent misuse.

92. Are there additional market quality metrics that the Commission should contemplate requiring exchanges to provide? If so, what value would they provide and how would they be used?

93. If the Commission determines that measures should be calculated in the same way by various exchanges in order to provide comparable measures of market quality, then how, specifically, should each of the above mentioned metrics be calculated in order to ensure that they are most valuable to market participants?

94. What timing and mode of dissemination is appropriate for each metric? For example, should measures be provided as daily averages?

95. Does the liquidity of a given market impact which market quality metrics would be reliable and useful when calculated for that market? If so, which metrics are inapplicable in less liquid markets, and why? What liquidity measures and thresholds are relevant to determining which metrics should apply to a given market?

3. Market Quality Incentives

The impact of ATSs, and particularly those implementing HFT strategies, is a topic of ongoing interest among researchers, market participants and others. Several studies have found that increases in automated trading are associated with improved market quality.[113] Some researchers and market participants, however, have also noted that the presence of HFT has the potential to shape the types of liquidity providers available in a market,[114] may discourage ATSs from submitting resting orders that remain in the order book long enough for humans to react, and may also be associated with undesirable trading practices that are more easily implemented by automated systems.[115] Various recommendations have been advanced to promote the benefits of HFT while simultaneously disincentivizing trading strategies that do not contribute to efficient price discovery.[116]

Those recommendations include for example, utilizing a trade allocation formula that is an intermediate between a cardinal ranking (time-weighted), Pro Rata allocation formula and a Price/Time allocation formula. This would be intended to reward market makers for leaving resting orders in the order book for a longer period of time, rather than simply for being first in the order book at a given price. Second, create a new limit order type that would prioritize orders that remain resting in the order book for some minimum amount of time. Third, require orders that are not fully visible in the order book (*e.g.,* iceberg orders) to go to the end of the queue (within limit price) with respect to trade allocation. Fourth, aggregate multiple, small orders from the same legal entity entered contemporaneously at the same price level and assign them the lowest priority time stamp of all such. Fifth, require exchanges to use batch auctions once per half second at random times rather than use continuous trade matching.[117] Lastly, limit visibility into the order book to aggregate size available at a limit price. This would help to ensure that automated traders are placing orders based on their knowledge of the economic value of the asset being traded rather than their knowledge of order book dynamics or of other market participants' trading patterns.

96. Should exchanges impose a minimum time period for which orders must remain on the order book before they can be withdrawn? If so, should this minimum resting time requirement apply to orders of all sizes or be restricted to orders smaller than a specific threshold? If there should be a specific threshold, how should that threshold be determined?

97. The Commission seeks to understand where time-weighted Pro Rata trade allocation is currently being utilized and what the effects have been. Please note examples from exchanges and, to the extent possible, please comment on the impact that such matching algorithms have had on the amount of time resting orders are left in the order book, as well as on other aspects of market quality.

98. If exchanges aggregated multiple, small orders entered by the same entity with the intent of abusing rounding conventions to gain a disproportionate share of allocations, what criteria should exchanges use to distinguish such orders from those that are entered by the same legal entity for legitimate trading purposes? Are there empirical patterns that could be used to reliably identify such manipulative intent?

99. Would batched order processing increase the number of milliseconds that are necessary for correlations among related securities to be established? If so, what specific costs would result from this change and how do those costs compare to the potential benefits described in recent research?

100. What costs and benefits result from providing market participants with real-time access to information about the order book that extends beyond aggregate size available at a limit price? Is there a legitimate economic benefit that results from market participants (both human participants, and ATSs) accessing such information? Is it possible for market participants to use such information to manipulate the order book?

101. The Commission seeks to understand whether any of the recommendations above are inapplicable or irrelevant to markets subject to the CEA. If so, please indicate which recommendation(s) and what makes it inapplicable or irrelevant to those markets.

[112] Meaning, behaviors that, while not strictly illegal, are used to advantage one's own orders in ways that do not contribute to efficient price discovery.

[113] *See* Jonathan Brogaard, Terrence Hendershott & Ryan Riordan, ''High Frequency Trading and Price Discovery'' (Apr. 22, 2013), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1928510*; Hasbrouck & Saar, *supra* note 18; Terrence Hendershott, Charles Jones & Albert Menkveld, ''Does Algorithmic Trading Improve Liquidity?'' Journal of Finance, Vol. 66 at 1–33 (August 30, 2010), available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1100635.*

[114] *See* J. Doyne Farmer & Spyros Skouras, ''An Ecological Perspective on the Future of Computer Trading,'' Quantitative Finance (2013); IOSCO Report on Regulatory Issues Raised by Technological Changes, *supra* note 4; William Barker & Anna Pomeranets, ''The Growth of High-Frequency Trading: Implications for Financial Stability,'' Bank of Canada Financial System Review (June 2011), available at *http://www.bankofcanada.ca/2012/01/publications/periodicals/fsr-article/the-growth-of-high-frequency-trading/.*

[115] *See* Farmer & Skouras, *supra* note 114; Eric Budish, Peter Cramton & John Shim, ''The High-Frequency Trading Arms Race: Frequent Batch Auctions as a Market Design Response'' (July 7, 2013), available at *http://faculty.chicagobooth.edu/eric.budish/research/HFT-FrequentBatchAuctions.pdf*; John McPartland, ''Recommendations for Equitable Allocation of Trades in High Frequency Trading Environments'' (July 25, 2013), available at *http://www.chicagofed.org/Webpages/publications/policy_discussion_papers/2013/pdp_1.cfm.*

[116] *See McPartland, supra* note 115.

[117] See Budish, *supra* note 115; J. Doyne Farmer & Spyros Skouras, ''Review of the Benefits of a Continuous Market vs. Randomised Stop Auctions and of Alternative Priority Rules (Policy Options 7 and 12),'' Foresight U.K. Government Office for Science, Economic Impact Assessment (2013), available at *http://www.bis.gov.uk/assets/foresight/docs/computer-trading/12-1072-eia11-continuous-market-vs-randomised-stop-auctions.pdf.*

4. Policies and Procedures To Identify ''Related Contracts''

Rule 38.255 of the Commission's regulations require DCMs to establish and maintain risk controls for trading.[118] Appendix B to the Part 38 regulations provides the following guidance on such risk controls: If a contract is linked to, or is a substitute for, other contracts, either listed on [the DCM's] market or on other trading venues, the designated contract market must, to the extent practicable, coordinate its risk controls with any similar controls placed on those other contracts.[119] The guidance contained in the appendix further provides that, to the extent practicable, DCMs should coordinate not only with other DCMs, but national security exchanges as well.[120] These measures could protect against market disruptions cascading from one trading platform to the next.

102. If you are a DCM, please address whether you have (i) identified all contracts that are linked to, or are a substitute for, other contracts either listed on your market or on other trading venues; and, if so, (ii) coordinated your risk controls with any similar controls placed on those other contracts. If you have not identified such contracts and coordinated risk controls on such contracts, please address any other means by which you are addressing risk controls applicable to contracts that are linked to, or are a substitute for, other contracts listed on your exchange or on other trading venues.

103. Please explain whether it would be beneficial for exchanges to develop and document policies and procedures for regularly reviewing contracts on other exchanges in order to identify those that are ''linked to'' or that are ''a substitute for'' contracts listed on its own market.

5. Standardize and Simplify Order Types

This Concept Release inquires about the possible standardization and simplification of order types that have complex logic embedded within them. A proliferation of order types, both within and across exchanges, can result in a similar increase in both the expected and unexpected responses of automated systems to order and trade signals. As of November 2012, for example, it was reported that BATS Global Markets alone listed more than 2,000 order types.[121] A review of current and proposed order types could be performed with the goal of consolidating and simplifying order types.[122] A proliferation of complex order types leads to complex testing scenarios. Therefore, it is possible that consolidation of order types could reduce the potential for instability resulting from unexpected interactions of multiple ATSs using multiple means of execution within the order book.[123]

104. Please explain whether the standardization and simplification of order types that have complex logic embedded within them would reduce the potential for instability and other market disruptions. If not, what other measures could achieve the same effect?

105. If the Commission were to consider the standardization and simplification of order types in a future rulemaking, please identify who should conduct this review (*i.e.,* the Commission, trading platforms, or other parties).

G. General Questions Regarding All Risk Controls Discussed Above

Finally, the Commission requests comment on the following general questions, with respect to each of the risk controls discussed above:

106. For each of the specified controls described above [*see* sections III.C–F], please indicate whether you are already using the control on customer and/or proprietary orders. If applicable, please also indicate how widely you believe the control is currently being used in the market, and how consistent the application of the control is among firms.

107. If possible, please indicate specific costs associated with implementing each of the risk controls described above [*see* sections III.C–F]. Please include detailed estimates, distinguishing between the cost of developing the functionality, the cost of implementation, and the cost of ongoing operations.

108. Please describe the specific benefits associated with each of the risk controls. Where possible, please indicate the market participant category(ies) to which the benefit would accrue.

109. Please comment on the appropriate order of implementation and timeline for each risk control, including any distinctions that should be made based on the category of registrant or market participant implementing the same or similar control, whether the market participant is using DMA, and whether implementation is already in place for certain categories.

110. Are any of the risk controls unnecessary, impractical for commercial or technological reasons, or inadvisable? If so, please note the control and provide reasons why.

111. A number of the pre-trade risk controls contemplated above are similar protections at distinct points in the life of an order.

a. Please comment on the utility of redundant pre-trade risk controls and the desirability of risk control systems in which controls are placed at one or more than one focal points.

b. If pre-trade risk controls should reside at one or more than one focal point, then please identify, for each risk control, what that focal point should be?

112. Are there risk controls that should be implemented across multiple entity types? If so, which controls and for which types of entities should they apply? Also, please comment generally on the factors the Commission should consider when determining the appropriate entity(ies) upon which to place a risk control requirement that could pertain to more than one entity.

113. Are there controls that should not be considered for overlapping implementation across exchanges, clearing members and market participants? If so, please explain which ones and why.

114. Each of the risk controls is described in general, principles-based terms. Should the Commission specify more granular or specific requirements with respect to any of the controls to improve their effectiveness or provide greater clarity to industry participants? If so, please identify the relevant control and the additional granularity or specificity that the Commission should provide. Are any of the controls, as

[118] *See* 17 CFR 38.255.

[119] *See* DCM Final Rules, 77 FR at 36718.

[120] *See id.*

[121] *See* Peter Chapman, ''Too Many Order Types, Traders Fret,'' Traders Magazine (Nov. 2012), available at *http://www.tradersmagazine.com/issues/25_344/order-types-equities-structure-110515-1.html.*

[122] The SEC is currently in the process of reviewing order types within securities markets. *See* Scott Patterson & Jean Eaglesham, ''Exchanges Retreat on Trading Tools,'' Wall St. J. (Oct. 24, 2012) (quoting former Chairwoman of the SEC, Mary Schapiro: ''I worry about the complexity in the market, I worry about the profusion of order types, I worry about the fragmentation.''), available at *http://online.wsj.com/article/SB10001424052970203400604578074963881803302.html. See also* SEC Roundtable Transcript, *supra* note 2, at 96–99.

[123] *See* SEC Roundtable Transcript, *supra* note 2, at 96 (''It is the proliferation of all these order types and the complexity of these order types that is adding unnecessary complexity to the market, which is already an extremely complex system as it is . . . when you have complex order types, it leads to extremely complex testing scenarios, and you are not going to pick up all the things you could or should because you don't know what that actual matching engine logic is in general.'').

currently drafted, inadequate to achieve the desired risk-reduction?

115. To the extent that there is any need to standardize or provide greater specificity regarding any measures discussed in this Concept Release, including those that reflect industry best practices, please describe the best approach to achieve such standardization (*i.e.,* through Commission regulation, Commission-sponsored committee or working group, or some other method).

116. How should risk control monitoring be implemented? Should compliance be audited by internal and external parties? For each control, please identify the appropriate entity(ies) to monitor compliance with the control. Also, please describe what an acceptable compliance audit would entail for each control.

117. Are there additional controls that should be considered, or other methods that could serve as alternatives to those described above [*see* sections III.C–F]? If so, please describe the control, its costs and benefits, the appropriate entity(ies) to implement such control, and whether there is any distinction to be drawn in the case of DMA.

118. Would any of the risk safeguards create a disincentive to innovate or create incentives to innovate in an irresponsible manner? If so, please identify the control, the concern raised, and how the control should be amended to address the concern. Responses should indicate how an amended risk control would still meet the Commission's objectives.

119. Should the Commission consider any pre-trade risk controls, post-trade reports, or system safeguards appropriate exclusively to market makers or to ATSs used by market makers? If so, please describe such controls or safeguards.

120. Should the Commission or Congress revisit its approach to issuing civil monetary penalties for violations of the Act, particularly as they relate to automated trading environments? Currently, the maximum civil monetary penalty the Commission may issue is capped at $140,000 ''per violation.'' Is such a civil monetary penalty sufficient to deter acts that constitute violations of the Act, given that an individual violation could impose costs to the market and the public well in excess of $140,000?

121. Please describe the documentation (or categories of documents) that would demonstrate that a market participant operating an ATS has implemented each risk control addressed in this Concept Release, including, for example, computer code, system testing results, certification processes and results, and calculations.

122. Would a fee (collected by, for example, the DCM or SEF) on numbers of messages exceeding a certain limit be more appropriate than a hard limit on the number or rate of messages?

123. Should such a penalty be based on a specified number or rate of messages or on the ratio of messages to orders filled over a specified time period?

124. Recent disruptive events in securities markets illustrate the importance of effective communication between exchanges' information technology systems. The Commission requests public comments regarding relevant systems in its regulated markets, including both DCMs and SEFs. What data transfers or other communications between exchanges are necessary for safe, orderly, and well-functioning derivatives markets? What additional measures, if any, would help promote the soundness of such systems (*e.g.,* testing requirements, redundancy standards, etc.)?

IV. List of All Questions in the Concept Release

Listed below are all questions raised in the preceding sections of this Concept Release.

High Frequency Trading

1. In any rulemaking arising from this Concept Release, should the Commission adopt a formal definition of HFT? If so, what should that definition be, and how should it be applied for regulatory purposes?

2. What are the strengths and weaknesses of the TAC working group definition of HFT provided above [*see* section II.A.1]? How should that definition be amended, if at all?

3. The definition of HFT provided above uses ''recurring high message rates (orders, quotes or cancellations)'' as one of the identifying characteristics of HFT, and lists three objective measures ((i) cancel-to-fill ratios; (ii) participant-to-market message ratios; or (iii) participant-to-market trade volume ratios) that could be used to measure message rates. Are these criteria sufficient to reliably distinguish between ATSs in general and ATSs using HFT strategies? What threshold values are appropriate for each of these measures in order to identify ''high message rates?'' Should these threshold values vary across exchanges and assets? If so, how?

4. Should the risk controls for systems and firms that engage in HFT be different from those that apply to ATSs in general systems? If so, how?

Reductions in Latency

5. Discussions on latency often focus on the how quickly an exchange processes orders, the time taken to submit orders, and how quickly a firm can observe prices of trades transacted on the exchange. The Commission is interested in understanding whether there are other types of messages transmitted between exchanges, firms and vendors wherein differences in latency could provide opportunities for informational advantage. Recent press reports have highlighted such advantages in the transmission of trade confirmations by a specific exchange. Are there other exchanges and trading venues where similar differences in latency exist? The Commission is interested in understanding whether the extent of latency in any such message transmission process can have an adverse impact on market quality or fairness. Should any exchanges, vendors and firms be required to audit their systems and process on a periodic process to identify and then resolve such latency?

Financial Integrity of the DCO

6. Are there distinct pre-trade risk controls, including measures not listed below, or measures in addition to those already adopted by the Commission, that would be particularly helpful in protecting the financial integrity of a DCO?

Risk Controls Applicable in the Case of DMA

7. Are there distinct pre-trade risk controls, including measures not listed below [*see* section III.C.], or measures in addition to those already adopted by the Commission, that should apply specifically in the case of DMA?

Message and Execution Throttles

8. If, as contemplated above [*see* section III.C.1], maximum message rates and execution throttles were used as a mechanism to prevent individual entities or accounts from trading at speeds that are misaligned with their risk management capabilities, how should this message rate be determined?

9. Message and execution throttles may be applied by trading firms (FCMs and proprietary trading firms), clearing firms, and by exchanges. The Commission requests public comment regarding the appropriate location for message and execution throttles.

a. If throttles should be implemented at the trading firm level, should they be applied to all ATSs, only ATSs employing HFT strategies, or both?

b. What role should clearing firms play in the operation or calibration of

throttles on orders submitted by the trading firms whose trades they guarantee?

10. Should the message and execution throttles be based on market conditions, risk parameters, type of entity, or other factors?

11. What thresholds should be used for each type of market participant in order to determine when a message or execution throttle should be used? Should these thresholds be set by the exchange or the market participant?

12. Are message and execution thresholds typically set by contract, or by algorithm? What are the advantages and disadvantages to each method?

13. Who should be charged with setting message rates for products and when they are activated?

14. Would message and execution throttles provide additional protection in mitigating credit risk to DCOs?

Volatility Awareness Alerts

15. The Commission is aware that alarms can be disruptive or counterproductive if ''false alarms'' outnumber accurate ones. How can volatility alarms be calibrated in order to minimize the risk that false alarms could interrupt trading or cause human monitors to ignore them over time?

Self-Trade Controls

16. What specific practices or tools have been effective in blocking self-trades, and what are the costs associated with wide-spread adoption of such practices or tools?

17. Please indicate how widely you believe exchange-sponsored self-trading controls are being used in the market.

18. Should self-trade controls cancel the resting order(s)? Or, instead, should they reject the taking order that would have resulted in a self-trade? If applicable, please explain why one mechanism is more effective than the other.

19. Should exchanges be required to implement self-trading controls in their matching engines? What benefits or challenges would result from such a requirement?

20. Please explain whether regulatory standards regarding the use of self-trading control technology would provide additional protection to markets and market participants.

21. If you believe that self-trading controls are beneficial, please describe the level of granularity at which such controls should operate (e.g., should the controls limit self-trading at the executing firm level? At the individual trader level?) What levels of granularity are practical or achievable?

22. If you believe that self-trading controls are beneficial, please explain whether exchanges should require such controls for market participants and identify the categories of participants that should be subject to such controls. For example, should exchanges require self-trading controls for all participants, some types of participants, participants trading in certain contracts, or participants in market maker and/or incentive programs? What benefits or challenges would result from imposing such controls on each category of participant?

Price Collars

23. The Commission is aware that some exchanges already have price collars in place for at least a portion of the contracts traded in their markets. Please comment on whether exchanges should utilize price collars on all contracts they list.

24. Would price collars provide additional protection in mitigating credit risk to DCOs?

Maximum Order Sizes

25. Are such controls typically applied to all contracts and customers, or on a more limited basis?

26. Do exchanges allow clearing members to use the exchange's technology to set maximum order sizes for specific customers or accounts?

27. Would additional standardization in the capabilities of this technology or more uniform application of this technology to all customers and contracts improve the effectiveness of such controls?

28. To what extent are clearing firms and trading firms conducting pre-trade maximum order size screens? Please explain whether firms are conducting such screens by utilizing: (1) Their own technology; (2) the exchange's technology, or (3) a combination of both.

29. Would regulatory standards regarding the use of such technology provide additional protection to the markets?

Trading Pauses

30. Trading pauses, as currently implemented, can be triggered for multiple reasons. Are certain triggers more or less effective in mitigating the effects of market disruptions?

31. Are there additional triggers for which pauses should be implemented? If so, what are they?

32. What factors should the Commission or exchanges take into account when considering how to specify pauses or what thresholds should be used?

33. How should the re-opening of a market after a trading pause be effected?

Credit Risk Limits

34. What positions should be included in credit risk limit calculations in order to ensure that they are useful as a tool for limiting the activity of a malfunctioning ATS? Is it adequate for such a screen to include only those positions entered into by a particular ATS or should it include all the firm's positions?

35. Should pre-trade credit screens require a full recalculation of margin based on the effect of the order?

36. In light of your answers to the previous two questions, where in the lifecycle of an order should the credit limits be applied and what entity should be responsible for conducting such checks?

37. If credit checks are conducted post-trade, what should be done when a trade causes a firm to exceed a limit?

38. Please describe any technological limitations that the Commission should be aware of with respect to applying credit limits.

39. The Commission is particularly interested to receive public comment on the ''hub'' model and its applicability to different types of pre-trade risk controls. What are the strengths and weaknesses of this approach relative to other pre-trade or post-trade approaches to checking trades against credit limits? How would the latency between the ''hub'' and the exchanges be managed to provide accurate limits for high frequency ATS?

40. If you believe that post-trade credit checks would be an effective safeguard against malfunctioning ATSs, what is the maximum amount of latency that should be allowed for conducting such checks? What technological or information flow challenges would have to be addressed in order to implement post-trade checks with that degree of latency?

41. With respect to any entity that you believe should be responsible for applying credit risk limits, please describe the technology necessary to implement that risk control and the cost of such technology.

Order, Trade and Position Drop Copy

42. What order and trade reports are currently offered by DCMs and DCOs? What aspects of those reports are most valuable or necessary for implementing risk safeguards? Please also indicate whether the report is included as part of the exchange or clearing service, or whether an extra fee must be paid.

43. If each order and trade report described above were to be standardized, please provide a detailed list of the appropriate content of the

report, and how long after order receipt, order execution, or clearing the report should be delivered from the trading platform to the clearing member or other market participant.

Trade Cancellation or Adjustment Policies

44. Is a measure that would obligate exchanges to make error trade decisions (*i.e.,* decisions to cancel a trade or to adjust its price) within a specified amount of time after an error trade is reported feasible? If so, what amount of time would be sufficient for exchanges, but would be sufficiently limited to help reduce risk for counterparties to error trades?

45. Should exchanges develop detailed, pre-determined criteria regarding when they can adjust or cancel a trade, or should exchanges be able to exercise discretion regarding when they can adjust or cancel a trade? What circumstances make pre-determined criteria more effective or necessary than the ability to exercise discretion, and vice versa?

46. Do error trade policies that favor price adjustment over trade cancellation effectively mitigate risk for market participants that are counterparties to error trades? Are there certain situations where canceling trades would mitigate counterparty risk more effectively? If so, what are they and how could such situations be identified reliably by the exchange in a short period of time?

47. Should error trade policies be consistent across exchanges, either in whole or in part? If so, how would harmonization of error trade policies mitigate risks for market participants, or contribute to more orderly trading?

Order Cancellation Capabilities

48. The Commission's discussion of kill switches assumes that certain benefits accrue to their use across exchanges, trading and clearing firms, and DCOs. Please comment on whether such redundant use of kill switches is necessary for effective risk control.

49. What processes, policies, and procedures should exchanges use to govern their use of kill switches? Are there any different or additional processes, policies and procedures that should govern the use of kill switches that would specifically apply in the case of DMA?

50. What processes, policies, and procedures should clearing firms use to govern their use of kill switches when using such a safeguard to cancel and prevent orders on behalf of one or more clients?

51. What objective criteria regarding kill switch triggers, if any, should entities incorporate into their policies and procedures?

52. What benefits or problems could result from standardizing processes, policies, and procedures related to kill switches across exchanges and/or clearing firms?

53. Please explain how kill switches should be designed to prevent them from canceling or preventing the submission of orders that are actually risk reducing or that offset positions that have been entered by a malfunctioning ATS.

54. The Commission requests comment regarding whether kill switches used by clearing firms already have or should have the following capabilities: (a) Distinguish client orders from proprietary orders; (b) distinguish among orders from individual clients; and (c) cancel working orders and prevent additional orders from one or more of the clearing firm's clients, or for all the clearing firm's proprietary accounts, without cancelling and preventing all orders from the clearing firm.

55. The Commission is aware of proposals that would enable FCMs to establish credit limits for customers that are stored at a central ''credit hub'' for the purpose of pre-trade credit checks. If such a model were implemented, is it possible that it could also be enabled with kill switches that cancel existing working orders and prevent additional orders from being submitted by one or more market participants? Should such an approach be designed to complement kill switches that are controlled by exchanges, clearing members, and trading firms, or to replace these kill switches? What benefits and drawbacks would result from each approach?

ATS Testing

56. Please describe the necessary elements of an effective ATS testing regime, in connection with both the initial deployment and the modification of an ATS.

57. With respect to testing of modifications, how should the Commission and market participants distinguish between major modifications and minor modifications? What are the objective criteria that can be used to make such distinctions? Should any testing regime applicable to ATS modifications distinguish between major and minor modifications, and if so, how?

58. What challenges or benefits may result from exchanges implementing standardized procedures regarding the development, change management and testing of exchange systems? Please describe, if any, the types of standardized procedures that would be most effective.

Crisis Management Procedures

59. Should basic crisis management procedures be standardized across market participants? If so, what elements should be addressed in an industry-wide standard?

60. Are there specific, core requirements that should be included in any crisis management procedures? Similarly, are there specific types of crisis events that should be addressed in any crisis management procedures? If so, please identify such requirements and/or crisis events and the level of granularity or specificity that the procedures should have with respect to each.

Self-Certification and Clearing Firm Certification

61. How often should a market participant certify that their pre-trade risk controls, post-trade reports and other measures, and system safeguards meet the necessary standards?

62. Which representative of the market participant should be required to attest that the certification standards have been met? Should it be the market participant's chief executive officer, chief compliance officer, or similar high-ranking corporate official, or some other individual?

63. Which entity(ies) should receive certifications from market participants? For example, should it be the market participant's clearing firm, its designated self-regulatory organization (if applicable), one or more trading platforms, a registered futures association, the Commission, or other entity?

64. Should DCMs, SEFs or clearing member firms be required to audit market participant certifications? What would be covered in an audit and how often should these audits occur? Should the same entity that receives the certification be required to perform the audit?

Risk Event Notification Requirements

65. Do commenters believe that risk event notifications would help to better understand and ultimately reduce sources of risk in automated trading environments? What information should be contained in a risk event notification to maximize its value?

66. What types of risk events should trigger reporting requirements, and what entities should receive risk event notifications from market participants operating ATSs?

67. Which entities should receive risk event notifications?

ATS or Algorithm Identification

68. Should the Commission define ATS or algorithm for purposes of any ATS identification system that may arise from this Concept Release? If so, how should ATS or algorithm be defined? Should a separate designation be reserved for high frequency trading algorithms and if so, what is the threshold difference?

69. What are the existing practices within trading firms for internally identifying ATSs or algorithms and for tracking their performance, including profit and loss? What elements of existing practices could be leveraged in any ATS or algorithm identification system proposed by the Commission in the future?

70. The Commission understands that an ATS may consist of numerous algorithms, each of which contributes to a trading decision. If an algorithm-based identification system is proposed, which of the potentially multiple algorithms that constitute an ATS should carry the ID? In addition, what degree of change to an algorithm should necessitate the use of a new ID, and how often does this change typically occur? What is the appropriate definition of ''algorithm'' for purposes of an algorithm identification system?

71. If the identification system resides at the ATS level, how should such IDs be structured to ensure that they are nonetheless sufficiently granular to identify components that may be leading or have led to unstable market conditions?

72. What message traffic between an ATS and a trading platform should include the ATS or algorithm ID (all messages, orders only, etc.)?

73. What relationship should this ATS ID have to the legal entity identifier (LEI)?

Data Reasonability Checks

74. Please describe existing practices in the industry concerning how and the extent to which ATSs use (1) market data; and (2) news and information providers, including social media, to inform trading decisions.

75. The Commission requests comment regarding any risk controls, including reasonability checks, currently being used by market participants operating ATSs to review market data and news and information providers, including social media. Please describe the risk control, including the purpose of the control, the extent of its use among derivatives market participants, and any other aspects of the risk control that you believe would be helpful for the Commission to understand.

76. The Commission requests public comment concerning the lock-up process for government economic reports, and any additional measures that might be taken to protect against inappropriate disclosure.

77. Please describe the extent to which potentially market-moving data from non-governmental economic reports can be obtained prior to its public release for a fee. Are there specific reports or types of reports for which early disclosure should not be permitted? What process should be used for identifying non-governmental economic reports whose early release should not be permitted? Should the data release process for such reports be similar to the data lock-up process implemented for the release of government economic data?

Registration of Firms Operating ATSs

78. Should firms operating ATSs in CFTC-regulated markets, but not otherwise registered with the Commission, be required to register with the CFTC? If so, please explain.

79. Please identify the firm characteristics, trading practices, or technologies that could be used to trigger a registration requirement.

80. Should all firms deploying ATS be required to register, and should there be different standards for firms deploying HFT strategies? What are the appropriate thresholds levels below which registration would not be required?

81. Since the floor trader distinction only addresses proprietary traders, please explain whether there is any other category of market participant, such as those deploying ATS or HFT strategies and trading on behalf of clients (aside from market participants already subject to Commission jurisdiction, such as Introducing Brokers and FCMs) that the Commission should consider with respect to potential registration requirements.

82. Should software firms providing algorithms be required to register, and under what authority? What standards should apply to such firms?

83. Please identify the functionalities discussed in this Concept Release that could be applied to floor brokers that operate ATSs. Are there any other controls not mentioned in this Concept Release that should be under consideration?

84. Please supply any information or data that would help the Commission in deciding whether firms may or may not meet the definition of ''floor trader'' in § 1a(23) of the Act.

85. Do you believe that the registration of such firms as ''floor traders'' would effectuate the purposes of the CEA to deter and detect price manipulation or any other disruptions to market integrity?

86. Considering the broad deployment of automated trading systems across both equities and derivatives markets, the Commission seeks to understand the appropriate level of coordination between itself and the SEC in defining and applying possible standards to the ATS and HFT trading space. How closely should the CFTC and SEC coordinate on possible rules and requirements for trading firms? The Commission also seeks public comment on the appropriate level of coordinated oversight between itself and relevant Self-Regulatory Organizations such as National Futures Association and FINRA.

87. Using the Flash Crash as an example, is it important to have identical definitions and remedies in the case of ATS and HFT registration requirements or do the existing market controls, such as circuit breakers, provide the necessary market protections in both the equities and derivatives markets? If the rules are not coordinated, what impact would this have on market interaction and oversight?

88. If trading venues apply mandatory functionalities to access derivatives markets, what benefit would a registration requirement provide to the Commission?

Market Quality Data

89. What market quality indicators are in place today? Please describe the metrics, how and where they are deployed, and how market participants access these indicators and at what cost.

90. What value would each of the market quality metrics described above [*see* section III.F.2] provide to market participants receiving them? If possible, please be specific about how each market quality measure could be used to enhance reliability and risk management of ATSs.

91. Conversely, could any of the market quality metrics described above [*see* section III.F.2] be used by market participants to manipulate the order book, to identify competitors' trading strategies, or to engage in other trading activities that do not contribute to effective risk management and efficient discovery the traded asset's economic value? If so, please provide specific information regarding how such information could be misused. If possible, please provide recommendations regarding steps the Commission could take to prevent misuse.

92. Are there additional market quality metrics that the Commission should contemplate requiring exchanges to provide? If so, what value would they provide and how would they be used?

93. If the Commission determines that measures should be calculated in the same way by various exchanges in order to provide comparable measures of market quality, then how, specifically, should each of the above mentioned metrics be calculated in order to ensure that they are most valuable to market participants?

94. What timing and mode of dissemination is appropriate for each metric? For example, should measures be provided as daily averages?

95. Does the liquidity of a given market impact which market quality metrics would be reliable and useful when calculated for that market? If so, which metrics are inapplicable in less liquid markets, and why? What liquidity measures and thresholds are relevant to determining which metrics should apply to a given market?

Market Quality Incentives

96. Should exchanges impose a minimum time period for which orders must remain on the order book before they can be withdrawn? If so, should this minimum resting time requirement apply to orders of all sizes or be restricted to orders smaller than a specific threshold? If there should be a specific threshold, how should that threshold be determined?

97. The Commission seeks to understand where time-weighted Pro Rata trade allocation is currently being utilized and what the effects have been. Please note examples from exchanges and, to the extent possible, please comment on the impact that such matching algorithms have had on the amount of time resting orders are left in the order book, as well as on other aspects of market quality.

98. If exchanges aggregated multiple, small orders entered by the same entity with the intent of abusing rounding conventions to gain a disproportionate share of allocations, what criteria should exchanges use to distinguish such orders from those that are entered by the same legal entity for legitimate trading purposes? Are there empirical patterns that could be used to reliably identify such manipulative intent?

99. Would batched order processing increase the number of milliseconds that are necessary for correlations among related securities to be established? If so, what specific costs would result from this change and how do those costs compare to the potential benefits described in recent research?

100. What costs and benefits result from providing market participants with real-time access to information about the order book that extends beyond aggregate size available at a limit price? Is there a legitimate economic benefit that results from market participants (both human participants, and ATSs) accessing such information? Is it possible for market participants to use such information to manipulate the order book?

101. The Commission seeks to understand whether any of the recommendations above [*see* section III.F.3] are inapplicable or irrelevant to markets subject to the CEA. If so, please indicate which recommendation(s) and what makes it inapplicable or irrelevant to those markets.

Policies and Procedures To Identify ''Related Contracts''

102. If you are a DCM, please address whether you have (i) identified all contracts that are linked to, or are a substitute for, other contracts either listed on your market or on other trading venues; and, if so, (ii) coordinated your risk controls with any similar controls placed on those other contracts. If you have not identified such contracts and coordinated risk controls on such contracts, please address any other means by which you are addressing risk controls applicable to contracts that are linked to, or are a substitute for, other contracts listed on your exchange or on other trading venues.

103. Please explain whether it would be beneficial for exchanges to develop and document policies and procedures for regularly reviewing contracts on other exchanges in order to identify those that are ''linked to'' or that are ''a substitute for'' contracts listed on its own market.

Standardize and Simplify Order Types

104. Please explain whether the standardization and simplification of order types that have complex logic embedded within them would reduce the potential for instability and other market disruptions. If not, what other measures could achieve the same effect?

105. If the Commission were to consider the standardization and simplification of order types in a future rulemaking, please identify who should conduct this review (*i.e.,* the Commission, trading platforms, or other parties).

General Questions Regarding All Risk Controls

106. For each of the specified controls described above [*see* sections III.C–F], please indicate whether you are already using the control on customer and/or proprietary orders. If applicable, please also indicate how widely you believe the control is currently being used in the market, and how consistent the application of the control is among firms.

107. If possible, please indicate specific costs associated with implementing each of the risk controls described above [*see* sections III.C–F]. Please include detailed estimates, distinguishing between the cost of developing the functionality, the cost of implementation, and the cost of ongoing operations.

108. Please describe the specific benefits associated with each of the risk controls. Where possible, please indicate the market participant category(ies) to which the benefit would accrue.

109. Please comment on the appropriate order of implementation and timeline for each risk control, including any distinctions that should be made based on the category of registrant or market participant implementing the same or similar control, whether the market participant is using DMA, and whether implementation is already in place for certain categories.

110. Are any of the risk controls unnecessary, impractical for commercial or technological reasons, or inadvisable? If so, please note the control and provide reasons why.

111. A number of the pre-trade risk controls contemplated above are similar protections at distinct points in the life of an order.

a. Please comment on the utility of redundant pre-trade risk controls and the desirability of risk control systems in which controls are placed at one or more than one focal points.

b. If pre-trade risk controls should reside at one or more than one focal point, then please identify, for each risk control, what that focal point should be?

112. Are there risk controls that should be implemented across multiple entity types? If so, which controls and for which types of entities should they apply? Also, please comment generally on the factors the Commission should consider when determining the appropriate entity(ies) upon which to place a risk control requirement that could pertain to more than one entity.

113. Are there controls that should not be considered for overlapping implementation across exchanges, clearing members and market participants? If so, please explain which ones and why.

114. Each of the risk controls is described in general, principles-based terms. Should the Commission specify more granular or specific requirements with respect to any of the controls to improve their effectiveness or provide greater clarity to industry participants? If so, please identify the relevant control and the additional granularity or specificity that the Commission should provide. Are any of the controls, as currently drafted, inadequate to achieve the desired risk-reduction?

115. To the extent that there is any need to standardize or provide greater specificity regarding any measures discussed in this Concept Release, including those that reflect industry best practices, please describe the best approach to achieve such standardization (*i.e.,* through Commission regulation, Commission-sponsored committee or working group, or some other method).

116. How should risk control monitoring be implemented? Should compliance be audited by internal and external parties? For each control, please identify the appropriate entity(ies) to monitor compliance with the control. Also, please describe what an acceptable compliance audit would entail for each control.

117. Are there additional controls that should be considered, or other methods that could serve as alternatives to those described above [*see* sections III.C–F]? If so, please describe the control, its costs and benefits, the appropriate entity(ies) to implement such control, and whether there is any distinction to be drawn in the case of DMA.

118. Would any of the risk safeguards create a disincentive to innovate or create incentives to innovate in an irresponsible manner? If so, please identify the control, the concern raised, and how the control should be amended to address the concern. Responses should indicate how an amended risk control would still meet the Commission's objectives.

119. Should the Commission consider any pre-trade risk controls, post-trade reports, or system safeguards appropriate exclusively to market makers or to ATSs used by market makers? If so, please describe such controls or safeguards.

120. Should the Commission or Congress revisit its approach to issuing civil monetary penalties for violations of the Act, particularly as they relate to automated trading environments? Currently, the maximum civil monetary penalty the Commission may issue is capped at $140,000 ''per violation.'' Is such a civil monetary penalty sufficient to deter acts that constitute violations of the Act, given that an individual violation could impose costs to the market and the public well in excess of $140,000?

121. Please describe the documentation (or categories of documents) that would demonstrate that a market participant operating an ATS has implemented each risk control addressed in this Concept Release, including, for example, computer code, system testing results, certification processes and results, and calculations.

122. Would a fee (collected by, for example, the DCM or SEF) on numbers of messages exceeding a certain limit be more appropriate than a hard limit on the number or rate of messages?

123. Should such a penalty be based on a specified number or rate of messages or on the ratio of messages to orders filled over a specified time period?

124. Recent disruptive events in securities markets illustrate the importance of effective communication between exchanges' information technology systems. The Commission requests public comments regarding relevant systems in its regulated markets, including both DCMs and SEFs. What data transfers or other communications between exchanges are necessary for safe, orderly, and well-functioning derivatives markets? What additional measures, if any, would help promote the soundness of such systems (*e.g.,* testing requirements, redundancy standards, etc.)?

V. Appendices (Specific Measures in Bold Font)

A. Pre-Trade Risk Controls

Potential pre-trade risk control	Party(s) to implement risk control	Substance of control
1a. Maximum Message Rate (Message Throttle).	*Market Participants Operating ATSs, Trading Platforms, and Clearing Firms.*	1a. Market participants operating ATSs must establish a maximum message rate per unit time for each ATS. This control should be calibrated to address the potential for unintended message flow (including orders) from a malfunctioning ATS. Market participants' systems must prevent the submission of messages in excess of the specified rate. Trading platforms' systems must prevent the acceptance of messages in excess of their own specified rates and must log instances when each ATS attempted to exceed such limits. Separately, trading platforms must establish systems enabling clearing firms to set rate limits directly at the trading platform. Trading platforms, clearing firms and market participants may set rates independently of each other. In all cases, human monitors must be alerted when limits are breached.
1b. Maximum Execution Rate (Execution Throttle).	*Market Participants Operating ATSs, Trading Platforms, and Clearing Firms.*	1b. Market participants operating ATSs must establish a limit on the maximum number of orders that each of their ATSs can execute in a given direction per unit time. The limit should be unique to each ATS and should be calibrated to address the potential for unintended executions arising from a malfunctioning ATS. Additional orders in excess of the limit should not be submitted or executed. Trading platforms must establish a maximum number of orders in the same direction they will execute per unit time from a uniquely identified ATS, and must prevent execution of trades that would violate this limit. Separately, trading platforms must establish systems enabling clearing firms to set per-customer message rate limits directly at the trading platform. Trading platforms, clearing firms and market participants may set rates independently of each other.

Potential pre-trade risk control	Party(s) to implement risk control	Substance of control
2. Volatility Awareness Alerts.	*Market Participants Operating ATSs*.	Market participants operating ATSs must implement automated solutions to immediately notify system supervisors when the prices of individual or groups of assets relevant to an ATS's trading strategies move either up or down by a given percentage within a predetermined period of time, or when the volume of individual or groups of assets relevant to an ATSs trading strategies over a specific period of time increase or decrease beyond a predetermined threshold. This control should help system supervisors identify market conditions which are not appropriate to the continued operation of a particular ATS or algorithm. The alert should be configurable by contract.
3. Self-Trade Controls	*Trading Platforms and All Market Participants*.	Trading platforms must provide, and all market participants must apply, technologies to identify and limit the transmission of orders from their systems to a trading platform that would result in self-trades.
4. Price Collars	*Trading Platforms and All Market Participants*.	Trading platforms must assign a range of acceptable order and execution prices for each of their products. All orders outside of this range would be automatically rejected, and orders already in the order book but outside of the acceptable range should not be elected by the matching engine. All market participants must establish similar product-specific price collars and should implement systems to ensure that orders outside of the collar are not transmitted to the relevant trading platform.
5. Maximum Order Size	*Trading Platforms, Clearing Firms, and All Market Participants*.	Trading platforms, clearing firms, and all market participants must each establish default maximum order sizes for orders submitted, transmitted, or processed by their systems. A market participant's systems must prevent the submission of orders in excess of its internally-specified limits. A clearing firm's systems must prevent the transmission of customer orders in excess of its limits for that customer. Trading platforms must prevent their systems from processing or executing orders in excess of the limit specified by the trading platform. In addition, for DMA customers, trading platforms must establish similar systems enabling clearing firms to set per-customer order size limits directly at the trading platform. Limits set by market participants, clearing firms, and trading platforms may be different from, and operate independently, of each other.
6. Trading Pauses	*Trading Platforms*	Trading platforms would be required to institute trading pauses, similar in nature to stop-logic functionality, but covering a wider array of adverse states of an automated central limit order book.
7. Credit Risk Limits	*Trading Platforms, Clearing Firms and/or Market Participants Operating ATSs*.	While some trading firms and FCMs conduct post-trade credit checks with varying degrees of latency and pre-trade credit risk screens are already required pursuant to Commission regulations, the Commission seeks public comments regarding any additional measures that could help protect the financial integrity of DCOs, as well as additional input from the public regarding the appropriate location and timing in the order lifecycle for credit checks.

B. Post-Trade Reports and Other Post-Trade Measures

Potential post-trade report or measure	Party(s) to implement report or measure	Substance of report or measure
8. Order Report (Post-order drop copy).	*Trading platforms*	Trading platforms must provide a duplicate copy of each order to the originating market participant and to the market participant's clearing firm(s) simultaneously with such order's receipt by the trading platform.
9. Trade Report (Post-trade drop copy).	*Trading platforms*	Trading platforms must provide a duplicate copy of each executed trade to the originating market participant and to the market participant's clearing firm(s) simultaneously with such trade's execution by the trading platform.
10. Position Report (Post-clearing drop copy).	*DCOs*	DCOs must provide net position per maturity per contract to the originating market participant and the market participant's clearing firm(s) as soon as the contract is matched at the clearinghouse.
11a. Uniform Adjust or Bust Error Trade Policies.	*Trading platforms and All Market Participants*.	11a. Trading platforms must establish policies for adjusting the price of trades or breaking trades that have been executed due to an error. Policies must favor price adjustments rather than trade cancellation. To the extent possible, policies must require decisions by the trading platform to be made on the basis of readily available objective criteria in order to facilitate rapid or immediate decisions.
11b. Standardized Reporting Window for Error Trades.	.....	11b. Market participants must report error trades to the trading platform within five minutes after the trades are executed. Trading platforms must notify market participants of a potential adjust-or-bust situation immediately. Trading platforms must make a decision and notify market participants of that decision within a specified period of time.

C. System Safeguards

Potential system safeguard	Party(s) to implement safeguard	Substance of safeguard
CONTROLS OVER ORDER PLACEMENT.	*Trading Platforms, Clearing Firms, and All Market Participants.*	Trading platforms, clearing members, and market participants must have systems and processes in place to:
Order Cancellation Capabilities		
12a. Auto-cancel on disconnect.	.....	12a. Exchanges should implement a flexible system that allows a user to determine whether their orders should be left in the market upon disconnection. This should only be implemented if the clearing firm's risk manager has the ability to cancel working orders for the trader if the trading system is disconnected. The exchange should establish a policy whether the default setting for all market participants should be to maintain or to cancel all working orders.
12b. Selective working order cancellation.	.....	12b. Immediately cancel one, multiple, or all resting orders from a market participant as deemed necessary in an emergency situation.
12c. Kill switch	.....	12c. Immediately cancel all working orders, and the ability to prevent submission (market participant), transmittal (clearing member), or acceptance (trading platform) of any new orders from a market participant, or particular trader or ATS of such market participant.
13. Repeated Automated Execution Throttle.	.....	13. Market participants operating ATSs must establish a limit on the maximum number of orders that each ATS can submit. When an ATS reaches that maximum it must be automatically disabled until a human re-enables it.
14. System heartbeats (see section III.E.1.a and footnote 90).	.....	14. Trading platforms must provide, and market participants operating ATSs must utilize, heartbeats that indicate proper connectivity between the trading platform and the ATS. Such heartbeats must also indicate the status of connectivity between an ATS and any systems used by the trading platform to provide the ATS with market data. If connectivity to any system is lost, the ATS should be disabled, and resting orders should be maintained or cancelled based on the pre-determined preferences of the firm that lost connectivity.
POLICIES AND PROCEDURES FOR THE DESIGN, TESTING, AND SUPERVISION OF ATSs **15a. ATS Design**	*Market Participants Operating ATSs.*	15a. Market participants operating ATSs must properly design their systems to avoid violations of the CEA, Commission regulations, or DCM and SEF rules related to fraud, disruptive trading practices, manipulation and trade practice violations. They must also ensure that their ATSs include all applicable pretrade risk controls and system safeguards as described herein.
15b. ATS Development and Change Management.	*Trading Platforms and Market Participants Operating ATSs.*	15b. Trading platforms and market participants operating ATSs must maintain a development environment that is adequately isolated from the production trading environment. The development environment may include computers, networks, and databases, and should be used by software engineers while developing, modifying, and testing source code. Firms must maintain a source code repository to manage source code access, persistence, and changes. Firms must establish and document procedures for communicating the functionality and requirements of, and changes to, their proprietary software. These procedures must include an audit trail of material changes that would allow them to determine, for each change: Who made it, when they made it, and what the purpose was for the change. Firms must have documented policies and procedures that allow representatives from trading, risk, and software management to approve changes and to verify internal testing before a new or modified trading system can be enable in production.
15c. ATS Testing	*Trading Platforms and Market Participants Operating ATSs.*	15c. Market participants operating ATSs must test each ATS both internally and on each trading platform on which an ATS will operate. Relevant tests include, but are not limited to, unit testing, functional testing (both integration and regression testing), non-functional testing, and acceptance testing. Functional testing must include all applicable pre-trade risk controls, post-trade reports and other measures and system safeguards. Non-functional testing must include testing under stressed market conditions. Market participants must perform such testing on each algorithm prior to initial deployment, and prior to re-deployment, after certain modifications to the algorithm. Trading Platforms must provide test environments that simulate the production trading environment so that market participants may conduct exchange-based conformance testing on their ATSs once they have completed internal testing. Conformance testing must include tests for all ATS risk mitigation controls that are able to be tested by the exchange. Exchange-based conformance testing must be done after certain modifications to the operating code.
15d. ATS Monitoring and Supervision.	*Market Participants Operating ATSs.*	15d. Market participants operating ATSs must ensure that their ATSs are subject to continuous real-time monitoring and supervision by trained and qualified staff at all times while engaged in trading.

Potential system safeguard	Party(s) to implement safeguard	Substance of safeguard
		Appropriate supervision includes automated alerts when ATS order behavior breaches design parameters or when market conditions diverge from program expectations. It also includes automated alerts upon loss of network connectivity or data feeds. Monitoring and supervision staff must have the ability and authority to disengage the ATS and to cancel resting orders when system or market conditions require it, including the ability to contact trading platform staff to seek information and cancel orders. They must also have acceptable dashboards and control panels to monitor and interact with the ATS. Monitoring and supervision staff must record the time when they assume responsibility for an ATS and the time when they relinquish control to others. Recording must be achieved through distinct log-ins to the required control panel by each staff person. Log-in must also be subject to access controls that ensure the correct staff person is identified.
15e. Training for ATS Monitoring Staff (see section III(E)(2)(b) and footnote 97).	*Market Participants Operating ATSs.*	15e. Firms operating ATSs must develop training for all staff involved in monitoring or designing ATSs. Training must, at a minimum, cover design standards, event communication procedures, and requirements for notifying exchange and commission staff when risk events occur. Additionally, each firm must develop, document, and implement training policies that ensure human monitors are adequately trained for each new algorithm that is implemented. Training must include, at a minimum, the economic rationale for the algorithm and mechanics of the underlying process, as well as the automated and non-automated risk controls that are applicable to the algorithm.
15f. Crisis Management Procedures.	*Trading Platforms and Market Participants Operating ATSs.*	15f. Trading platforms and market participants operating ATSs must develop and document procedures that direct the actions of ATS supervisors, exchange trading monitors, and support staff in the event that an algorithm malfunctions or responds to market signals in an unanticipated manner. Procedures should direct the process for evaluating, managing, and mitigating market disruption and firm risk. The procedures should also specify people to be notified in the event of an error that results in violations of risk profiles or potential violations of exchange or Commission rules.
SELF-CERTIFICATIONS AND NOTIFICATIONS		
16a. Self-Certification and Clearing Firm Certification.	Market Participants Operating ATSs.	16a. All firms operating ATSs must certify annually that their ATSs individually and collectively (*i.e.* at the algorithm, account, and firm levels) comply with all Commission and trading platform requirements regarding pre-trade risk controls and post-trade reports and other measures, as well as all applicable risk controls. Clearing firms must institute reasonable measures to confirm that their client trading firms implement the pre-trade risk controls that are required.
16b. Risk Event Notification Requirements.	*Market Participants Operating ATSs, Trading platforms.*	16b. Market participants operating ATSs must notify the exchange, and the exchange must notify the Commission whenever an algorithm violates its design parameters or whenever risk control technologies or processes do not function as planned even if they do not result in destabilization of the markets. The exchange must also notify the Commission whenever any of its own risk management technologies or processes violate design parameters or do not function as planned.
17. ATS or Algorithm Identification.	*Market Participants Operating ATSs.*	A unique identifier would be assigned to each ATS or algorithm, and all orders submitted by that ATS or algorithm would be tagged with the identifier.
18. Data Reasonability Checks.	*Market Participants Operating ATSs.*	All firms operating ATSs must have ''reasonability checks'' on incoming market data and other data (including social media).

D. Other Protections

Potential additional protection	Party(s) to implement protection	Substance of protection
19. Registration of All Firms Operating ATSs.	*Market Participants Operating ATSs.*	All firms operating ATSs to trade solely for their own account and not otherwise registered with the Commission must register with the Commission.
20. Market Quality Data	*Trading Platforms*	Trading platforms must provide to all market participants a daily summary of market quality for each product traded on its platform. The feeds would include measures of execution quality including: (1) Effective spreads; (2) order to fill ratios; (3) execution speed for different types of orders and different order sizes; (4) aggressiveness imbalance; (5) price impact for given trade sizes; (6) average order duration; (7) order efficiency; (8) rejection order ratio; (9) net position changes versus volume; (10) branching ratios; (11) volume imbalance and trade intensity; (12) Herfindahl-Hirschman Indexes based on market share of open positions under common control; and (13) metrics on the number of price changing trades involving ATSs.

Potential additional protection	Party(s) to implement protection	Substance of protection
21. Market Quality Incentives.	*Trading Platforms*	Trading platforms must implement changes that will limit market participants' abilities to improperly advantage their own orders in ways that do not contribute to efficient price discovery, including, for example: (1) Utilize a trade allocation formula that is an intermediate between a cardinal ranking (time-weighted), Pro Rata allocation formula and a Price/Time allocation formula; (2) Create a new limit order type that would prioritize orders that remain resting in the order book for some minimum amount of time; (3) Require orders not fully visible in the order book to go to the end of the queue (within limit price) with respect to trade allocation; (4) Aggregate multiple, small orders from the same legal entity entered contemporaneously at the same price level and assign them the lowest priority time stamp of all the orders so aggregated; (5) Require exchanges to use batch auctions once per half second at random times rather than use continuous trade matching; and (6) Limit visibility into the order book to aggregate size available at a limit price.
22. Policies and Procedures for identifying ''related'' contracts.	*Trading Platforms*	Trading platforms must develop and implement policies and procedures for identifying securities or products listed on other exchanges that would constitute ''related'' contracts to those that are listed on their own exchange.
23. Standardize and Simplify Order Types.	*Trading Platforms*	Trading platforms must work with the Commission to standardize order types across exchanges, and to reduce the overall number of order types that have complex logic embedded within them.

Issued in Washington, DC, on September 9, 2013, by the Commission.

Christopher J. Kirkpatrick,

Deputy Secretary of the Commission.

Appendices to Concept Release on Risk Controls and System Safeguards for Automated Trading Environments

Appendix 1—Commission Voting Summary

On this matter, the following Commissioners voted in the affirmative: Chairman Gensler, Commissioner Chilton (with the concurrence set out below in Appendix 3), Commissioner O'Malia (with the concurrence set out below in Appendix 4), and Commissioner Wetjen. No Commissioner voted in the negative.

Appendix 2—Statement of Support of Chairman Gary Gensler

We have witnessed a fundamental shift in markets from human-based trading to highly automated electronic trading. Automated trading systems, including high frequency traders, enter the market and execute trades in a matter of milliseconds without human involvement. Electronic trading makes up over 91 percent of the futures market. The swaps market also is moving toward electronic trading.

In our oversight of U.S. derivatives markets, both futures and swaps, the Commodity Futures Trading Commission (CFTC) must look to continually adapt our regulations in these changing times. Our mission to promote transparency, ensure for market integrity and prohibit abuses is just as important in the fast-moving world of electronic trading as it was when people traded over the phone, in a pit or on a floor.

The CFTC already has taken a number of important steps to keep pace with rapidly evolving 21st-century markets. We have adopted rules to implement pre-trade risk filters for futures commission merchants, swap dealers, designated contract markets and swap execution facilities. We also have new rules to prohibit disruptive trading practices and other market abuses.

In publishing this Concept Release, we are seeking public input on what additional risk controls and system safeguards are appropriate given this ever-changing technological environment. Traditional risk controls and system safeguards, many of which were developed according to human speed and floor-based trading, must be evaluated in light of new market realities.

Further, as sure as computers and programs have had technical glitches in the past, we must look to risk controls and system safeguards to protect markets when such glitches inevitably occur again. This Concept Release is intended to stir public discussion and debate on how best to protect the functioning of markets for the benefit of farmers, ranchers, merchants and other end users who rely on markets to hedge risk—particularly in light of the reality that the majority of the market is using automated trading systems.

Appendix 3—Concurrence of Commissioner Bart Chilton

While I concur in the concept release, am most appreciative of the staff work, and am largely pleased at the result, this has taken far too long to come to fruition.

In general, those involved in financial markets seem to have blindly accepted that technology is almost always a good thing. Yet we continue to see major technology problems, like NASDAQ shutting down twice in as many weeks. Last year it was NYSE. In the futures world, we see technology glitches that simply should not occur. I acknowledge that, with the staggering volume of trading, some might simply be astounded that—in the main—it works so well. But it doesn't work well enough if we continue to see aberrations—particularly if they are market missteps that could have been avoided. That's to say nothing of the high frequency cheetah traders who have, some I am convinced intentionally, contorted markets in a manipulative fashion. In addition, there are a shocking number of transactions that appear to be wash trades—that also has the possibility of impairing the fair and effective functioning of financial markets.

I'm pleased we are moving this concept release forward, but given this environment it has taken way too long. If we continue at this pace, Rip Van Winkle could keep up with any possible action we might take. We need to understand that some of these issues are urgent and need action now. They can't wait another year or more.

At the same time, there is one thing that can be done now. In fact, I suggested this policy shift be included in the concept release, but since it is a larger issue than just a technology-related matter, it was decided to omit it. That's fine, because my suggestion is really an action for the Congress.

As long as we have a puny penalty regime at the CFTC, we are going to see traders risk getting caught because the potential profits are so great. We can only impose a civil monetary penalty (CMP) of $140,000 per violation. That's the law. Furthermore, the case history suggests that a ''violation'' may be only once per day. In these millisecond markets where we have seen a million change hands in a minute, $140k is a joke—and it's not very funny.

This Agency is hampered by staffing needs due to a lack of funding. We have hundreds of cases being investigated right now. The least Congress can do, so that we can try and keep up—and if need be, cage the cheetahs and others who violate the Commodity Exchange Act—is to increase the CMPs. Specifically, I've suggested increasing the maximum penalty levels to $1 million per violation for individuals and $10 million for firms. That would be a deterrent. That would stop some of the cheetahs and others out there who are tempted to use powerful technologies in unlawful ways.

I look forward to receiving comments, and hope that we let no moss grow on this matter.

Appendix 4—Statement of Concurrence by Commissioner Scott D. O'Malia

During my time at the Commodity Futures Trading Commission (''Commission''), I have

consistently emphasized that the Commission must have a strong understanding of today's highly automated and interconnected trading environments in order to oversee its markets effectively. As head of the Commission's Technology Advisory Committee (''TAC''), I have committed considerable TAC time and resources to strengthening our understanding of automated markets. I am grateful for all the hard work of the TAC members as well as the efforts of the members of the Subcommittee on Data Standardization and the Subcommittee on Automated and High Frequency Trading, who have devoted hours of work on issues related to automated trading systems and pre-trade functionality. I hope that this Concept Release, and in particular the public comments the Commission receives in response, will build on this work.

The Concept Release asks over a hundred questions, which is appropriate given the importance of hearing from all sectors of the industry and benefiting from their knowledge and views of automated trading. I would like to highlight a few questions that I believe it would be particularly constructive to receive feedback from the public on. The first is to establish what current protections are in the market today and the extent to which the technology is deployed, as well as its effectiveness. The second is an overarching question: Whether there is a need for regulatory action with regard to any of the measures currently in the market. In other words, should the Commission federalize any current industry practices/standards? Third, it would be helpful to receive public feedback on the definitions for high-frequency trading and automated trading systems that the TAC, after extensive effort by its Subcommittee on Automated and High Frequency Trading, has proposed. Finally, it would be beneficial to receive feedback on the possibility of a registration requirement for firms operating automated trading systems and not otherwise registered with the Commission. The Concept Release cites the definition of ''floor broker'' as the potential basis for such a requirement; I am interested to get public input on whether this, or any other provision in the Commission's statute or regulations, can serve as a valid foundation for registration.

The Concept Release is far from perfect. For example, it could have provided a more thorough and clear cataloguing of existing industry practices and recommendations; a recent TAC reference document is more clear and concise in compiling existing standards and recommendations in the market today.[124] Nevertheless, I support today's issuance of the Concept Release in order to receive input from market participants on all of the issues contained herein. I look forward to reviewing the comments submitted in response to the Concept Release.

[FR Doc. 2013–22185 Filed 9–10–13; 8:45 am]

BILLING CODE 6351–01–P

[124] This document is available at *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/tac103012_reference.pdf.*

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Part V

Department of Housing and Urban Development

Changes to the Home Equity Conversion Mortgage Program Requirements: Financial Assessments—Solicitation of Comment; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5735–N–01]

Changes to the Home Equity Conversion Mortgage Program Requirements: Financial Assessments—Solicitation of Comment

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: On September 3, 2013, the Federal Housing Administration (FHA) issued Mortgagee Letter 2013–27, announcing the implementation of several changes to the Home Equity Conversion Mortgage (HECM) program, consistent with the authority to make such changes by the Reverse Mortgage Stabilization Act, signed into law on August 9, 2013. With the exception of new financial assessment requirements and funding requirements for the payment of property charges, the new HECM requirements will take effect for case numbers assigned on or after September 30, 2013. The financial assessment requirements and the funding requirements for payment of property charges take effect for case numbers assigned on or after January 13, 2014. This notice solicits comment for a period of 30 days on the financial assessment requirements to be applied on or after January 13, 2014.

DATES: *Comment Due Date:* October 15, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Karin Hill, Director, Single Family Housing Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9280, Washington, DC 20410–9000, telephone number 202–708–4308. (This is not a toll-free number). Hearing or speech impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service during business hours at 1–800–877–8337.

SUPPLEMENTARY INFORMATION: On August 9, 2013, the President signed into law the Reverse Mortgage Stabilization Act of 2013 (Pub. L. 113–29). This new law gives FHA the authority to establish, by notice or mortgagee letter, any additional or alternative requirements that the Secretary, in the Secretary's discretion, determines are necessary to improve the fiscal safety and soundness of the HECM program authorized by section 255 of the National Housing Act, which requirements shall take effect upon issuance.

Since the 2009 housing and economic recession, the HECM portfolio has experienced major mortgagor demographic and behavioral changes that have contributed to additional risks to the FHA Mutual Mortgage Insurance Fund (MMIF). Some of the changes include shifting from a predominately adjustable interest rate mortgage with mortgagors electing to receive payments over time using the line of credit or modified tenure/term payment options to a fixed interest rate mortgage where mortgagors draw down all funds at the time of closing; younger mortgagors with higher amounts of property indebtedness; stagnant house prices; and increasing property charge defaults. These and other factors have caused higher payouts of insurance claims. Many of these changes are highlighted in the June 28, 2012, ''Reverse Mortgages Report to Congress'' that was published by the Consumer Financial Protection Bureau.[1] The specific issues facing the HECM program were highlighted in the Annual Report to Congress on the Fiscal Year 2012 Financial Status of the FHA Mutual Mortgage Insurance Fund, issued November 16, 2012. This report highlighted the need for FHA to act quickly to reverse the high rate of defaults and claims in the HECM program.[2] Recognizing FHA's need to act quickly, Congress passed the Reverse Mortgage Stabilization Act of 2013, giving FHA the authority to quickly set in place changes to improve the fiscal safety and soundness of the HECM program. Acting on this authority, on September 3, 2013, FHA issued Mortgagee Letter 2013–27.[3] The changes being made to the HECM program by Mortgagee Letter 2013–27 are listed on the second page of the mortgagee letter and discussed in more detail throughout the mortgagee letter.

To help inform a future rule on changes to the HECM program, this notice solicits comment on the financial assessment component of the mortgagee letter, including the benefits and costs involved with the financial assessment. The purpose of the financial assessment is to evaluate mortgagors' willingness and capacity to meet their financial obligations, and their ability to comply with the mortgage requirements. The financial assessment is also used to determine whether, and under what conditions, the prospective mortgagor meets FHA eligibility criteria. An

[1] This report is available at *http://www.consumerfinance.gov/reports/reverse-mortgages-report/.*

[2] This report is available at *http://portal.hud.gov/hudportal/HUD?src=/press/press_releases_media_advisories/2012/HUDNo.12-171.*

[3] The Mortgagee Letter can be found at *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/hudclips/letters/mortgagee.*

increasing number of tax and hazard insurance defaults by mortgagors have heightened the need for an assessment of a potential mortgagor's financial capacity and willingness to comply with mortgage provisions. Accordingly, the mortgagee letter requires FHA-approved lenders to perform a financial assessment of all prospective mortgagors on all HECM transactions types, i.e., traditional, refinance, and purchase. Key components of underwriting HECM transactions include a credit history analysis, a cash flow/residual income analysis, an analysis of compensating factors and extenuating circumstances and ultimately a determination of whether the HECM applicant is eligible for the loan. This financial assessment requirement will become effective January 13, 2014.

While the financial assessment component will be part of FHA's upcoming proposed rule on HECM, FHA solicits comment in advance of the proposed rule. Comments submitted in response to this solicitation will be taken into consideration in the development of the proposed rule.

Dated: September 6, 2013.

Carol J. Galante,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 2013–22213 Filed 9–11–13; 8:45 am]

BILLING CODE 4210–67–P

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Part VI

The President

Notice of September 10, 2013—Continuation of the National Emergency With Respect to Certain Terrorist Attacks

Federal Register
Vol. 78, No. 177
Thursday, September 12, 2013

Presidential Documents

Title 3—

The President

Notice of September 10, 2013

Continuation of the National Emergency With Respect to Certain Terrorist Attacks

Consistent with section 202(d) of the National Emergencies Act, 50 U.S.C. 1622(d), I am continuing for 1 year the national emergency previously declared on September 14, 2001, in Proclamation 7463, with respect to the terrorist attacks of September 11, 2001, and the continuing and immediate threat of further attacks on the United States.

Because the terrorist threat continues, the national emergency declared on September 14, 2001, and the powers and authorities adopted to deal with that emergency must continue in effect beyond September 14, 2013. Therefore, I am continuing in effect for an additional year the national emergency that was declared on September 14, 2001, with respect to the terrorist threat.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
September 10, 2013.

[FR Doc. 2013–22406
Filed 9–11–13; 11:15 am]
Billing code 3295–F3

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CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

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